

Department of Health & Human Services

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



Date: November 10, 2016

**From: Center for Consumer Information and Insurance Oversight (CCIIO),
Centers for Medicare & Medicaid Services (CMS)**

Title: Draft 2018 Letter to Issuers in the Federally-facilitated Marketplaces

The Centers for Medicare & Medicaid Services (CMS) is releasing this draft 2018 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 MarketplaceSM 1 in 2018. 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 2018.²

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 has proposed additional standards in the proposed rule titled, “Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2018” (2018 Payment Notice Proposed Rule), CMS 9934-P, published on September 6, 2016.³ CMS

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

² Plan years in the FF-SHOPs will not always align with calendar year 2018.

³ Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2018; Proposed Rule; 81 FR 61456 (September 6, 2016).

expects issuers to consult all applicable regulations, in conjunction with the final version of this Letter, to ensure full compliance with the requirements of the Affordable Care Act (ACA). While certain parts of the Letter explain certain associated regulatory requirements, the Letter is not a complete list of regulatory requirements for issuers, and issuers need to comply with all regulatory requirements even if they are not explicitly discussed in the Letter.

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

Comments

CMS welcomes comments on this proposed guidance. To the extent that this guidance summarizes policies in proposed rules that have not yet been finalized, stakeholders should comment on those underlying policies through those ongoing rulemaking processes, not in comments on this draft Letter. We note that the comment period for the 2018 Payment Notice Proposed Rule closed on October 6, 2016. Please send comments on other aspects of this Letter to FFEcomments@cms.hhs.gov by December 1, 2016. Comments will be most helpful if organized by subsections of this Letter.

CHAPTER 1: CERTIFICATION PROCESS FOR QUALIFIED HEALTH PLANS	6
Section 1. QHP Application and Certification Process	6
i. QHP Application and Certification Timeline.....	6
ii. Registration and QHP Application.....	9
iii. QHP Review Coordination with States	10
iv. CMS Review of QHP Applications	13
v. Data Changes.....	13
vi. QHP/SADP Certification Agreement, and Senior Officer Acknowledgement.....	17
vii. Sale of Ancillary Products on the FFM's	18
Section 2. Certification of 2017 Qualified Health Plans.....	18
Section 3. Plan ID Crosswalk	18
i. General Crosswalk Requirements	18
ii. Suggested Alternate Enrollments for Enrollees Who Will Not Have Plans Offered By Their Current Issuers Available To Them Through The Marketplace	19
Section 4. OPM Certification of Multi-State Plan Options	19
Section 5. Standardized Options	20
CHAPTER 2: QUALIFIED HEALTH PLAN AND STAND-ALONE DENTAL PLAN CERTIFICATION STANDARDS	21
Section 1. Licensure and Good Standing.....	21
Section 2. Service Area.....	22
i. General Requirements	22
ii. Silver/Gold Offer Requirements	23
Section 3. Network Adequacy	24
i. Network Adequacy Standard and Certification Review	24
ii. Provider Transitions	26
iii. Out-of-Network Cost Sharing for In-Network Settings.....	27
iv. Network Transparency	27
v. Specialty Access.....	29
Section 4. Essential Community Providers.....	30
i. Evaluation of Network Adequacy with respect to all ECPs.....	30
ii. Evaluation of Network Adequacy with respect to Dental ECPs.....	34

iii. Requirements for Payment to Federally Qualified Health Centers	35
Section 5. Accreditation	36
Section 6. Patient Safety Standards for QHP Issuers	37
Section 7. Quality Reporting Requirements	38
Section 8. Quality Improvement Strategy Requirements	40
Section 9. Review of Rates	41
Section 10. Discriminatory Benefit Design	42
i. EHB Discriminatory Benefit Design	42
ii. QHP Discriminatory Benefit Design	43
iii. Treatment Protocol Calculator	44
Section 11. Prescription Drugs	44
i. Formulary Outlier Review	45
ii. Clinical Guideline-Based Review of Prescription Drug Coverage	45
iii. Review of Tier Placement of Prescription Drugs Recommended for Treatment of Specific Medical Conditions	45
Section 12. Supporting Informed Consumer Choice/Meaningful Difference	46
Section 13. Third Party Payment of Premiums and Cost Sharing	47
Section 14. Cost-sharing Reductions	47
Section 15. Data Integrity Tool	49
CHAPTER 3: CONSUMER SUPPORT TOOLS AND PUBLIC INFORMATION	49
Section 1. Provider Directory Links and Provider Lookup Tool	50
Section 2. Formulary Drug List and Formulary Lookup Tool	50
Section 3. Out-of-Pocket Cost Comparison Tool	51
Section 4: Transparency in Coverage Reporting	52
CHAPTER 4: STAND-ALONE DENTAL PLANS: 2018 APPROACH	52
Section 1. Stand-alone Dental Plans: 2018 Approach	53
Section 2. Intent to Apply	53
Section 3. SADP Annual Limitation on Cost-Sharing	53
Section 4. Prohibition of Waiting Periods	54
Section 5. Off-Marketplace SADP Enrollment Periods	54
CHAPTER 5: QUALIFIED HEALTH PLAN PERFORMANCE AND OVERSIGHT	54

Section 1. Account Management	54
Section 2. QHP Issuer Compliance Monitoring	55
Section 3. QHP Issuer Compliance Reviews	56
Section 4. FFM Oversight of Agents and Brokers.....	56
i. QHP Issuer Responsibilities.....	57
ii. Agent and Broker Agreements.....	58
iii. Monitoring and Oversight	59
iv. Web-brokers.....	61
v. Compensation.....	63
vi. Registration Requirements for Initial Enrollment and Re-enrollment Transactions.....	65
vii. HHS-Approved Vendors of FFM Training.....	66
Section 5. Oversight of Marketing Activities	67
Section 6. Issuer Participation for Full Plan Year.....	69
CHAPTER 6: FF-SHOPS	70
Section 1. Enrollment Periods for Newly Qualified Employees	70
Section 2. SHOP Participation Provision.....	71
Section 3. FF-SHOP Enrollment Reconciliation	72
CHAPTER 7: CONSUMER SUPPORT AND RELATED ISSUES	73
Section 1. Consumer Case Tracking and Resolution.....	73
Section 2. Coverage Appeals	75
Section 3. Meaningful Access.....	75
Section 4. Summary of Benefits and Coverage	79
CHAPTER 8: TRIBAL RELATIONS AND SUPPORT	81
CHAPTER 9: STATE-BASED MARKETPLACES ON THE FEDERAL PLATFORM	82

CHAPTER 1: CERTIFICATION PROCESS FOR QUALIFIED HEALTH PLANS

The ACA 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 ACA. 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 ACA, and 3) a direct enforcement State where CMS is performing plan management functions and enforcing market-wide standards under the ACA (but the State continues to enforce State law requirements with which issuers must be in compliance).⁴ The QHP certification process CMS will conduct in calendar year 2017 for plan year 2018 maintains many aspects of the process that CMS conducted in calendar year 2016 for plan year 2017. CMS intends to incorporate some modified review standards as well as operational changes for the QHP certification process for plan year 2018, as noted in this Letter.

Each of the following sections describes the process for QHP issuers to apply for CMS QHP certification for plan year 2018.

Section 1. QHP Application and Certification Process

i. QHP Application and Certification Timeline

This section describes the timeline for CMS's QHP certification process for plan year 2018. 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 for 2018, issuers must submit a complete QHP application for all plans they intend to have certified in an FFM State. CMS conducts QHP certification annually. In the case of an FF-SHOP QHP certification, except when the QHP is decertified pursuant to 45 CFR 155.1080, the QHP certification remains in effect through the end

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

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 2018. 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.

CMS expects issuers 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 3, 2017, and to make necessary updates to the QHP application prior to the last deadline for issuer submission on August 21, 2017. New to the QHP certification timeline for plan year 2018, CMS aligns the deadline for issuers to make changes to QHP applications (August 21, 2017) with the final deadline for submission of the plan ID Crosswalk. In addition, CMS plans to send countersigned Agreements with the Certification Notices, eliminating the need for Validation Notices.

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.⁵

We seek comment on this timeline – in particular, whether the timeline should be moved one week earlier to allow for earlier completion of the certification process.

Table 1.1. Timeline for QHP Certification in the FFMs

Note: All dates are subject to change.

⁵ 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.

Activity	Dates
Initial QHP Application Submission Window ⁶	4/5/2017 – 5/3/2017
CMS reviews Initial QHP Applications as of 5/3/17	5/4/2017 – 6/5/2017
CMS sends issuers initial plan confirmation lists	5/12/2017
CMS sends First Correction Notice	6/12/2017 – 6/13/2017
Deadline for submission of revised QHP Data	6/27/2017
CMS reviews revised QHP submission as of 6/27/17	6/28/2017 – 7/28/2017
CMS sends Second Correction Notice	8/7/2017 – 8/8/2017
Service Area Petition Deadline	8/9/2017
Deadline for issuer submission of changes to QHP Applications and issuer changes to Plan Crosswalk ⁷	8/21/2017
CMS reviews Final QHP submission as of 8/21/17	8/22/2017 – 9/5/2017
States send CMS Final Plan Recommendations	9/8/2017 ⁸
CMS sends Final Correction Notice to Issuers	9/11/2017
Issuers send Agreements to CMS	9/12/2017 – 9/15/2017
CMS sends Certification Notices with countersigned Agreements and final plan lists to Issuers ⁹	9/21/2017 – 9/22/2017
Limited data correction window: Outreach to issuers with CMS or State identified data errors; issuers submit corrections; CMS reviews and finalizes data for Open Enrollment	9/12/2017 – 10/23/2017
Open Enrollment	11/1/2017 – 1/31/2018

⁶ 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.

⁷ New to the QHP certification timeline for plan year 2018, CMS aligns the deadline for issuers to make changes to QHP applications (August 21, 2017) with the final deadline for submission of changes to the plan ID Crosswalk.

⁸ Separate from Correction Notices, CMS will send plan lists for confirmation to States with an FFM, including FFMs in States performing plan management functions, and to States with SBM-FPs. CMS requires responses to that State outreach by September 8, 2017, including if plans were transferred in error or a State otherwise recommends against (for FFMs) or is denying (SBM-FPs) certification of a plan. States must communicate that information to CMS in order for the information to be incorporated into certification decisions and Certification Notices, as applicable.

⁹ CMS plans to send countersigned agreements with the Certification Notices for plan year 2018, as opposed to with Validation Notices as done in previous certification cycles.

ii. *Registration and QHP Application*

To offer QHPs in the FFMs for plan years beginning in 2018, 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.¹⁰ Issuers must obtain HIOS product and plan IDs.

Between April 5, 2017, and May 3, 2017, issuers applying to offer QHPs in FFMs should 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.

CMS will use the QHP application to collect both issuer-level information and plan-level benefit and rate data,¹¹ 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 the Unified Rate Review (URR) module in HIOS. Issuers do not need to submit URRTs for SADPs. Issuers in a State with an Effective Rate Review Program¹² 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 June 1, 2017. 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. Issuers will be able to make corrections to their URRT and upload supplemental materials needed to complete the review. If a State requires an issuer to make

¹⁰Additional information on HIOS registration is available in the HIOS Portal User Manual, available at: https://www.cms.gov/ccio/Resources/Forms-Reports-and-Other-Resources/index.html#Content_Requirements_for_Plan_Finder.

¹¹ Issuers in FFMs and SBM-FPs are required to submit their QHP Rates Table Template by May 3, 2017 even if their Rate Filing Justification is not due until a later date.

¹² See 45 CFR 154.301 for a list of criteria that CMS considers when evaluating whether a State has an Effective Rate Review Program.

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 CMS have matching URRTs.

iii. QHP Review Coordination with States

As was the case for prior benefit years, CMS will 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.¹³ States that have Effective Rate Review¹⁴ Programs should also consult forthcoming guidance from CMS regarding timelines for rate filings for 2018 plan year coverage. CMS must receive confirmation that, in addition to complying with ACA requirements, all QHP issuers, including SADP issuers, are licensed and in good standing to offer health insurance coverage in each State in which the issuer offers health insurance coverage, and confirmation that they are in compliance with all applicable State laws that are conditions of offering health insurance in the State. Therefore, to certify QHPs in the FFMs, CMS must receive confirmation that issuers receive applicable form and rate filing approval from the appropriate State regulatory authority. Issuers should follow State guidance regarding compliance with the processes, criteria, and timeline for reviews conducted by States.

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 ACA such as

¹³ 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, CMS enforces the market-wide provisions. The list of direct enforcement states is available at: <https://www.cms.gov/ccio/programs-and-initiatives/health-insurance-market-reforms/compliance.html>. 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.

¹⁴ See 45 CFR 154.301 for a list of criteria that CMS considers when evaluating whether a State has an Effective Rate Review Program.

essential health benefits (EHB) and actuarial value (AV) standards.¹⁵ State regulators may request access to QHP data templates to facilitate review of these plans.

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.

CMS expects that States will establish the timeline, communication process, and resubmission window for any reviews conducted under State authority. As noted previously, issuers should comply with any State-specific guidelines for review and resubmission related to State review standards. CMS notes that issuers may be required to submit data to State regulators in addition to that required for QHP certification through the FFMs, if required by a State, and must comply with any requests for resubmissions from the State or from CMS in order to be certified. CMS will seek to coordinate with States so 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 3, 2017. Issuers may contact the CMS Rate Review team at ratereview@cms.hhs.gov for details.¹⁶ Issuers will also have obligations under State law, and should consult with their State for details on any State-specific guidelines or requirements.

¹⁵ 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 ACA standards.

¹⁶ Additional information on the CMS requirements for rate and form filings in direct enforcement States is available at: [http://www.cms.gov/ccio/Resources/forms-reports-and-other-resources/index.html#Health Insurance Market Reforms](http://www.cms.gov/ccio/Resources/forms-reports-and-other-resources/index.html#Health%20Insurance%20Market%20Reforms).

FFMs (Excluding FFMs in 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. 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. 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.

FFMs in States Performing Plan Management Functions

In FFMs where the State is performing plan management functions, issuers should work directly with the State to submit all QHP issuer application data in accordance with State guidance.¹⁷ States performing review of QHP applications use SERFF to collect QHP applications from issuers.

In States performing plan management functions, the State will review QHP applications for compliance with the standards described in this guidance and will provide a certification recommendation for each 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 2017 submissions. These State transfers should include all plans submitted to the State for certification, including SADPs for off-Marketplace sale.¹⁸ 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.

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 ACA certification requirements, as early in the certification process as practicable. For CMS to ensure this information is taken

¹⁷ 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.

¹⁸ SBM-FPs should not transfer off-Marketplace SADPs.

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.

iv. CMS 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 3, 2017. 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 medical 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 three rounds. Following each review period, CMS will send applicants notices summarizing any need for corrections identified during CMS's review. After the first and second rounds of 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 21, 2017. After the final review and after the final deadline to submit changes to the QHP application, CMS will conduct outreach to issuers that are required to enter the limited data correction window to correct critical data errors prior to open enrollment. During this window, issuers will submit data corrections, and CMS will review and finalize QHP data for open enrollment. Issuers whose applications are not accurate after the deadline for issuer submission of changes to the QHP application, which is August 21, 2017, and are then required to enter the limited data correction window, may be subject to compliance action by CMS. Issuer changes made in the limited data correction window not approved by CMS and the State may result in CMS suppressing the issuer's plans from display on HealthCare.gov.

CMS will then conduct a final review round of application data submitted by August 21, 2017 and send Certification Notices by September 22, 2017.

v. Data Changes

Issuers applying for QHP certification will be able to view plan data in the Plan Preview environment in order to identify and correct data submission errors before the final QHP application data submission deadline. Issuers should use the Plan Preview environment to verify that their plan display reflects their State-approved filings. Discrepancies between the issuer's QHP application and approved State filings may result in a plan not being certified or a compliance action if CMS has already certified a plan as a QHP. All issuers must complete quality assurance activities to ensure the completeness and accuracy of QHP application data,

including reviewing plan data in the Plan Preview environment, as set forth in Chapter 5, Section 2 “QHP Issuer Compliance Monitoring.”

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 2018, 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 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
Initial Application Submission	Issuers will submit QHP applications for 2018 QHPs, including SADPs. Issuers may make any changes to their data without State or CMS authorization.	4/5/17-5/3/17
QHP Review and Modification	<p>No new plans may be submitted.</p> <p>Issuers may not change plan type. Child-only value cannot be changed for QHPs (excluding SADPs).</p> <p>Petition to CMS required for changes to service area. Issuers must submit petitions by August 9, 2017. Issuers may submit plan withdrawal requests.</p> <p>For all other changes, issuers are not required to submit petitions or document State authorization to CMS. CMS will monitor all data changes and contact issuers if there are concerns about changes made.</p>	5/4/17-8/21/17
After Final Application Submission	<p>No further data changes allowed prior to certification. 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.</p> <p>Post-certification data corrections require data change petitions</p>	8/21/17 – onward

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

Initial Application Submission

As described in Section 1 of Chapter 1, issuers will submit their initial QHP applications between April 5, 2017, and May 3, 2017. This includes applications for SADPs to be offered on and off the FFMs. Issuers must submit their 2018 QHP application data during this submission window. Issuers requesting certification of 2017 QHPs for plan year 2018 must follow the guidelines in Chapter 1, Section 2. 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 3, 2017.

Shortly after the initial application submission deadline, issuers intending to offer QHPs or SADPs in the FFMs, including issuers in States performing plan management functions, will be required to validate their initial plan list. Issuers will submit confirmation of this as the list of plans to be reviewed for 2018 certification.

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 21, 2017, with certain exceptions.

After May 3, 2017, issuers may not 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.

After May 3, 2017, an issuer also may not make changes to its plans' service areas without submitting a petition to CMS. Changes to service area may not be made in the QHP application unless the petition is approved by CMS. For further information about what constitutes a change to an issuer's plans' service areas, please review Chapter 2, Section 2 "Service Area." Issuers must submit petitions for all changes to service area, including responding to a CMS-identified correction 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 requires 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, 2017, in order to allow CMS sufficient time for review. Issuers must submit changes to QHP applications after CMS has approved the petition and prior to the final data submission deadline of August 21, 2017.

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 service area petitions. CMS will monitor all data changes issuers make 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 QHPs certified for plan year 2017 that are being considered for certification for plan year 2018 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, "Certification of 2017 Qualified Health Plans."

To withdraw a plan from QHP certification consideration, an issuer must submit to CMS a plan withdrawal form. After submission of an initial QHP application, an issuer should not remove plan data from the application templates, even if the issuer withdraws a plan. In addition, issuers seeking to change an on-Marketplace SADP under certification consideration to an off-Marketplace SADP for certification consideration must submit a plan withdrawal request.

Prior to the final data submission, CMS will provide each issuer a list of plans received during the QHP application process. The list includes on and off-Marketplace SADPs and on-Marketplace medical QHPs.¹⁹ Issuers must review the list and respond to CMS by August 21, 2017 with a final plan confirmation list that will confirm whether or not CMS's list is accurate.

After Final Application Submission

After August 21, 2017, HIOS will close and CMS will not allow additional QHP data changes until it completes its certification decisions and issuers sign the QHP Privacy and Security Agreement and Senior Official Acknowledgement.

CMS will conduct a limited data correction window between September 12, 2017 and October 23, 2017. During this window, issuers will only make corrections requested by CMS. Issuer changes made in the limited data correction window that are not approved by CMS and the State may result in CMS suppressing the issuer's plans from display on HealthCare.gov.

After the limited data correction window occurs, CMS may offer additional data correction windows, during which issuers will be prohibited from making further changes to QHP data (including plan crosswalk) 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. CMS will only consider approving changes that do not alter the QHP's certification status or require re-review of data previously approved by the State or CMS.

¹⁹ 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.

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. Data correction windows are also opened when issuers request to make quarterly SHOP rate updates for quarter 2, quarter 3 and quarter 4. 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 ACA, Federal regulations, and all other guidelines discussed in this Letter.

A request for a data change after August 21, 2017, excluding administrative changes, may be made due to inaccuracies in 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.

vi. *QHP/SADP Certification Agreement, and Senior Officer Acknowledgement*

As with the certification process for plan years beginning in 2017, issuers intending to offer QHPs or SADPs in the FFM, including issuers in States performing plan management functions, will sign and submit to CMS a QHP Certification Agreement and Privacy and Security Agreement (the QHP Certification Agreement) and a Senior Officer Acknowledgement.

The QHP Certification Agreement will include provisions for safeguarding the privacy of plan applicant and participant data in the FFM 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.

CMS will review the QHP Certification Agreement and the Senior Officer Acknowledgment, and if they are accurate and complete, sign and return the QHP Certification Agreement to issuers, along with a final list of certified QHPs. 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.

vii. Sale of Ancillary Products on the FFM

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. Certification of 2017 Qualified Health Plans

For plan year 2018, CMS's process for certifying a plan, including an SADP, which was certified for the 2017 plan year will mirror the process for certification of a plan for 2017. Issuers seeking certification will submit all information required under the 2018 QHP application for plans that were QHPs, including SADPs, in 2017.

CMS expects issuers to use the same HIOS plan identification numbers for plans submitted for certification for plan year 2018 that are the same plans certified as QHPs, including SADPs, for plan year 2017, as defined in 45 CFR 144.103. The same definition of "plan" also will apply to reenrollment of current enrollees into the same plan, pursuant to §155.335(j).

If an issuer chooses to not to seek certification of a plan for a subsequent, consecutive certification cycle in the Marketplace, or, if the proposal in the 2018 Payment Notice Proposed rule is finalized as proposed, fails to have a plan certified for plan year 2018 that had been certified for plan year 2017, it is subject to the standards outlined in 45 CFR 156.290.

Section 3. Plan ID Crosswalk

i. General Crosswalk Requirements

Issuers that offered individual market QHPs through an FFM in 2017 – including issuers in States performing plan management functions in an FFM and issuers in SBM-FPs – are required to complete and submit plan ID Crosswalk templates to CMS. For the FFMs, this template crosswalks all prior year QHP plan ID and service area combinations (e.g., plan ID and county combinations) to a QHP plan ID for the subsequent year. This data facilitates 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 2017 to 2018 QHPs in the FFMs and SBM-FPs. As a result, issuers that offered plans, including QHPs and SADPs, on the individual market FFMs and SBM-FPs in plan years beginning in 2017 should submit plan ID Crosswalk data to crosswalk all prior year QHPs to a QHP plan ID for the subsequent year.

SADPs, as excepted benefits, are not subject to the guaranteed renewability standards specified at 45 CFR 147.106. However, as CMS 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 2018 plan ID Crosswalk Template to SADPs in order to support automatic re-enrollment for plan years beginning in 2018.

CMS will conduct an overall data integrity review of submitted plan ID Crosswalk data to ensure all QHPs, including Multi-State Plan (MSP) Options and SADPs, have been cross-walked in 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 2017 and 2018.

ii. Suggested Alternate Enrollments for Enrollees Who Will Not Have Plans Offered By Their Current Issuers Available To Them Through The Marketplace

45 CFR 155.335(j)(3) establishes that if no QHP from the same issuer is available to an enrollee through the Marketplace, the Marketplace may, to the extent permitted by applicable State law, generally select an alternate plan offered by a different issuer unless the enrollee terminates coverage, including through selecting a different QHP. This is done to help maintain coverage through the Marketplace for affected enrollees who fail to return to the Marketplace to make their own plan selection by December 15. Unless otherwise directed by the State consistent with 45 CFR 155.335, the Marketplace directs such selections. In the FFMs and the SBM-FPs, this process applies to all QHP enrollees where the issuer no longer has a QHP available through the FFMs for the upcoming plan year with a service area that covers the enrollee's location, even if the issuer continues to offer QHPs through that Marketplace that cover other service areas.

CMS will send communications to outline the steps it expects States with an FFM, including States performing plan management functions, and states with SBM-FPs to take if they wish to direct this activity for plan year 2018. For States that defer to CMS for direction of this activity, CMS, if feasible and to the extent permitted by applicable State law, will crosswalk affected enrollees into another QHP available through an FFM with a service area that covers the enrollee's location.

This activity does not apply to SADPs for plan year 2018.

Section 4. OPM Certification of Multi-State Plan Options

This section provides additional guidance for issuers seeking to offer 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 ACA. In accordance with section 1334(d) of the

ACA, 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 2018 plan year will largely mirror that used for 2017. 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.

OPM will post specific instructions regarding the 2018 application when available.²⁰

Section 5. Standardized Options

As with the 2017 plan year, in the 2018 Payment Notice Proposed Rule, CMS proposed standardized options, which issuers would have the choice to offer for the 2018 plan year, and which would receive differential display on HealthCare.gov and be referred to as "Simple Choice Plans" on all consumer-facing websites and materials. CMS also proposed that SBM-FPs would be given the option to elect to allow differential display of HHS standardized options. This section applies to issuers in all FFMs, including those in States performing plan management functions. If the proposals in the 2018 Payment Notice Proposed Rule are finalized as proposed, this also will apply to issuers in SBM-FPs that notify CMS that they plan to participate in differential display of HHS standardized options.

In the 2018 Payment Notice Proposed Rule, we proposed three sets of standardized options, with the aim that at least one set would comply with each State's cost sharing requirements. Each State would still only have one set of standardized options. Each proposed set of standardized options includes a plan at each of the bronze, silver, silver cost-sharing reduction, and gold levels of coverage. For the 2018 plan year, we also proposed a standardized option at the bronze level of coverage that qualifies as a high deductible health plan (HDHP) under section 223 of the Internal Revenue Code, eligible for use with a health savings account (HSA), that issuers may choose to offer, as long as the plan complies with State requirements.

²⁰ For more information on requirements for MSP issuers, issuers should visit <http://www.opm.gov/healthcare-insurance/multi-state-plan-program/issuer/>.

Issuers in the State would then have the option to offer one or more of the standardized options that apply in that State, except that if an issuer offers a silver standardized option, it must also offer the silver cost-sharing reduction variations. As with the 2017 plan year, an issuer would have the option to offer a silver (and silver cost-sharing reduction variation) standardized option without offering a bronze or gold standardized option, and vice versa.

As in the 2017 plan year, each standardized option would have a fixed in-network deductible, fixed annual limitation on cost sharing, and fixed copayment or coinsurance for a key set of EHBs that comprise a large percentage of the average enrollee's total spending. The standardized options would also be limited to a single in-network provider tier and four drug tiers (those currently used in our consumer-facing applications—generic, preferred brand, non-preferred brand, and specialty) with the option to offer one additional lower-cost generic drug tier.

Also in line with the 2017 plan year, we proposed to give issuers the option to offer more than one standardized option at each level of coverage. An issuer could offer more than one standardized option at each metal level by varying network, additional benefits covered, or other features, subject to the meaningful difference requirements discussed in Chapter 2, Section 12 of this Letter.

Finally, the proposed 2018 standardized options are not considered the same plans as the 2017 standardized options under the definition of “plan” at 45 CFR 144.103. Therefore, if the proposed standardized options are finalized as proposed, issuers that offered standardized options in the 2017 plan year and that intend to offer standardized options in the 2018 plan year should not assume that 2017 standardized plan enrollees should automatically be crosswalked to the 2018 standardized option at the same metal level under 45 CFR 155.335(j). Issuers may voluntarily discontinue their products consisting of 2017 standardized options and, to the extent consistent with guaranteed renewability requirements and applicable State law, crosswalk the 2017 standardized plans to the 2018 standardized options.

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

This Chapter provides an overview of key QHP certification standards for both QHPs and SADPs in FFMs, including those in States performing plan management functions. This Chapter also provides an overview on how CMS will evaluate and conduct reviews of 2018 QHPs and SADPs for compliance with these certification standards in FFMs, including those with States performing plan management functions. Each section describes the QHP certification standard, provides an overview of the tools and processes that CMS will use to review prospective QHPs and SADPs for that standard, including what procedures and documentation are expected from the issuer, and explains the process in FFMs with States performing plan management functions.

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 2017.

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)).

As part of the QHP application, issuers must provide one of the following supporting documents in the licensure section: 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.

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. CMS interprets “good standing” to mean that an issuer faces no outstanding sanctions imposed by a State’s regulatory authority. Therefore, the specific violations or infractions that would jeopardize standing may vary by State. In addition, an issuer is not considered to be in good standing if it is not licensed.

Section 2. Service Area

i. General Requirements

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 2017 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 Public Health Service (PHS) Act, or other factors that exclude specific high utilizing, high cost or medically underserved populations (see 45 CFR

155.1055(b)).²¹ 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 permitted 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.

Issuers submitting through SERFF should ensure all service areas are included in their initial service area templates. Issuers submitting through SERFF that add plans (to include off-Marketplace plans) that use a service area not previously used during the first round of submissions will be considered to be making a service area change. Accordingly, issuers must submit a petition prior to adding such plan.

Petitions for service area changes must follow a CMS-prescribed format that will be detailed in guidance and will only be allowed with State approval. CMS will approve changes to service areas only 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 1, Subsection v.

ii. Silver/Gold Offer Requirements

In the 2018 Payment Notice Proposed Rule, we proposed that to satisfy the requirements of 45 CFR 156.200(c)(1), QHPs must be offered through the applicable Marketplace at both the silver and gold coverage levels as described in section 1302(d)(1) of the ACA throughout each service area in which the issuer applying for certification offers coverage through the Marketplace. We further explained that an issuer could meet this proposed standard by offering MSP options certified by OPM as described in Chapter 1, Section 4 above in both silver coverage and gold coverage levels throughout each service area in which it offers QHPs through a Marketplace.

²¹ Note that a service area that is at least the entire geographic area of a county may still be found to be discriminatory if it has been established based on racial, ethnic, language, health status-related, or other prohibited factors.

If the proposed rule is finalized as proposed, the FFMs would apply this certification standard by ensuring that both a silver and gold level QHP (and/or MSP options) are offered throughout each individual and FF-SHOP service area in which the QHP issuer offers coverage. The proposed certification standard under paragraph 156.200(c)(1) would not apply to SADPs.

Section 3. Network Adequacy

This section includes information on network adequacy evaluation and network provider directory requirements.

i. Network Adequacy Standard and Certification Review

This section describes how CMS will conduct the network adequacy review for QHPs in FFMs for plan year 2018, including SADPs. Issuers in States performing plan management functions will submit the same data to CMS and the same criteria will apply. CMS will use the same approach to review network adequacy that was used in 2017. 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.

As with previous plan years, 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) for plan year 2018. CMS will again use time and distance criteria to aid in assessing whether an issuer is meeting this regulatory standard. For plan year 2018, as in prior years, CMS will review issuers’ network adequacy templates that are submitted as part of the certification process. The network adequacy template should only list providers with whom the issuer has a valid contract for the upcoming plan year. For 2018, as in 2016 and 2017, CMS will review provider data with a focus on the following specialists, 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. The specific time and distance criteria which will be used is in the table below, and it is the same as the criteria used for plan year 2017.

Table 1.3. Specialties and Standards for Marketplace Plan Year 2018 Certification.²²

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.

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, CMS 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. As in plan year 2017, in addition to permitting issuers to add additional providers if it is determined that they are not meeting the time and distance criteria, CMS will use a justification process. The justification process requires that QHP issuers detail patterns of care and other relevant information to explain why it 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.

CMS will use any updated provider data and written justification submitted as part of the certification process to assess 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 States should it be necessary to remedy potential deficiencies.

ii. Provider Transitions

This section discusses the provider transitions policies that were finalized in the HHS Notice of Benefit and Payment Parameters for 2017 (2017 Payment Notice Final Rule)²³ at 45 CFR 156.230(d). This section applies to QHP issuers in FFMs, including SADPs. 45 CFR 156.230(d) also applies to issuers in states performing plan management functions and SBM-FPs. We also note that these standards are not intended to, and do not, preempt State provider transition notices and continuity of care requirements, and that we intend to defer to a State's enforcement of substantially similar or more stringent standards.

The first provision, at 45 CFR 156.230(d)(1), requires QHP issuers 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 that are seen on a regular basis by the provider or that 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 that are patients of a provider that 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.

The second provision, at 45 CFR 156.230(d)(2), is related to continuity of care and requires the issuer, in cases where the provider is terminated without cause, to allow an enrollee in an 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. Issuers should refer to 45 CFR 156.230(d)(2) for the definition of active course of treatment.

²³ HHS Notice of Benefit and Payment Parameters for 2017; Final Rule; 81 FR 12204 (March 8, 2016).

We expect QHP issuers in the FFMs to have updated internal processes and procedures to implement 45 CFR 156.230(d)(1) and (2). For additional information on these provisions, please refer to the 2017 Payment Notice.

iii. Out-of-Network Cost Sharing for In-Network Settings

This section discusses the policy for QHP out-of-network cost sharing for in-network settings that was finalized in the 2017 Payment Notice Final Rule at 45 CFR 156.230(e) and applies to all QHPs. This section applies to QHP issuers in FFMs, including SADPs. 45 CFR 156.230(e) also applies to issuers in states performing plan management functions and SBM-FPs.

Beginning in plan year 2018, QHP issuers in FFMs are required to count cost sharing paid by an enrollee for an EHB provided by an out-of-network ancillary provider at an in-network setting towards the in-network annual limitation on cost sharing in certain circumstances. That is, if a QHP enrollee received an EHB in an in-network setting, such as an in-network hospital, but as part of the provision of the EHB the enrollee was charged out-of-network cost sharing for an EHB provided by an out-of-network ancillary provider, that cost sharing would apply towards the annual limitation on cost sharing. Alternatively, the plan could provide a written notice to the enrollee by the longer of 1) when the issuer would typically respond to a prior authorization request timely submitted, or 2) 48 hours before the provision of the benefit. The written notice would state that additional costs may be incurred for the EHB provided by an out-of-network ancillary provider in an in-network setting, including balance billing charges, unless such costs are prohibited under State law, and that any additional charges may not count toward the in-network annual limitation on cost sharing. This alternative would not be available if the issuer does not meet the timeframe established in regulation.

To implement this policy, CMS expects QHP issuers to update internal processes and procedures. For additional information on this provision, please refer to the 2017 Payment Notice.

iv. Network Transparency

This section discusses how CMS will label each QHP network's breadth as compared to other QHP networks on HealthCare.gov. This section applies to all QHP issuers in FFMs, including where the State is performing plan management functions, and SBM-FPs, excluding SADPs. This information will be available to consumers to provide them with information on a network's relative breadth. The purpose of the labeling is to provide increased transparency to enrollees about the type of provider network in the coverage they are selecting.

For the 2017 plan year, CMS plans to implement a pilot to display information on HealthCare.gov on the relative size of provider networks for plans in a limited number of States. CMS released details about the pilot on September 30, 2016 in the guidance entitled "Updated CMS Bulletin on Network Breadth Information for Qualified Health Plans on

HealthCare.gov.”²⁴ Additionally, CMS stated that it will collect data on the 2017 consumer experience from consumers in the States in which this information will be displayed and use the information to inform the HealthCare.gov display in future years. CMS plans to continue to test consumer use and experience on HealthCare.gov to enhance and improve the display of QHP network breadth information. The results of this pilot will determine if CMS expands the pilot to more States for 2018.

This section describes CMS’s anticipated methodology for plan year 2018. If CMS does expand the pilot, CMS will issue additional guidance in plan year 2017 based on the results of the pilot. CMS anticipates that in 2018 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 plan year 2018 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 a separate classification for each of the three categories. CMS chose these specialty areas based on consumer feedback that access to specific hospitals and preferred primary care physicians is important to potential enrollees when comparing plans.

The classifications of network breadth for each plan will be at the county level. CMS will determine these classifications 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 based on a time and distance calculation. To calculate network breadth, CMS 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, CMS will classify networks that are within one standard deviation of the mean PPR as Standard. CMS will classify those with a PPR that is more than one standard deviation above the mean PPR as Broad. CMS will classify those with a PPR that is more than one standard deviation below the mean PPR as Basic. These calculations will be based on the network provider data that each QHP issuer submits as part of QHP certification and would be updated at least annually. In developing the calculations, CMS will also undertake a process, to the best of CMS’s ability, to validate specialty taxonomy codes and remove duplicates based on NPI code and location. CMS will compute the thresholds for these three levels at a national level based on the total QHP provider population, which may vary from year to year.

²⁴ The Updated CMS Bulletin on Network Breadth Information for Qualified Health Plans on HealthCare.gov is available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/NA-Pilot-Final-Guidance-Clean-093016.pdf> (September 30, 2016).

In the 2018 Payment Notice Proposed Rule, CMS explained that it is considering whether to incorporate more specificity into the network breadth indicators to identify for consumers whether a particular plan is offered as part of an integrated delivery system. If finalized, this integrated delivery system specificity will be incorporated into the network information displayed for plan year 2018 in all States where network breadth is displayed.

To define which plans use an integrated delivery system, we proposed to use the alternate ECP standard at 45 CFR 156.235(b), and would identify a plan as part of an integrated delivery system if it provides a majority of covered professional services through physicians employed by the issuer, or through a single contracted medical group. If this policy is finalized, CMS may also identify as integrated delivery systems other plans that may not meet the alternate ECP standard. CMS would identify other issuers that meet the criteria below as part of an integrated delivery system:

- (1) The network is controlled by a single governance structure or can demonstrate shared control and accountability among network professional and facility components;
- (2) The issuer shares risk with the network providers through contracting mechanisms such as capitation, shared savings, or pay for performance;
- (3) Enrollees using the network are assigned to a primary care medical home (or other organized delivery system model);
- (4) The issuer can demonstrate integration of behavioral and physician health services within the network;
- (5) The issuer can demonstrate integration of hospital and inpatient services, and connection to the primary care medical home, including in the handling of emergency department services; and
- (6) The network employs a common electronic health record system that is used to share information among its professionals and facilities.

We welcome feedback and comments on the above criteria. If we finalize such an approach, we will provide details in the 2018 certification instructions on how issuers will notify CMS if they meet the above criteria.

For display, the indicators for integrated plans may include additional explanatory text to the current indicator or a separate indicator. If this policy is finalized, CMS intends to use the results from consumer testing to inform its display of integrated delivery systems.

v. *Specialty Access*

In addition to the QHP network adequacy standard set in 45 CFR 156.230(a)(2), pursuant to 45 CFR 156.225, QHPs may not employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs. For plan year 2018, CMS is considering assessing consumer access to higher cost specialist providers. A

relative lack of such providers may negatively impact the ability of individuals with commonly diagnosed conditions that are chronic by nature and expensive to treat to access their necessary medical care. Moreover, limited specialty provider networks may discourage such consumers from enrolling in certain QHPs in favor of those with wider specialist networks. CMS is considering assessing QHP specialist networks relative to other QHPs in the service area. CMS is considering monitoring consumer access to cardiology, endocrinology, gynecology (OB/GYN), infectious diseases, nephrology, neurology, oncology, ophthalmology, pediatrics, psychiatry, pulmonology and rheumatology specialists as well as access to general acute hospitals, outpatient dialysis, and cancer treatment centers 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 2018. States performing plan management functions in the FFM 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,²⁵ 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 ACA – “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 2.2. 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

In the 2018 Payment Notice Proposed Rule, CMS proposed to continue using 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:

²⁵ Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016; Final Rule, 80 FR 10750 (February 27, 2015).

- Contracts with at least 30 percent of available ECPs in each plan’s service area to participate in the plan’s provider network;
- Offers contracts in good faith to all available Indian health care providers in the service area, to include the Indian Health Service (IHS), Indian Tribes, Tribal organizations, and urban Indian organizations, applying the special terms and conditions necessitated by Federal law and regulations as referenced in the recommended model QHP Addendum²⁶ for Indian health care providers developed by CMS; 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.

Table 2.2. 2018 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
Federally Qualified Health Centers (FQHCs)	FQHCs and FQHC “Look-Alike” Clinics, Outpatient health programs/facilities operated by Indian tribes, tribal organizations, programs operated by Urban Indian Organizations
Hospitals	Disproportionate Share Hospitals (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	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.

For the 2018 plan year, CMS will rely exclusively on the updated list of available ECPs based on data maintained by CMS, as well as provider data that CMS receives directly from providers through the ECP petition process for the 2018 plan year. CMS will include on the HHS ECP list for the 2018 plan year those providers that submitted an ECP petition during the ECP petition

²⁶ The model QHP Addendum for Indian health care providers is available at: <http://www.cms.gov/ccio/programs-and-initiatives/health-insurance-marketplaces/qhp.html>.

window that closed on October 15, 2016, and meets the definition of an ECP under 45 CFR 156.235.

As described more fully in the 2017 Letter to Issuers, HHS launched its ECP petition initiative on December 9, 2015, 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. CMS intends to maintain an ongoing initiative to collect provider data directly from providers through the ECP petition process so that all issuers are held to a uniform ECP standard.²⁷ Given that the ECP petition process is designed to add qualified ECPs to the 2018 HHS ECP list, CMS will not allow ECP write-ins for plan year 2018.

For plan year 2018, CMS will determine issuer satisfaction of the 30 percent general ECP standard using the following calculation methodology:

- The numerator of the issuer's contracted ECPs listed on its ECP template consists of any ECPs from the final plan year 2018 HHS ECP list located within the plan's service area.
- The denominator of available ECPs consists of any ECPs on the final plan year 2018 HHS ECP list located within the plan's service area.
- We have proposed in the 2018 Payment Notice Proposed Rule that 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).

As in previous years, if an issuer's application does not satisfy the ECP standard, the issuer will be required to include as part of its application for QHP certification 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. At a minimum, such narrative justification would include the number of contracts offered to ECPs for plan years beginning in 2018, the number of additional contracts an issuer expects to offer and the timeframe of those planned negotiations, the names of the specific ECPs to which the issuer has offered contracts that are still pending, 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.

Alternate ECP Standard

²⁷ The web-based ECP petition link is available at https://data.healthcare.gov/ccio/ecp_petition.

Issuers that qualify for the alternate ECP standard articulated at 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 single 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 Health Professional Shortage Areas (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).²⁸

For plan year 2018, 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 numerator of the issuer's employed or contracted ECPs consists of the following:
 - Any ECPs that the issuer has listed on its ECP template from the non-exhaustive final plan year 2018 HHS ECP list located within the plan's service area; and
 - Any allowable providers that the issuer has listed on its ECP template that are located in a low-income ZIP code or HPSA and employed by the issuer or participate in the issuer's single contracted medical group as part of the issuer's integrated health care delivery system and therefore would not appear on the ECP list as being available to contract with other issuers. Such providers 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.
- The denominator of available ECPs consists of the following:
 - Any ECPs on the non-exhaustive final plan year 2018 HHS ECP list located within the plan's service area; and
 - Any allowable providers that the issuer has listed on its ECP template that are located in a low-income ZIP code or HPSA and employed by the issuer or participate in the issuer's single contracted medical group as part of the issuer's integrated health care delivery system and, therefore, would not appear on the ECP list as being available to contract with other issuers. Such providers must not limit their practice on the basis of a particular source of coverage (e.g., Medicare,

²⁸ CMS provides issuers with a database of zip codes listed as HPSAs or low-income areas where 30 percent or more of the population falls below 200 percent of the FPL. The database is available at <http://www.cms.gov/ccio/programs-and-initiatives/health-insurance-marketplaces/qhp.html>.

Medicaid, CHIP, private health insurance, etc.), unless limited to only the employed or contracted issuer's coverage.

- We have proposed in the 2018 Payment Notice Proposed Rule that 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.

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 submitted by an issuer that qualifies for the alternate ECP standard that does not demonstrate compliance with the 30 percent ECP standard would be required to include a narrative justification describing how the issuer's provider network(s) complies with the regulatory standard. At a minimum, such narrative justification 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 identified in the ECP categories in Table 2.2.

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

CMS intends to maintain its 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 IHS, 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 Addendum²⁹ for Indian health care providers developed by CMS.

As for medical QHPs, CMS intends to maintain an ongoing initiative to collect provider data directly from dental providers through the ECP petition process so that all issuers are held to a uniform ECP standard. Given that the ECP petition process is designed to add qualified dental ECPs to the 2018 HHS ECP list, CMS will not allow ECP write-ins for plan year 2018.

For plan year 2018, CMS will determine SADP issuer satisfaction of the 30 percent ECP standard using the following calculation methodology:

- The numerator of the issuer’s contracted dental ECPs consists of:
 - Any ECPs that the issuer has listed on its ECP template from the non-exhaustive final plan year 2018 HHS ECP list located within the plan’s service area;
 - 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.
- The denominator of available dental ECPs consists of any ECPs on the non-exhaustive final plan year 2018 HHS ECP list located within the plan’s service area.
- We have proposed in the 2018 Payment Notice that 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.

As noted above, if an issuer’s application does not satisfy the ECP standard, a satisfactory narrative justification must be provided.

iii. Requirements for Payment to Federally Qualified Health Centers

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)

²⁹ The model QHP Addendum for Indian health care providers is available at: <http://www.cms.gov/ccio/programs-and-initiatives/health-insurance-marketplaces/qhp.html>.

of the Social Security Act for such item or service, as specified in section 1302(g) of the ACA. 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. 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. As previously stated, QHP issuers in their second or later year of certification must be accredited. QHP issuers should review the 2015, 2016, and 2017 Letters to Issuers for specific requirements for accreditation for issuers entering their second, third, or fourth year of certification. Issuers entering their initial year of QHP certification for plan years beginning in 2018 (i.e., issuers that did not offer a QHP in 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 2017, 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,” “Conditional,” or “Provisional” 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

As part of the certification process for plan year 2018, QHP issuers are required to demonstrate compliance with the applicable patient safety standards outlined in 45 CFR 156.1110 and that were 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 with more than 50 beds. CMS will review issuer compliance with the patient safety standards for purposes of QHP certification for issuers in the FFM. States performing plan management functions may use a similar approach. SADP issuers will not be reviewed for patient safety standards compliance in 2018.

CMS guidance with regard to QHP patient safety standards is unchanged from the 2017 Letter to Issuers.³⁰ Please refer to that document for details regarding guidance for QHP issuers who contract with a hospital with more than 50 beds. Such network hospitals must: 1) work with a Patient Safety Organization³¹; or 2) meet the reasonable exception criteria by implementing 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 (i.e., hospital participation and tracking documentation such as hospital attestations or current agreements to partner with Hospital Engagement Networks; and Quality Innovation Networks-Quality Improvement Organizations).

³⁰ The 2017 Letter to Issuers in the Federally-facilitated Marketplaces is available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2017-Letter-to-Issuers-2-29-16.pdf>.

³¹ See Agency for Healthcare Research and Quality, Dep’t of Health and Human Services, available at <https://www.pso.ahrq.gov/>.

Section 7. Quality Reporting Requirements

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 in the FFMs. For the QRS and QHP Enrollee Survey requirements, FFMs where States perform plan management functions may use a similar approach. Child-only plans and SADPs are not subject to these quality reporting standards at this time.³²

QHP issuers should refer to the Quality Rating System and Qualified Health Plan Enrollee Experience Survey: Technical Guidance for 2017³³ for more detailed information on issuer data collection and reporting requirements for the 2017 calendar year. 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 156.1125.³⁴ Consistent with 45 CFR 156.200(b)(5), QHP issuers will be required to attest that they comply with the specific quality reporting and implementation requirements related to the QRS and QHP Enrollee Survey as part of certification process for the 2018 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. 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 2018 data submissions in the fall of 2017.

³² 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 plans and SADPs, and will consider developing a quality rating system and a QHP Enrollee Survey for these plan types in the future.

³³ The Quality Rating System and Qualified Health Plan Enrollee Experience Survey: Technical Guidance for 2017 is available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/2017_QRS_and_QHP_Enrollee_Survey_Technical_Guidance.pdf.

³⁴ See Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond; Final Rule, 79 FR 30240 (May 27, 2014).

CMS will calculate the quality performance ratings for QHPs offered through all Marketplaces, regardless of the Marketplace model.³⁵ CMS will apply the QRS rating methodology to validated QRS clinical measure data and a subset of the QHP Enrollee Survey validated response data (QRS survey measures) to produce quality ratings on a 5-star rating scale.³⁶ CMS will calculate quality ratings for each QHP issuer's product type (e.g., EPO, HMO, POS, and PPO) within each State and apply those ratings to each of the issuer's QHPs by product type in that State. QHP issuers will receive their QRS and QHP Enrollee Survey results and have an opportunity to 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. CMS intends to use information and feedback from the quality rating information pilot, in which some Marketplaces are displaying quality rating information for the 2017 open enrollment period, to inform national public reporting.

QHP issuers may reference their respective QRS scores and ratings, as well as QHP Enrollee Survey results, in a manner specified by CMS.³⁷ CMS guidelines related to the use of the 2017 QRS and/or QHP Enrollee Survey results in 2018 plan year marketing materials are included in the Quality Rating System and Qualified Health Plan Enrollee Experience Survey: Technical Guidance for 2017.³⁸

³⁵ Marketplace models include FFMs and SBMs (including FFMs where the State performs plan management and SBM-FPs, respectively).

³⁶ For 2017 calendar year reporting, QHP issuers are required to collect and submit validated QRS clinical measure data and QHP Enrollee Survey response data for each unique combination of product type and State for QHPs offered through a Marketplace (i.e. "reporting unit"). QHP issuers may not combine product types or States. Product types subject to the QRS and QHP Enrollee Survey requirements include EPOs, HMOs, POSs, and PPOs. At this time, QRS and QHP Enrollee Survey requirements do not apply to indemnity plans (i.e., fee for service plans). QHP issuers are required to collect and submit validated QRS clinical measure data and QHP Enrollee Survey response data for each reporting unit that was: offered through a Marketplace in 2016, offered through a Marketplace in 2017, that had more than 500 enrollees as of July 1, 2016, and had more than 500 enrollees as of January 1, 2017. For further details on the 2017 calendar year QRS and QHP Enrollee Survey requirements, please see the "Quality Rating System and Qualified Health Plan Enrollee Experience Survey: Technical Guidance for 2017," available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Health-Insurance-Marketplace-Quality-Initiatives.html>.

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

³⁸ The Quality Rating System and Qualified Health Plan Enrollee Experience Survey: Technical Guidance for 2017 is available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/2017_QRS_and_QHP_Enrollee_Survey_Technical_Guidance.pdf.

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. Pursuant to Section 1311(c)(1)(E) of the ACA and as described in 45 CFR 156.1130 and 45 CFR 156.200(b), all issuers offering QHPs through the Marketplaces that meet the QIS participation criteria must comply with the QIS requirements as a condition of certification and participation in the Marketplaces. Based on that authority and building on the regulations outlined in the 2016 Payment Notice Final Rule,³⁹ CMS annually publishes the QIS Technical Guidance and User Guide, a detailed guide to the QIS requirements, and the QIS Implementation Plan and Progress Report form, which is the QIS reporting tool for issuers applying for QHP Certification. CMS anticipates publishing the QIS Technical Guidance and User Guide for the 2018 Plan Year and the 2018 QIS Implementation Plan and Progress Report Form on the CMS Marketplace Quality Initiatives website no later than January 2017.

The QIS requirements apply to all QHP and MSP issuers that have been operating in a Marketplace for two consecutive years and that meet the applicable minimum enrollment threshold (e.g., have more than 500 enrollees within a product type per State as of July 1, 2016), whether through the individual market or through the SHOP Marketplace. QHP and MSP issuers applying for QHP certification in the Marketplaces should refer to the QIS Technical Guidance and User Guide for the 2018 Plan Year (once released) for details on the minimum enrollment threshold and other QIS participation criteria for the 2018 plan year.

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 Marketplaces for the 2018 plan year that meet the applicable QIS participation criteria are expected to submit a QIS Implementation Plan and Progress Report form during the 2018 QHP Application Submission and Review Period (QHP Application Period) to either: 1) implement a new QIS beginning no later than January 2018, or 2) provide a progress update on an existing QIS. An issuer must submit a Progress Report to the Marketplaces through which it offers QHPs during the QHP Application Period in the year after the issuer submitted its QIS Implementation Plan. For example, issuers that submitted QIS

³⁹ Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016; Final Rule, 80 FR 10750 (February 27, 2015).

Implementation Plans as part of their QHP certification in the Marketplaces for the 2017 plan year are expected to submit QIS Progress Reports to the relevant Marketplaces during the 2018 QHP Application Period. All eligible QHPs within eligible product types must be included in a QIS. Issuers should refer to the forthcoming QIS Technical Guidance and User Guide for the 2018 Plan Year for further details.

The QIS evaluation process for the FFMs will take place annually as part of the QHP Certification process. This aligns with the standards in Section 1311(g)(3) of the ACA, which requires periodic reporting to the applicable Marketplace, and 45 CFR 155.200(d), which directs Marketplaces to evaluate quality improvement strategies. All Marketplaces are required to evaluate issuers' QIS submissions, 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 FFMs where States perform plan management functions, issuers applying to offer QHPs will undergo a joint review of their QIS submissions by the State and CMS with the final evaluation determination being made by CMS.

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. 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.

OPM will evaluate QIS submissions for MSP issuers for all Marketplaces. For more information on requirements for MSP issuers, issuers should contact OPM at MSPPIssuer@opm.gov.

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 156.210(c) and 155.1020, a QHP issuer must submit a rate filing justification for a rate increase prior to implementation of such an increase and a Marketplace must consider all rate increases when certifying plans as QHPs. A rate filing justification includes:⁴⁰

⁴⁰ 45 CFR 154.215.

- (1) Unified rate review template (URRT) (Part I), required for all single risk pool products, including new and discontinuing products;
- (2) URRT (Part I) and actuarial memorandum (Part III), required for each single risk pool product that includes a plan that is subject to a rate increase, regardless of the size of the increase⁴¹; or
- (3) URRT (Part I), written description justifying the rate increase (also known as a consumer justification narrative) (Part II), and actuarial memorandum (Part III), required for each single risk pool product that includes a plan with a rate increase that is subject to review under 45 CFR 154.200.

CMS does not plan to duplicate reviews by States to enforce State law, and will integrate State and other rate reviews performed by CMS for direct enforcement states 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 (FOIA) regulations.⁴²

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 non-discrimination 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.

⁴¹ Issuers may also submit a redacted version of the actuarial memorandum if their actuarial memorandum contains trade secrets or confidential commercial or financial information as defined in HHS's FOIA regulations. See instructions at https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/Instructions_for_the_Redacted_Actuarial_Memorandum_20150416.pdf.

⁴² 45 CFR 5.65.

Issuers must use the 2017 benchmark plans,⁴³ which are based on 2014 plans, when designing their plans. CMS reiterates our cautions from the 2017 Letter to Issuers regarding potentially discriminatory age limits, inappropriately labeling benefits as “pediatric services,” and potentially discriminatory formulary exclusions and/or tier structures.

The enforcement of this standard is largely conducted by States. CMS encourages States that are enforcing the ACA 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.

ii. QHP Discriminatory Benefit Design

CMS guidance with regard to QHP Discriminatory Benefit Design is unchanged from the 2017 Letter to Issuers. CMS will continue to assess compliance with the discriminatory benefit design standards outlined in 45 CFR 156.200(e). CMS will continue to collect issuer attestations affirming QHPs will not discriminate against individuals on the basis of health status, race, color, national origin, disability, age, sex, gender identity or sexual orientation. Additionally throughout the plan year, CMS will conduct ongoing assessments of non-discrimination standards through issuer monitoring and compliance reviews.

Pursuant to 45 CFR 156.225, QHPs may not employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs. Issuers are expected to impose limitations and exclusions, if any, based on clinical guidelines and medical evidence and are expected to use reasonable medical judgment. In accordance with the standards set in plan year 2017, CMS will continue to perform outlier analysis on QHP benefits and cost sharing (e.g., co-payments and co-insurance) in order to uncover plans with potentially discriminatory benefit and cost-sharing structures. CMS will also analyze information contained in the Plans and Benefits Template to identify discriminatory features or wording. CMS will also continue to identify QHP outliers for estimated out-of-pocket costs associated with standard treatment protocols for medical services and drug regimens.

Issuers may be asked to provide clinical evidence to support plan designs which have less generous benefits for subsets of individuals. CMS cautions that the existence of other plans with

⁴³ More information on the benchmark plans is available at: <https://www.cms.gov/ccio/resources/data-resources/ehb.html>.

similar features within a market does not ensure that a benefit design is not discriminatory. CMS may use additional evidence provided by issuers to determine if plan designs are discriminatory.

iii. Treatment Protocol Calculator

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 commonly diagnosed, chronic and high cost medical conditions. These protocols are based upon nationally recognized clinical guidelines. Medical conditions considered for plan year 2018 review include: bipolar disorder, diabetes, Hepatitis C, HIV, multiple sclerosis, opioid dependence, 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. 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.

Section 11. Prescription Drugs

This section describes how CMS will conduct a review of issuer's prescription drug benefit offerings. This section does not apply to SADPs, as the EHB prescription drug requirements do not apply to SADPs. The prescription drug reviews described below helps ensure that QHPs are in compliance with 45 CFR 156.125 and 45 CFR 156.225, and are essential components of CMS's efforts to prevent discrimination on the basis of health conditions. If CMS identifies a QHP for follow-up based on these reviews, 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. States performing plan management functions may use a similar approach.

We also note that for non-grandfathered individual and small group market plans that are required to comply with EHB, 45 CFR 156.122(a)(1) establishes that, generally, a health plan does not provide EHB unless it covers at least the greater of: 1) one drug in every USP category and class; or 2) the same number of prescription drugs in each category and class as the EHB-benchmark plan. 45 CFR 156.122(a)(1) is referred to as the EHB prescription drug count standard. As of the 2017 benefit year, the EHB prescription drug count standard is based upon the USP Medicare Model Guidelines (MMG) Version 6.0 drug classification system, which includes an Anti-Addiction/ Substance Abuse Treatment Agents (Opioid Reversal Agent) class. Naloxone is the only drug in the Opioid Reversal Agent class, and as a result, starting with the 2017 benefit year, QHPs, which are required to provide EHB, are being required to cover naloxone in order to comply with the EHB prescription drug count standard. CMS expects to continue using USP MMG Version 6.0 for the EHB prescription drug count standard for the

2018 benefit year and therefore the requirement to cover at least one drug under the Opioid Reversal Agent class will apply to QHPs in 2018.

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.

In addition to the USP categories/classes reviewed for plan year 2017 CMS will also review the following USP categories/classes for plan year 2018: Antivirals/Anti-cytomegalovirus (CMV) Agents, Antivirals/Anti-hepatitis B (HBV) Agents, Antivirals/Anti-hepatitis C (HCV) Agents, Antivirals/Antiherpetic Agents, and Antiemetics/Emetogenic Therapy Adjuncts.

ii. Clinical Guideline-Based Review of Prescription Drug Coverage

As 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. In some cases, the review also evaluates whether certain first-line therapies are available without step therapy or prior authorization. We recognize that issuers regularly update their drug formularies so that providers and their patients have access to a broad array of treatment options. In limited instances, the review may include certain drugs that may not be FDA-indicated for the specific medical condition if the drug is recommended by the clinical guidelines as part of the overall therapy that includes treatment of a symptom associated with the primary condition (e.g., the use of antiemetic drugs such as ondansetron for prevention of nausea and vomiting associated with emetogenic cancer chemotherapy). To further support provider and patient access to a broad range of treatment options, drugs included in this review are not limited to those included on the EHB-Rx Crosswalk. 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. Other 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. We are thus considering an adverse tiering review to identify plans that place most of the needed medications for specific high-cost medical

conditions on the highest cost-sharing tiers, as this may discourage enrollment of individuals with such conditions in the plan. The review CMS is considering would evaluate plan coverage of drugs needed to treat medical conditions considered commonly diagnosed, chronic and high cost.

If this review is implemented, we would flag plan formularies as being adversely tiered if the effective cost sharing of condition-specific medications, taking into account metal level and cost-sharing structure, exceeds condition-specific thresholds. Medical conditions considered for review include: diabetes, Hepatitis C, HIV, multiple sclerosis, opioid dependence and rheumatoid arthritis. CMS is interested in receiving further comments on both the utility of and factors relevant for identifying potentially discriminatory benefit designs in such a review.

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 2018. States performing plan management functions in the FFMs may use a similar approach. This section does not apply to SADPs.

As set forth at 45 CFR 156.298, meaningful difference review assesses whether plans proposed to be offered by potential QHP issuers are meaningfully different from other plans the issuer submitted for certification, thereby supporting informed consumer choice among meaningfully different plans.

For 2018, CMS intends to apply the same criteria for meaningful difference review that were described in the final 2017 Letter to Issuers. In addition, CMS will consider differences in drug list ID as a material difference in covered benefits for purposes of meaningful difference review.

CMS will organize an issuer's proposed QHPs from a given State into subgroups based on market, plan type, metal level, child-only plan offering status, and overlapping counties/service areas. 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.

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 drug list ID, or 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, 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 and cost sharing on behalf of QHP enrollees. Issuers offering individual market QHPs, including SADPs, and their downstream entities, must accept premium and cost-sharing payments on behalf of QHP enrollees from the following third-party entities (in the case of a downstream entity, to the extent the entity routinely collects premiums or cost sharing):

- Ryan White HIV/AIDS Program under title XXVI of the PHS;
- An Indian tribe, tribal organization, or urban Indian organization; and
- A local, State, or Federal government program, including a grantee directed by a government program to make payments on its behalf.

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 (CSRs) do not apply to SADPs. In the 2018 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 2018 AV requirements.
- Do not have an annual limitation on cost sharing that exceeds the permissible threshold for the specified plan variation, as proposed in 2018 Payment Notice Proposed Rule. For 2018, the proposed reduced maximum annual limitation for self-only coverage is \$2,450 for 94 percent and 87 percent plan variations, and \$5,850 for the 73 percent 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)⁴⁴) 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 copay for a specialist visit, the specialist visit copay 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 2018 maximum annual limitation on cost sharing for individuals or, as applicable, the 2018 reduced maximum annual limitation on cost sharing for individuals.

⁴⁴ 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 CSRs are not eligible for HHS reimbursement.

- 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 copay, coinsurance, deductible, or application of an annual limitation on cost sharing.⁴⁵
- Are designed such that, for limited cost-sharing plan variations and zero cost-sharing plan variations, the cost-sharing values (for example, copayment and/or coinsurance) for a non-EHB are the same or less than the values for the non-EHB under the associated standard plan.

Section 15. Data Integrity Tool

This section describes the Data Integrity Tool and the data integrity reviews that CMS will conduct for 2018 QHP and SADP 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 validation 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.

All issuers must complete quality assurance activities to ensure the completeness and accuracy of QHP application data, including using the Data Integrity Tool, as set forth in Chapter 5, Section 2 “QHP Compliance Monitoring.” CMS expects issuers to use the Data Integrity Tool to run checks specific to individual and SHOP market plans because it is in the best interest of both the issuers and CMS. . CMS will release an updated version of the Data Integrity Tool that will incorporate validations specific to the 2018 QHP application templates.

CMS will conduct data integrity reviews on all QHP and SADP applications for plan years beginning in 2018. 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.

CHAPTER 3: CONSUMER SUPPORT TOOLS AND PUBLIC INFORMATION

CMS has developed a number of decision support tools to help consumers select plans.

⁴⁵ 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.

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 FFM, CMS, and OPM. CMS will consider a provider directory to be up-to-date if the issuer updates it at least monthly. CMS considers 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 QHP's provider directory URLs as part of the QHP application.

Under 45 CFR 156.230(c), CMS also requires QHP issuers in the FFM, 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. 45 CFR 156.230(c) also applies to issuers in States performing plan management functions in an FFM and issuers in SBM-FPs. This information is used by CMS to populate its provider directory lookup tool on HealthCare.gov. QHP issuers in an FFM must submit the data in compliance with the data requirements in the Information Collection for Machine Readable Data for Provider Network and Prescription Formulary Content for FFM QHPs (CMS-10558),⁴⁶ update this information at least monthly, and submit the machine readable link at: <https://marketplace.cms.gov/submission/>.

Section 2. Formulary Drug List and Formulary Lookup Tool

Under 45 CFR 156.122(d), issuers' formulary drug lists are required to be up-to-date, accurate, and include a complete list of all covered drugs. Similar to previous years, 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

⁴⁶ Information regarding the data requirements and specifications is available at: <http://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=0938-1284>.

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. 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. 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 SBC, in accordance with 45 CFR 147.200(a)(2). 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 website 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 §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. Section 156.122(d)(2) also applies to issuers in States performing plan management functions in an FFM and issuers in SBM-FPs. This information is used by CMS to populate a formulary lookup tool on HealthCare.gov. QHP issuers in the FFMs must submit the data in compliance with the data requirements in the Information Collection for Machine Readable Data for Provider Network and Prescription Formulary Content for FFM QHPs (CMS-10558),⁴⁷ 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 Cost Comparison Tool that is available on <http://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 Out-of-Pocket 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 out-of-pocket estimate for the costs they could expect to pay throughout the year given the cost-sharing design for a particular health insurance plan. The Out-of-Pocket Cost Comparison tool allows

⁴⁷ Information regarding the data requirements and specifications is available at: <http://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=0938-1284>.

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 Out-of-Pocket 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.

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

Section 4: Transparency in Coverage Reporting

This section discusses the transparency in coverage reporting requirements as applied to QHP issuers, including SADP issuers, in FFMs, including in States performing plan management functions, and SBM-FPs.

Pursuant to section 1311(e)(3) of the ACA, as implemented by 45 CFR 155.1040(a) and 156.220, QHP issuers must post and make available to the public, data related to transparency in coverage in plain language and submit this data to HHS, the Marketplace, and the State insurance commissioner. These standards provide greater transparency for consumers and assist in the decision-making process. CMS anticipates releasing issuer instructions and submission template for the 2018 plan year in late spring. The data submission will largely mirror the 2017 collection process.⁴⁸

CHAPTER 4: STAND-ALONE DENTAL PLANS: 2018 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 2018 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)
--

⁴⁸ The Transparency in Coverage QHP Issuer Instruction Guide for Plan Year 2017 is available at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Step-6-Certify-and-Offer-Plans-.html>.

EHBs*	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
Transparency in Coverage Reporting	Machine Readable* (SADPs must comply with provider directory standards but not drug formulary standards)
Rates submission*	

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: 2018 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 2018 plan years, SADP issuers will complete the rating templates in accordance with the associated rating and business rules and to indicate in the 2018 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 prior 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 2018.

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 based upon the percentage increase in the Consumer Price Index (CPI) for dental services. In the 2018 Payment Notice Proposed Rule, we noted that, because there was no percentage increase, the dental annual limitation on cost sharing for plan year 2018 would remain \$350 for one child and \$700 for two or more children.

Section 4. Prohibition of Waiting Periods

In May 2016, CMS released new guidance⁴⁹ that revised our previous policy to no longer allow waiting periods for pediatric orthodontia EHB. We noted in the guidance that the prohibition of waiting periods for all EHBs is applicable for plan years beginning on or after January 1, 2018. We also note that pursuant to 45 CFR 156.115(a)(1), a plan providing EHB must be substantially equal to the EHB–benchmark plan, both in terms of the covered benefits and any limits on those benefits, or substitute a benefit that is actuarially equivalent to the EHB in accordance with 45 CFR 156.115(b).

Section 5. Off-Marketplace SADP Enrollment Periods

As we noted in recent guidance,⁵⁰ nothing in CMS regulations prohibits Marketplace-certified SADPs offered off-Marketplace from accepting enrollments outside the Marketplace enrollment periods. Under 45 CFR 155.410(a)(2), a Marketplace may only permit a qualified individual to enroll in a QHP or an enrollee to change QHPs during an enrollment period specified in the Marketplace regulations. Therefore, enrollments through a Marketplace are limited to these enrollment periods. However, the Marketplace would not be involved in off-Marketplace enrollments. Therefore, we are confirming that nothing in CMS regulations would prohibit Marketplace-certified SADPs that wish to enroll consumers outside the Marketplace outside the enrollment periods specified in the Marketplace regulations from doing so, provided they comply with applicable State laws.

CHAPTER 5: QUALIFIED HEALTH PLAN PERFORMANCE AND OVERSIGHT

Section 1. Account Management

⁴⁹ Ctr. Consumer Info. & Ins. Oversight, Ctrs. for Medicaid & Medicare Serv., Waiting Period Frequently Asked Questions (May 26, 2016), available at: <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/Waiting-period-FAQ-05262016-Final-.pdf>.

⁵⁰ Ctr. Consumer Info. & Ins. Oversight, Ctrs. for Medicaid & Medicare Serv., Off Marketplace Enrollment Period Frequently Asked Questions (October 14, 2016), available at: <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQ-on-OffMarketplace-Enrollment-Periods-09282016.pdf>.

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 2018 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 technical outreach and 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.

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 2018. CMS anticipates adopting the same approach in States that are performing plan management functions.

Pursuant to 45 CFR 155.1010(a)(2), CMS monitors 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; and indicators of customer service and satisfaction. 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 2018, issuers will have gained more experience operating in the FFM environment, be more familiar with the Marketplace requirements, and have updated their policies and procedures to reflect the applicable standards, guidelines, and operations. In addition, CMS expects QHP issuers to have in place a process to monitor their own operations in order to identify potential issues and work diligently to resolve any identified issues. That process should include making a reasonable effort to complete and maintain a record of quality assurance activities to ensure the completeness and accuracy of QHP Application data, such as reviewing plan data in Plan Preview, using the Data Integrity Tool, and maintaining a record of when and how QHP data was updated.

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 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 and available performance data, to select issuers for 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 review only select areas specific to the area(s) of potential non-compliance. In some cases, to minimize the potential harm to consumers, CMS may conduct compliance reviews on an expedited basis to ensure that potential operational problems can be identified and addressed quickly.

CMS may conduct either a desk review or an on-site review⁵¹ 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 documentation⁵² reasonably necessary to evaluate and verify compliance with the applicable requirements.

CMS intends to continue its coordination with the State regulatory entities, when appropriate, in conducting the compliance reviews. At the conclusion of all compliance reviews for the year, CMS intends to share a summary of the results of the reviews conducted by CMS, and lessons learned, with States and issuers, as well as make this information generally available to the public on a CMS website.

Section 4. FFM Oversight of Agents and Brokers

⁵¹ On-site reviews will take place at the issuer's place of business.

⁵² Additional documentation could include sample sets of applicable data (i.e., notices, claims, casework, etc.).

This section describes how CMS will approach oversight of agents and brokers participating in the FFMs and SBM-FPs. 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 assist with enrollment in QHPs offered through the FFMs. Unless otherwise noted, references to agents and brokers include web-brokers.⁵³

i. QHP Issuer Responsibilities

Pursuant to 45 CFR 156.340, a QHP issuer participating in FFMs, including Marketplaces where States perform plan management functions, maintains responsibility for ensuring that its delegated and downstream entities, including affiliated agents and brokers, comply with applicable laws and regulations. Accordingly, QHP issuers must confirm all affiliated agents' and brokers' licensure statuses, and verify fulfillment of the applicable FFM registration and training requirements⁵⁴ before allowing access to the QHP issuers' tools to assist with enrollment through the FFMs and/or providing compensation for Marketplace transactions. QHP issuers in the FFMs, including Marketplaces where States perform plan management functions, must verify agents' and brokers' FFM registration and training status for each plan year by visiting the CMS agent and broker resources page and linking to the Registration Status Lists (Registration Completion List (RCL) and Registration Termination List) on Data.HealthCare.Gov.⁵⁵ As described in the 2017 Letter to Issuers, QHP issuers are also 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 and State standards.⁵⁶

⁵³ 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 or SBM-FPs in accordance with 45 CFR 155.220(c)(3)-(4).

⁵⁴ In accordance with 45 CFR §155.220(l), agents and brokers assisting Marketplace consumers in an SBM-FP must complete FFM registration and training requirements, and QHP issuers in an SBM-FP must confirm completion of these requirements prior to allowing access to the QHP issuers' tools to assist with enrollment through an SBM-FP and/or providing compensation for SBM-FP transactions.

⁵⁵ Registration Status Lists are available at https://data.healthcare.gov/ffm_ab_registration_lists. RCL and RTL data dictionaries are available at: https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/62416-AB-Registration-Completion-List-Data-Dictionary-Web_v1.pdf. QHP issuers participating in the FFMs, including Marketplaces where States perform plan management functions, as well as the SBM-FPS may use the “expiration date” on the RCL, or the Registration Termination List, to check for suspension or termination (voluntary or for cause) of an agent's or broker's registration status for a particular plan year.

⁵⁶ 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>.

ii. *Agent and Broker Agreements*

Agents and brokers must comply with all applicable privacy and security requirements, including but not limited to the standards established by HHS pursuant to 45 CFR 155.260, related to the use of personally identifiable information (PII) by non-Marketplace entities.⁵⁷ Before assisting consumers in the FFMs and SBM-FPs, agents and brokers must execute the individual market and/or SHOP Privacy/Security Agreement (depending on whether the agent or broker is participating in the FFMs or SBM-FPs for the individual market, the FF-SHOP/SBM-FP-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 individual market Federally-facilitated Exchanges and the State-Based Exchanges on the Federal Platform (General Agreement) — all agents and brokers who wish to assist individual market consumers in the FFMs and SBM-FPs must electronically execute this General Agreement.
- Agreement between Agent or Broker and the Centers for Medicare & Medicaid Services for individual market Federally-facilitated Exchanges and the State-Based Exchanges on the Federal Platform (IM Privacy and Security Agreement) — all agents and brokers who wish to assist individual market consumers in the FFMs and SBM-FPs must electronically execute this Privacy and Security Agreement.
- Agreement between Agents and Brokers and the Centers for Medicare & Medicaid Services for the Small Business Health Options Programs of the Federally-Facilitated Exchanges and State-based Exchanges on the Federal Platform (SHOP Privacy and Security Agreement) — all agents and brokers who wish to assist FF-SHOP and SBM-FP SHOP consumers must electronically execute this Privacy and Security Agreement.
- Agreement between Web-Broker Entity and the Centers for Medicare & Medicaid Services for individual market Federally-facilitated Exchanges and State-based Exchanges on the Federal Platform (Web-Broker Agreement) — all web-brokers who wish to assist individual market consumers in the FFMs and SBM-FPs must electronically execute this Web-Broker Agreement.

These agreements require agents, brokers, and web-brokers to comply with applicable laws and regulations, including Marketplace privacy and security standards.

⁵⁷ These include the eight privacy principles listed at 45 CFR 155.260(a)(3).

iii. Monitoring and Oversight

As in prior years, CMS will continue to work with States to coordinate oversight activities related to agents and brokers. CMS may investigate complaints pertaining to agents and brokers in the FFM, and will monitor QHP issuer activities to confirm they are meeting their responsibilities for oversight of affiliated agents and brokers. Agents and brokers registered with the FFM must comply with all applicable privacy and security requirements, and execute the IM Privacy and Security Agreement and/or the SHOP Privacy and Security Agreement (depending on whether the agent or broker is participating in the FFM or SBM-FPs for the individual market, the FF-SHOP/SBM-FP-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 CMS 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.⁵⁸ States, QHP issuers, as well as members of the public can review the Registration Termination List to see the National Producer Numbers (NPNs) of agents and brokers whose agreements and registration have been suspended or terminated by CMS, or who have voluntarily terminated their agreements and registration. The RCL also includes an end date which reflects the expiration date of the agreements or the suspension/termination date of the agreements, whichever date is soonest.⁵⁹

We note that termination of the agreement(s) results in termination of registration, which includes the following:

- Adding the agent's or broker's NPN to the Registration Termination List,
- Changing the registration expiration date on the RCL, and
- Removal of the agent/broker role from FFM user credentials through the Enterprise Identity Management (EIDM) system, which prevents the agent or broker from logging into the agent/broker landing page on a QHP issuer or web-broker website for direct

⁵⁸ 45 CFR 155.220(g).

⁵⁹ The Registration Status Lists include the dates that the agreements expire for reference. The 2017 agreements expire October 31, 2017; the 2018 agreements expire October 31, 2018

enrollment, and prevents the agent or broker from logging into the SHOP agent/broker portal.

Termination bars the agent or broker from assisting with enrollments through the FFM or SBM-FPs and from being compensated by QHP issuers for actively facilitating FFM or SBM-FP enrollments for the remainder of the plan year.⁶⁰ If an agent's or broker's agreement(s) are terminated (either by the agent or broker or by CMS), the agent or broker must continue to protect any PII that was accessed during the term of his or her relationship with the FFM or SBM-FPs in accordance with the IM and/or SHOP Privacy/Security Agreement and the applicable requirements under 45 CFR 155.260.

The 2017 Letter to Issuers described CMS's suspension and immediate termination authority, established in the 2017 Payment Notice Final Rule under 45 CFR 155.220(g)(5), which continues for the 2018 plan year. CMS may suspend the agent's or broker's agreement(s) for 90 days if it 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 or SBM-FP applicants or enrollees, or in connection with an FFM or SBM-FP enrollment or application. CMS may immediately terminate the agent's or broker's agreement(s) with CMS for cause if there is a finding or determination by a Federal or State entity that an agent or broker engaged in fraud or abusive conduct, parallel to the suspension provision. Agents and brokers whose agreement(s) are suspended or immediately terminated in these circumstances may submit evidence to rebut the allegation, as described in §155.220(g)(5)(i)(B) in the case of suspension or §155.220(h) in the case of immediate termination. During the suspension period and following immediate termination of the agreements, the agent or broker will not be registered with the FFMs, or be permitted to facilitate enrollments through an FFM or SBM-FP, or be permitted to assist individuals with applying for advance payments of the premium tax credit (APTC) or CSRs. Effective as of the date of the notice of suspension or immediate termination, CMS will add the NPN of the agent or broker to the Registration Termination List, change the expiration date on the RCL, and disable the agent/broker role from the FFM user credentials through the EIDM system. If the suspension is lifted or the immediate termination reconsidered, the registration status lists will be updated to reflect the end date of the suspension, or the reconsideration of the immediate termination, and the agent/broker role will be restored through the EIDM system.

CMS notifies 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

⁶⁰ Auto re-enrollment, where the consumer is enrolled in the same or similar plan without changes to the application or enrollment information, does not require the associated agent or broker to have a current registration status because the agent or broker has not provided Marketplace assistance to the consumer.

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. QHP issuers who suspect that an agent, broker, or web-broker is engaging in fraudulent or abusive conduct related to enrollments through the FFMs or SBM-FPs should report the incident or activity to the State DOI, and their CMS Account Managers.

Under 45 CFR 155.220(j), agents and brokers must comply with FFM standards of conduct to protect consumers and ensure the proper administration of the FFMs. CMS may, using the authority under 45 CFR 155.220(k) deny an agent or broker the right to enter into an agreement(s) with CMS in future years and/or impose civil money penalties under 45 CFR 155.285 for non-compliance with requirements under 45 CFR 155.220. As described at 155.220(k)(1)(i), CMS has the authority to bar agents and brokers from entering into agreements with CMS in future plan years. We interpret this authority to allow CMS to terminate an agent or broker's current plan year agreement(s) for a violation that occurred in a previous plan year, but was only discovered after that plan year's agreement(s) had expired. If an agent or broker has been barred from entering into agreements and registering with CMS in future plan years, the NPN will appear on the Registration Termination List for those plan years. Unless the agent or broker is barred from entering into agreements with CMS in future plan years, an agent or broker who CMS has terminated in one plan year may enter into agreements with CMS in future plan years.

iv. Web-brokers

Meaningful Access

CMS specified the standards for web-brokers with respect to oral interpretation, written translation, the use of taglines indicating the availability of language services, and website translation. For web-brokers' obligations under these standards, please see Chapter 7, Section 3, Meaningful Access below.

Direct Enrollment

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 (including SADPs) through the FFMs or SBM-FPs online, alongside traditional agents and brokers who assist consumers with enrollment through the Marketplaces. This enrollment pathway is referred to as "direct enrollment."

a. Differential display requirements

Currently, web-brokers and issuers that use the direct enrollment pathway to facilitate enrollment through an Exchange that offers standardized options are not required to give differential display to standardized options.

If finalized as proposed in the 2018 Payment Notice Proposed Rule, for plan year 2018 and beyond, pursuant to 45 CFR 155.205(b)(1), CMS would require web-brokers and issuers that use the direct enrollment pathway to differentially display standardized options when they facilitate enrollment through an FFM or an SBM-FP that has elected to implement differential display; however, CMS would not require the manner of differentiation to be identical to the one adopted for displaying standardized options on HealthCare.gov. CMS recognizes that web-brokers and issuers may have system constraints that prevent them from mirroring the HealthCare.gov display approach, and if the proposal is finalized, a web-broker or issuer that uses the direct enrollment pathway wants to deviate from the manner adopted by HHS for display on HealthCare.gov, such deviations would be permitted, subject to approval by HHS. As proposed, in approving deviations, HHS would consider whether the same level of differentiation and clarity is being provided under the deviation requested by the web-broker or issuer as is provided on HealthCare.gov.

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 FFMs. For more information, please review 45 CFR 155.220(c)(3)–(4), as well as the guidance and other resources available on the CMS agent and broker resources website.⁶¹

b. Enhanced direct enrollment pathways

CMS is considering methods to implement an enhanced direct enrollment process that would allow a consumer to fully enroll without being redirected to HealthCare.gov. We believe that an enhanced direct enrollment process would allow the consumer to have a more streamlined experience and would permit the Exchange to offer a diverse set of enrollment channels to reach consumers. The 2018 Payment Notice Proposed Rule⁶² provides more detail on this matter.

CMS must consider any additional risks an enhanced enrollment process may pose to consumer privacy and the security of the consumer data. We intend to conduct a privacy impact assessment as required by OMB Memorandum M-10-23. This will help to identify and assess any privacy and security risks presented by the enhanced direct enrollment pathway and will help identify necessary safeguards that need to be in place to protect the personal data that consumers would

⁶¹ The CCIIO agent and broker resources website can be accessed at: <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/a-b-resources.html>.

⁶² Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2018; Proposed Rule; 81 FR 61456, 61498 (September 6, 2016).

entrust to enhanced direct enrollment partners. These requirements would only apply upon implementation of any expansions made to the direct enrollment pathway.

c. Direct enrollment oversight

As proposed in the 2018 Payment Notice Proposed Rule, CMS has proposed modifications to existing requirements and established new requirements for agents and brokers that use the current direct enrollment process to ensure adequate consumer protection if a web-broker is facilitating enrollment through an FFM or SBM-FP. These include new display requirements for APTC and CSR eligibility, additional agent broker obligations and web-broker operational readiness assessments. Additionally, as part of our expanded oversight, CMS has proposed allowing for immediate suspension of an agent's or broker's ability to transact with the Exchange if circumstances demonstrate that there is an unacceptable risk to the Exchange. The 2018 Payment Notice Proposed Rule⁶³ also sought comments to inform the potential expansion of the monitoring and audits authorized by §155.220(c)(5) and proposed new standards to establish greater accountability by web-brokers of their downstream entities.

v. *Compensation*

This section describes issuer agent and broker compensation standards which reflect the same approach as 2017. QHP issuers directly compensate agents and brokers 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. The FFMs do not play a role in 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. QHP issuers should compensate only agents and brokers that are compliant with applicable Federal requirements, including those for registration with the FFMs, and are not required to compensate unaffiliated agents and brokers.⁶⁵ CMS believes that withholding compensation from affiliated agents and brokers who fail to comply with FFM registration and other applicable Federal requirements

⁶³ Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2018; Proposed Rule; 81 FR 61456, 61500 (September 6, 2016).

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.

would generally be required for an issuer to demonstrate compliance with 45 CFR 156.340 as it relates to oversight of agents and brokers.

The FFM's 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 FFM's, 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 issuer 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 may include a consent form from the consumer, an issuer's broker of record form, or similar documentation to demonstrate that the consumer was the agent's or broker's client for the enrollment in question.

Agents and brokers who are acting as Navigators, certified application counselors, and/or (in FFM's, including FFM's where States are 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.

Under Marketplace regulations at 45 CFR 156.200(f), a QHP issuer must pay the same agent or broker compensation for QHPs offered through an FFM that it pays for similar health plans offered in the State outside an FFM. We remind issuers that compliance with this rule is a required participation standard for QHP issuers offering coverage in the FFM's, including both the individual market and SHOP. We note that in determining whether a health plan offered in the State outside of the Marketplace is similar to a QHP offered through the FFM's, 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.⁶⁶ 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 and SBM-FPs must meet all applicable State and Federal requirements, including those for State licensure and FFM registration, at the time they are providing assistance.⁶⁷ When assisting a consumer with initial enrollment in a QHP through the FFMs or SBM-FPs, the agent or broker must have a current FFM registration. In any future plan year, the requirement for FFM registration depends on whether the agent or broker is providing assistance with updates to the Marketplace application or enrollment (active re-enrollment), or if the consumer re-enrolls passively (whether in the same plan or through the suggested alternative plan mechanism).⁶⁸

- If the agent or broker is actively assisting the consumer to make changes to the Marketplace 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 or through the suggested alternative plan mechanism without making any changes to the Marketplace 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 or SBM-FP, the QHP issuer has the discretion to pay commissions, in accordance with State law and applicable contractual requirements, for the coverage renewal.

⁶⁶ 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.

⁶⁷ See 45 CFR 155.220(d), (e), (j), and (l).

⁶⁸ 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.

The issuer should use the Registration Status Lists to verify that the NPN of the agent or broker who is credited for the Marketplace enrollment was registered at the time of the original enrollment or the active re-enrollment. Although the RCL for plan year 2018 will indicate State licensure status, QHP issuers should validate RCL data against State and the NAIC records to confirm an agent or broker's State-level authority to sell health insurance.

vii. HHS-Approved Vendors of FFM Training

HHS established standards at 45 CFR 155.222 for approved vendors to provide training for agents and brokers seeking to complete the training requirements necessary to assist consumers seeking coverage through the FFMs and SBM-FPs. Although HHS continues to offer training at no cost, this program provides an additional avenue by which agents and brokers may satisfy FFM training requirements while receiving state licensure continuing education credits for a fee.

To become an approved vendor of FFM agent and broker training,⁶⁹ an organization must:

- Complete and submit an application that demonstrates the organization's ability to meet HHS' specified criteria to offer FFM training to agents and brokers. Vendors that have previously received HHS approval to offer FFM training to agents and brokers must reapply and be re-approved by HHS each plan year.
- Adhere to HHS specifications for content, format, and delivery of training.
- Offer continuing education unit credits in at least five States in which an FFM or SBM-FP is operating.
- Collect, store, and share with HHS agent and broker training completion data in a manner, format, and frequency specified by HHS.
- Protect all data from agents and brokers in accordance with applicable privacy and security requirements.
- Execute the Agent Broker Vendor Agreement with HHS.
- Permit any individual who holds a valid State license (or equivalent State authority to sell health insurance products) to access the vendor's training.
- Provide technical support to agents and brokers participating in the vendor's training.

⁶⁹ 45 CFR 155.222(b).

To ensure ongoing compliance with these standards, HHS continues to monitor vendors after their respective training programs launch and may revoke approval if a vendor does not comply with HHS standards. Entities whose applications are not approved or who have their approval revoked may request an appeal.⁷⁰

The list of approved vendors offering plan year 2017 FFM agent and broker training is posted on the CMS agent and broker resources website.⁷¹

Section 5. Oversight of Marketing Activities

This section describes how CMS will monitor QHP marketing during plan years beginning in 2018 in the FFMs. States performing plan management functions in the FFMs are encouraged to take a similar approach.

QHP issuer discrimination on the basis of race, color, national origin, disability, age, sex, gender identity or sexual orientation is prohibited under 45 CFR 156.200(e).⁷² The QHP certification standards at 45 CFR 156.225(a) requires that a QHP issuer must comply with all applicable State laws on health plan marketing by issuers. Under guaranteed availability and Marketplace regulations at 45 CFR 147.104(e) and 156.225(b), issuers of non-grandfathered health insurance coverage offered in the group or individual market, through or outside of the Marketplaces, including QHPs, cannot employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage.

CMS recommends that QHP issuer 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.” The HHS Office for Civil Rights (OCR) has finalized its rulemaking on section 1557 of the ACA, which prohibits discriminatory marketing practices. The section 1557 implementing regulation requires a nondiscrimination notice that CMS expects QHP issuers to modify to include the language

⁷⁰ 45 CFR 155.222(e).

⁷¹ The CCIIO agent and broker resources website can be accessed at: <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/a-b-resources.html>.

⁷² See also 45 CFR 147.104(e), for the market-wide prohibition on discrimination.

suggested here.⁷³ We note that compliance with section 1557 regulations is separate from compliance with the CMS regulations described in this Letter, and QHP issuers should review guidance from OCR for additional standards that may apply.

As noted in the 2017 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 FFMs, CMS may review QHP marketing materials for compliance with 45 CFR 156.200(e) and 45 CFR 156.225(b).

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 work with States to determine where additional monitoring and review of marketing activities may be needed. If CMS receives a consumer complaint about an issuer's marketing activities (e.g., false advertising/false information, privacy/security violations) or about an agent's, broker's, or web-broker's conduct which is generally overseen by the State (or another Federal entity), CMS will send the complaint to the State regulators (or another Federal entity), as appropriate, for investigation. In addition, CMS may take enforcement action against the QHP issuer or agent, broker, or web-broker.

As described at 45 CFR 155.220(j)(2)(i) agents and brokers (including web-brokers) must provide consumers with correct information, without omission of material fact, regarding the FFMs, QHPs (including SADPs⁷⁴) offered through the FFMs, and insurance affordability programs, and refrain from marketing or conduct that is misleading or coercive, or discriminates based on race, color, national origin, disability, age, sex, gender identity, or sexual orientation. We 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

⁷³ 45 CFR 92.8 (requiring a nondiscrimination notice that satisfies seven elements, including a statement that the entity does not discriminate on the basis of race, color, national origin, sex, age, or disability); Sample Notice Informing Individuals About Non-discrimination and Accessibility Requirements and Sample Non-discrimination Statement: Discrimination is Against the Law (81 FR 31472 (May 18, 2016)) (45 CFR pt. 92 Appendix A). CMS regulations for QHP issuers at 45 CFR §§ 156.200(e) and 156.225(b) also include gender identity, sexual orientation, and health status.

⁷⁴ 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 FR 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.

could reasonably cause confusion with a Federal program or website. In the 2018 Payment Notice Proposed Rule⁷⁵, we proposed also prohibiting agents, broker, and web-brokers having a direct enrollment website that HHS determines could mislead a consumer into believing they are visiting HealthCare.gov.

Additionally, web-broker websites must provide consumers the ability to view all QHPs offered through the Marketplace.⁷⁶ If an agent or broker assists a consumer with individual market FFM or FF-SHOP QHP selection through the agent's, broker's, or web-broker's non-FFM website, a standardized disclaimer must be prominently displayed to indicate that the site is not a Health Insurance Marketplace website, and an active link to HealthCare.gov must also be provided.⁷⁷

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 conflict of interest standards and disclosure requirements, including disclosure of financial relationships with QHP issuers.

Section 6. Issuer Participation for Full Plan Year

In the 2018 Payment Notice Proposed Rule, CMS proposed that issuers would be required to make their QHPs available for enrollment through the Marketplace for the full plan year for which the plan was certified, unless a basis for suppression under 45 CFR 156.815 applies. We also proposed that issuers in all SHOP Marketplaces must make their QHPs available for enrollment through the SHOP Marketplace for the full plan year for which the plan was certified, unless a basis for suppression under §156.815 applies. This requirement would ensure that consumers enrolling in the individual market during limited open enrollment periods have the same plan choice as those who enrolled during open enrollment, and that qualified employers and qualified employees would have generally consistent plan choices throughout the plan year.

If this proposal is finalized, QHP issuers in FFMs and FF-SHOPs that did not comply with proposed §156.272(a) and (b) could be subject to civil money penalties under our existing civil money penalty authority at §156.805(a)(1). In this event, we would expect that civil money penalties would be reserved for extreme circumstances. We also proposed at §156.272(c) that if

⁷⁵ Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2018; Proposed Rule; 81 FR 61455, 61500 (September 6, 2016).

⁷⁶ 45 CFR 155.220(c)(3)(i)(B).

⁷⁷ See 45 CFR 155.220(c)(3)(i)(G). Also see 45 CFR 155.220(i), which allows SHOPs to permit agents and brokers, in States that permit such activity under State law, to use an Internet website to provide assistance to qualified employers and facilitate enrollment of enrollees in SHOP QHPs, subject to the requirements of 45 CFR 155.220(c)(3); and 45 CFR 155.220(l), which extends the FFM agent broker standards to agents and brokers assisting with enrollments in SBM-FPs.

an issuer fails to comply with those sections, HHS could, at its discretion, preclude that issuer from participating in the FFMs and FF-SHOPs, for up to the two succeeding years. Under the proposal, issuers would not be subject to civil money penalties or preclusions from Marketplace participation if a basis for suppression under §156.815 applies.

CHAPTER 6: FF-SHOPS

Section 1. Enrollment Periods for Newly Qualified Employees

This section describes some of the proposals in the 2018 Payment Notice Proposed Rule related to the process for newly qualified employees to enroll in coverage through a SHOP and the coverage effective date for newly qualified employees.

In order to ensure that newly qualified employees have a full 30 days to make their plan selections, we proposed in the 2018 Payment Notice Proposed Rule at 155.725(g)(1) to require that a 30-day enrollment period for a newly qualified employee would begin on the date that the qualified employer notifies the SHOP about the newly qualified employee. We also proposed at 45 CFR 157.205(f)(1) and 155.725(g)(1) that a qualified employer would be required to notify the SHOP of an employee who has become a qualified employee outside of the initial or annual open enrollment period on or before the 30th day after the day that the employee becomes eligible for SHOP coverage—this date is often the date that an employee is hired or becomes a full-time employee.

We also proposed in the 2018 Payment Notice Proposed Rule a number of amendments to minimize the risk of an employer exceeding the limitations on waiting period length at §147.116 due to SHOP enrollment timelines and processes. For example, we proposed that the coverage effective date for a newly qualified employee would be the first day of the month following the plan selection, unless the employee is subject to a waiting period consistent with §147.116 and proposed paragraph 155.725(g)(3), in which case the effective date would be on the first day of the month following the end of the waiting period, but in no case may the effective date fail to comply with §147.116. We also proposed that if a newly qualified employee's waiting period ends on the first day of a month and the employee has already made a plan selection by that date, coverage would also be effective on that date. Additionally, we proposed that if a qualified employer with variable hour employees makes regularly having a specified number of hours of service per period, or working full-time, a condition of employee eligibility for coverage offered through a SHOP, any measurement period that the qualified employer elects to use under §147.116(c)(3)(i) to determine whether an employee meets the applicable eligibility conditions with respect to coverage offered through the SHOP must not exceed 10 months, beginning on any date between the employee's start date and the first day of the first calendar month following the employee's start date.

To further minimize the risk of employers exceeding waiting period limitations, as defined at §147.116, and to avoid potential operational complications of the proposed enrollment period amendments, we proposed in the 2018 Payment Notice Proposed Rule that waiting periods in SHOPS may not exceed 60 days in length. To minimize operational complexity in the Federal platform build for the SHOP, we also proposed that in an FF-SHOP or SBM-FP utilizing the Federal platform for SHOP functions, employers would only have waiting period options of 0, 15, 30, 45, and 60 days. We also proposed that waiting periods in SHOPS would be calculated beginning on the date the employee becomes eligible for coverage, regardless of when the qualified employer notifies the SHOP about the newly qualified employee.

If these amendments are finalized as proposed, we would expect issuers to effectuate coverage for newly qualified employees in accordance with the provisions of §155.725 (see §156.285(b)). FF-SHOP and SBM-FP issuers are also required to effectuate SHOP Marketplace coverage unless the issuer receives a cancellation transaction prior to the coverage effective date (see §156.285(c)(8)(iii) and §156.350(a)(2)).

Section 2. SHOP Participation Provision

This section describes the request for comments in the 2018 Payment Notice Proposed Rule on whether the SHOP participation provision at 45 CFR 156.200(g) is still necessary or appropriate in the FF-SHOPS, on whether CMS should eliminate this policy for the FF-SHOPS for plan years beginning on or after January 1, 2018, and on the implications of removing this provision for small businesses.

In the 2014 Payment Notice, CMS finalized the SHOP participation provision at 45 CFR 156.200(g), under which an individual market FFM will certify a QHP only if the QHP issuer (or an issuer in the same issuer group) offers through the FF-SHOP of the State at least one QHP in the silver coverage level and at least one QHP in the gold coverage level, unless no issuer in the issuer group has a greater than 20 percent share of the small group market in the State, based on earned premiums. We indicated in the preamble of the 2014 Payment Notice that we would reevaluate the effectiveness of the policy on an ongoing basis.

In the 2018 Payment Notice Proposed Rule, we sought comment on whether the SHOP participation provision is still necessary or appropriate in the FF-SHOPS and sought comment on whether we should eliminate this policy for the FF-SHOPS for plan years beginning on or after January 1, 2018. We also recognized that eliminating the SHOP participation provision could have the effect of reducing FF-SHOP issuer participation, and sought comment on the implications for small businesses and how to accommodate such an effect. For example, in such a circumstance, in consideration of the ongoing investments that would be required to maintain the FF-SHOPS, including for premium aggregation services, we stated that we were considering providing for elimination of enrollment through FF-SHOP websites and providing for alternative means of enrollment into SHOP QHPs, either in States that would be particularly affected by this

change or in all FF-SHOPs. An FF-SHOP website would still be maintained, consistent with section 1311(d)(4)(C) of the ACA, but would not support online enrollment, except perhaps for the continuation of services for existing groups in the FF-SHOP through the end of any plan year that began before January 1, 2018. We also sought comment on how entities such as web-brokers or third party administrators could help to facilitate enrollment in available SHOP QHPs.

We anticipate that any alternative means of enrollment into SHOP QHPs would be proposed through notice-and-comment rulemaking that would provide additional information on the potential impact on employers and their employees, issuers, and States. Until further notice, the SHOP participation provision and the current enrollment process in FF-SHOPs and SBM-FPs using the Federal platform for SHOP enrollment functions remain in effect.

Section 3. FF-SHOP Enrollment Reconciliation

This section describes the monthly enrollment reconciliation process for the FF-SHOPs, including the form and frequency of file submissions, and the requirement for FF-SHOP issuers to transmit enrollment transactions.

As described in the 2017 Letter to Issuers, 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, and pursuant to 45 CFR 156.285(c)(5), SHOP issuers must send enrollment reconciliation files to the SHOPs on at least a monthly basis. In the Final 2017 Payment Notice, CMS amended §156.285(c)(5) to specify that in an FF-SHOP, issuers must send enrollment reconciliation files according to a process, timeline, and file format established by the FF-SHOP. Additional details and technical specifications for the enrollment reconciliation process for the FF-SHOPs can be found at

https://www.regtap.info/uploads/library/SHOP_EnrReconICDv1.11_5CR_090116.docx.

Additionally, if a proposal in the 2018 Payment Notice Proposed Rule at 45 CFR 156.350(a)(2) is finalized as proposed, then, in order to participate in an SBM-FP using the Federal platform for SHOP enrollment functions, a QHP issuer would be required to send enrollment reconciliation files on at least a monthly basis according to a process, timeline, and file format established by the FF-SHOPs, consistent with 45 CFR 156.285(c)(5).

Pursuant to 45 CFR 155.725(a), the SHOP must ensure that enrollment transactions are sent to QHP issuers and that such issuers adhere to coverage effective dates in accordance with 155.725. QHP issuers in FF-SHOPs are required to send the FF-SHOPs 834 effectuation transaction files. CMS expects these files to be sent as soon as possible, but no later than 30 days after the coverage effective date. If CMS does not receive the Issuer Assigned Member IDs on effectuation files, it will show as a discrepancy during the monthly enrollment/reconciliation process. It is critical that Issuer Assigned Member IDs are submitted on X12 834 effectuations for enrollment/reconciliation and renewal purposes. Additionally, if the Issuer Assigned Member

IDs on the reconciliation file do not match the FF-SHOP's records, CMS would ask the FF-SHOP issuer to confirm the correct Issuer Assigned Member ID. In order to resolve this type of discrepancy, the issuer would be expected to submit a new effectuation file to the FF-SHOP with the updated information. Effectuation files can be sent at any time to update the Issuer Member Assigned IDs. If the proposed amendments at §156.350 are finalized as proposed, then these procedures would also apply to issuers in SBM-FPs using the Federal platform for SHOP enrollment functions.

Issuers will receive a group-level maintenance transaction from the FF-SHOP when a group's contact information or broker changes. When a group's enrollment or coverage through an FF-SHOP is terminated, issuers should not terminate transactions. Instead, the FF-SHOP will always generate termination transactions.

To minimize confusion for consumers and others, issuers participating in FF-SHOPs and in SBM-FPs using the Federal platform for SHOP enrollment functions are also encouraged to:

- Avoid sending notices, such as premium payment delinquency notices, that are not required by state or Federal law or regulation. CMS sends regular premium payment delinquency notices and follows up with phone calls when employers are behind with their monthly premium payments for SHOP Marketplace coverage.
- Not directly invoice employers for premiums owed. CMS sends monthly invoices to SHOP employers and remits full payments received to issuers on a weekly basis.
- Not make account updates outside of the SHOP Marketplace online system. Consumers in an FF-SHOP or SBM-FP using the Federal platform for SHOP functions who want to make an update to their SHOP Marketplace coverage should be advised to log into their HealthCare.gov SHOP Marketplace account, contact the FF-SHOP Call Center, or reach out to the associated agent/broker on the account.

Issuers with questions about an enrollment or premium payment issue in an FF-SHOP or an SBM-FP using the Federal platform for SHOP enrollment functions should contact the FF-SHOP Call Center or submit a ticket to CMS_FEPS@cms.hhs.gov.

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 and SBM-FPs.

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 FFM 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, 2015.⁷⁸

HICS will also be used to record anonymized matters brought to CMS’s 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.

Although the anonymized matters will not be considered cases, CMS expects issuers to monitor them 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 delayed enrollment processing, 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, adjustments of effective dates based on special enrollment periods (SEPs), final appeals decisions, or other enrollment errors. In all cases, CMS expects QHP and SADP issuers operating in the FFM and SBM-FPs to conduct appropriate research using all of the tools and systems available to them, including 834 transactions and pre-audit files. Additionally, CMS expects QHP and SADP issuers operating in the FFM and SBM-FPs to contact consumers as

⁷⁸ Ctr. Consumer Info. & Ins. Oversight, Ctrs. for Medicaid & Medicare Serv., Health Insurance Casework System Access Guide (May 21, 2015), available at https://www.regtap.info/uploads/library/QHP_HICS_Access_Resource_052115_5CR_072015.pdf.

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-FPs, 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 and SBM-FPs. This does not apply to SADPs.

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 ACA. Section 2719 of the PHS Act requires that all non-grandfathered group health plans and non-grandfathered 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) and web-brokers to ensure meaningful access by limited English proficient (LEP) individuals and by individuals with disabilities.

45 CFR 155.205(c) specifies access standards for certain entities, including QHP issuers and web-brokers, and includes language access standards with respect to oral interpretation, written translation, the use of taglines indicating the availability of language services, and website

translation. 45 CFR 156.250 requires 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 accordance with the standards in 45 CFR 155.205(c).

Under 45 CFR 155.205(c)(2)(i), QHP issuers and web-brokers are required to provide oral interpretation services to LEP individuals at no cost to the individual, including by making available telephonic interpretation services in at least 150 languages. The requirement to make available telephonic interpretation services in at least 150 languages applies to web-brokers only when they have been registered with the Marketplace for at least one year.

45 CFR 155.205(c)(2)(ii) requires all entities subject to 155.205(c), including QHP issuers and web-brokers, to provide written translations to LEP individuals at no cost to the individual.

45 CFR 155.205(c)(2)(iii) establishes a general requirement for all entities subject to 155.205(c), including QHP issuers and web-brokers, to provide taglines in non-English languages indicating the availability of language services for LEP individuals at no cost to the individual. For QHP issuers and web-brokers, this requirement includes providing taglines on website content and documents that are 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. For QHP issuers, this requirement applies beginning no later than November 1, 2016. For web-brokers, this requirement applies beginning on November 1, 2016, or when the web-broker has been registered with the Marketplace for at least one year, whichever is later. These taglines must be provided in at least the top 15 languages spoken by the LEP population of the relevant State. Documents are considered to be “critical” under §156.250 and §155.205(c) if State or Federal law or regulation requires that the document be provided to a qualified individual, applicant, qualified employer, qualified employee, or enrollee.

In March 2016, HHS issued guidance providing language data and sample taglines in the top 15 languages spoken by the LEP population in each State.⁷⁹ The 2016 guidance also provides a non-exhaustive list of what CMS considers to be critical documents.

⁷⁹ Ctr. Consumer Info. & Ins. Oversight, Ctrs. for Medicaid & Medicare Serv., Guidance and Population Data for Exchanges, Qualified Health Plan Issuers, and Web-Brokers to Ensure Meaningful Access by Limited-English Proficient Speakers Under 45 CFR 155.205(c) and 156.250 (March 30, 2016), available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Language-access-guidance.pdf>; Appendix A - Top 15 Non-English Languages by State, available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Appendix-A-Top-15.pdf>; Appendix B - Sample Translated Taglines, available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Appendix-B-Sample-Translated-Taglines.pdf>.

As we explained in the March 2016 guidance, QHP issuers are also responsible for complying with the culturally and linguistically appropriate standards set forth in the internal claims and appeals and external review processes under the rules implementing section 2719 of the PHS Act and in the SBC and uniform glossary rules implementing section 2715 of the PHS Act. These provisions require that group health plans and health insurance issuers offering group and individual health insurance coverage provide taglines in a particular non-English language if 10 percent or more of the population residing in the county is literate only in that same non-English language. In January 2016, HHS released updated guidance on the languages and counties that meet this threshold.⁸⁰

We have also indicated that QHP issuers must provide an addendum with language taglines as required under 155.205(c)(2)(iii)(A) with their SBCs for QHPs offered through a Marketplace. Any additional taglines required under PHS Act 2715 and its implementing regulations must also be included in this addendum. However, any taglines that are included in the addendum are not required to also be included in the SBC document. The addendum, which must only include tagline information required by the applicable language access standards, must be provided along with the SBC 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.

As we stated in the March 2016 guidance and the preamble to the 2016 Payment Notice, if an entity's service area covers multiple states, the top 15 languages spoken by LEP individuals may be determined by aggregating the top 15 languages spoken by all LEP individuals among the total population of the relevant States.⁸¹ In the 2018 Payment Notice Proposed Rule, we proposed amendments to §155.205(c) to provide more specificity about when entities subject to §155.205(c)(2)(iii)(A) and (B) would be permitted to aggregate limited English proficient populations across States to determine the languages in which taglines must be provided. Under the proposed amendments, a QHP issuer would be permitted to aggregate the limited English proficient populations across all States served by the health insurance issuers within the issuer's controlled group (as defined under a definition proposed at §147.106(d)(3)(i) in the 2018 Payment Notice Proposed Rule), whether or not those health insurance issuers offer plans through the Marketplace in each of those States, to determine the top 15 languages in which it must provide taglines. Additionally, as proposed, web-brokers that are licensed in and serving multiple States would be permitted to aggregate the limited English proficient populations in the States they serve to determine the top 15 languages in which they must provide taglines under

⁸⁰ Ctr. Consumer Info. & Ins. Oversight, Ctrs. for Medicaid & Medicare Serv., CLAS County Data (January 2016), available at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/CLAS-County-Data_Jan-2016-update-FINAL.pdf.

⁸¹ 80 FR 10788 (February 27, 2015).

§155.205(c)(2)(iii)(B). In FAQs published in August 2016, we indicated that we were intending to make these proposals, and that in the meantime we will not take enforcement action against QHP issuers or web-brokers that comply with the rule by providing taglines in accordance with the FAQs.⁸² Additionally, in the 2018 Payment Notice Proposed Rule, we explained that the proposed aggregation policy related to 155.205(c)(2)(iii)(A) would not apply under the tagline rules for SBCs under §147.200(a)(5) or under the tagline rules for internal claims and appeals and external review under §147.136(e). Additionally, as proposed in the 2018 Payment Notice Proposed Rule, QHP issuers and web-brokers could satisfy tagline requirements with respect to website content if they post a web link prominently on their home page that directs individuals to the full text of the taglines indicating how individuals may obtain language assistance services, and if they also include taglines on any standalone document linked to or embedded in the website, such as one in PDF or word processing software format, that is critical within the meaning of the rule. We also indicated in our August 2016 FAQs that we intended to make this proposal, and that in the meanwhile, we will not take enforcement action against QHP issuers or web-brokers that comply with § 155.205(c)(2)(iii)(A) and (B) by providing taglines in accordance with the FAQs.

Under 45 CFR 155.205(c)(2)(iv), beginning no later than November 1, 2016, QHP issuers must translate content that is “critical” within the meaning of 45 CFR 156.250 on a website maintained by the QHP issuer 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. Also under 45 CFR 155.205(c)(2)(iv), beginning November 1, 2016 or when the web-broker has been registered with the Marketplace for at least one year, whichever is later, web-brokers must translate content that is intended for qualified individuals, applicants, qualified employers, qualified employees, or enrollees on a website that is maintained by the web-broker into any non-English language that is spoken by an LEP population that reaches 10 percent or more of the population of the relevant State, as determined in HHS guidance. In the preamble to the 2016 Payment Notice, we explained that under 155.205(c)(2)(iv), if an entity’s service area covers multiple States and at least one language in one of the States the entity serves meets the 10 percent threshold specified in the rule, then the applicable information on the entity’s website must be translated into that language. HHS’s March 2016 guidance identifies the non-English languages that are triggered by these standards.

⁸² Ctr. Consumer Info. & Ins. Oversight, Ctrs. for Medicaid & Medicare Serv., Language Access Tagline Frequently Asked Questions (August 10, 2016), available at <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/Tagline-FAQs-7-27-16-clean-letterhead-MM-508.pdf>.

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 individuals and by people with disabilities.⁸³

Finally, QHP issuers operating in the FFM are reminded that the meaningful access requirements at 45 CFR 155.205(c), 155.230(b), and 156.250, as well as non-discrimination prohibitions at 45 CFR 156.200(e), are independent of other obligations QHP issuers might have. For example, QHP issuers that receive Federal financial assistance are subject to Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973,⁸⁴ and section 1557 of the ACA,⁸⁵ and as a result, have separate responsibilities under the law related to providing meaningful access, auxiliary aids and services, language assistance services, and notice and taglines indicating the availability of those 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 and SBM-FPs.

QHP issuers are required to provide the 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 ACA. 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.”

⁸³ For instance, CMS intends to continue coordinating with OCR in OCR’s implementation of section 1557 of the ACA.

⁸⁴ 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>.

⁸⁵ Non-discrimination in Health Programs and Activities; Final Rule, 81 FR 31375 (May 18, 2016) (finalizing 45 CFR 92.8 that establishes, among other things, notice and tagline requirements on covered entities regarding provision of language assistance services and auxiliary aids and services; and finalizing 45 CFR 92.201 that requires, 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).

On April 6, 2016, the Departments published an updated SBC template and associated documents (referred to in this document as the “2017 SBC”).⁸⁶ The 2017 SBC instructions provide that: “Health plans and issuers that maintain an annual open enrollment period will be required to use the April 2017 edition of the SBC template and associated documents beginning on the first day of the first open enrollment period that begins on or after April 1, 2017, with respect to coverage for plan years (or, in the individual market, policy years) beginning on or after that date. For plans and issuers that do not use an annual open enrollment period, the 2017 SBC template and associated documents is required beginning on the first day of the first plan year (or, in the individual market, policy year) that begins on or after April 1, 2017.” On July 7, 2016, HHS published further guidance on the applicability date in a Q&A, which provides direction for plans with an annual open enrollment period versus plans with rolling enrollment periods. The Q&A also clarifies that issuers in States where HHS is doing direct enforcement should submit for review SBCs based on the 2017 template at least 60 days prior to use, similar to other forms. Issuers in States where the State is enforcing SBC requirements should follow applicable State guidelines for State enforcement activity with respect to SBCs.⁸⁷

QHP issuers are required 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 manner specified in guidance by the Secretary.⁸⁸ The instructions for the 2017 SBC require that for plans preparing an SBC for a QHP offered through a Marketplace, plans that cover excepted and non-excepted abortion services must list “abortion” in the covered services box and plans that exclude all abortions should list “abortion” in the excluded services box. Plans that cover only excepted abortions should list in the excluded services box “abortion (except in cases of rape, incest, or when the life of the mother is endangered)” and may also include a cross-reference to another plan document that more fully describes the exceptions.

In the 2016 Payment Notice Final Rule, CMS required 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 CSRs), provide the individual an SBC that

⁸⁶ The 2017 SBC template and associated documents are available online at: [https://www.cms.gov/ccio/Resources/forms-reports-and-other-resources/index.html#Summary of Benefits and Coverage and Uniform Glossary](https://www.cms.gov/ccio/Resources/forms-reports-and-other-resources/index.html#Summary%20of%20Benefits%20and%20Coverage%20and%20Uniform%20Glossary) .

⁸⁷ Q&A on the Summary of Benefits and Coverage Applicability Date available online at: <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/SBC-FAQs-07072016-final-MM-508.pdf>.

⁸⁸ 45 CFR 147.200(a)(2)(i)(N).

accurately reflects the new plan variation (or standard QHP without CSRs) as soon as practicable following receipt of notice from the Marketplace, but not later than 7 business days following receipt of notice. CMS released sample completed SBCs for an AI/AN limited cost-sharing plan and an AI/AN zero cost-sharing plan. As with the other SBC documents, these documents are posted to the CMS website and can be used as a resource for issuers to develop SBCs for AI/AN consumers in zero cost-sharing⁸⁹ or limited cost-sharing plans.⁹⁰

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 as required under 155.205(c)(2)(iii)(A) with their SBCs for QHPs offered through a Marketplace. Any additional taglines required under PHS Act sections 2715 and 2719 or their implementing regulations must also be included in this addendum. Taglines required under Section 1557 must also be included in this addendum. However, any taglines that are included in the addendum are not required to also be included in the SBC document. The addendum, which must only include tagline information required by the applicable language access standards, must be provided along with the SBC 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).

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 IHS, Tribes and Tribal organizations and Urban Indian organizations. These are collectively known as Indian health care providers. CMS guidance concerning Indian health care providers remains unchanged from the 2017 Letter to Issuers. In adhering to QHP certification standards, CMS reminds QHPs to contract with Indian health care providers, through which a significant number of American Indians and Alaska Natives (AI/AN) access health care. To promote contracting between issuers and Indian health care providers, CMS is continuing to require QHPs to offer contracts in good faith to all available Indian health care providers in the QHP's service area, applying the special

⁸⁹ Sample AI/AN Zero Cost sharing available: <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/SBC-2017-Template-AI-AN-zero-6-7-16-clean-508-MM.PDF>

⁹⁰ Sample AI/AN Limited Cost-sharing (PDF) available: <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/SBC-2017-Template-AI-AN-limited-6-7-16-clean-508-MM.PDF>

terms and conditions necessitated by Federal law and regulations as referenced in the Model QHP Addendum (Addendum).⁹¹

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. For the 2018 plan year, CMS has collected via the ECP petition more complete Indian health care provider data that will enhance an issuer's ability to identify and contact Indian health care and other providers interested in participating in QHP networks. For further details, please refer to Chapter 2, Section 4. Essential Community Providers in this document.

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

State-based Marketplaces on the Federal Platform, or SBM-FPs, 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 conform to CMS user

⁹¹ The model QHP Addendum for Indian health providers is available at: <http://www.cms.gov/ccio/programs-and-initiatives/health-insurance-marketplaces/qhp.html>.

fee collection requirements. SBM-FPs will retain the authority and primary responsibility for plan management functions, including QHP certification. In the 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. SBM-FPs will execute the Federal platform agreement in coordination with CMS for plan year 2018.

Although an SBM-FP will retain primary responsibility for overseeing QHPs and issuers, under 45 CFR 155.200(f), an SBM-FP must establish, oversee, and 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.

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 the 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 2018. 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.

The 2018 Payment Notice Proposed Rule proposes to apply all FFM binder payment rules to SBM-FPs. In particular, as proposed in 45 CFR 155.400(e)(2), SBM-FPs would be required to allow issuers experiencing billing or enrollment problems due to high volume or technical errors to implement a reasonable extension of the binder payment deadlines the issuer has set under

§155.400(e)(1). In the case of most high volume situations or technical errors we would not expect this type of reasonable extension to be more than 45 calendar days' duration.

Under 45 CFR 155.200(f)(3), CMS will work collaboratively with SBM-FPs to enforce certain FFM standards that apply to SBM-FP issuers. In the circumstance where CMS determines that an SBM-FP is not substantially enforcing one or more of these standards, CMS 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 believes 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.

The 2018 Payment Notice Proposed Rule proposed to make differential display of standardized options, as set out in the final 2017 Payment Notice, available in SBM-FPs at the State's option, as well as to require differential display of standardized options by QHP issuers and web-brokers using a direct enrollment pathway to facilitate enrollment through an FFM or SBM-FP.

In the 2018 Payment Notice Proposed Rule at 45 CFR 155.200(f)(4), because certain FF-SHOP requirements are an integral part of the Federal platform's functionality and system build, and to avoid sizeable costs associated with permitting SBM-FPs to use the Federal platform for SHOP functions, we proposed to require SBM-FPs that choose to rely on the Federal platform for certain SHOP functions to establish standards and policies with respect to the following topics that are consistent with the following rules applicable in FF-SHOPs:

- Premium calculation, payment, and collection requirements as specified under 45 CFR 155.705(b)(4) (for SBM-FPs using the Federal platform for SHOP eligibility, enrollment, or premium aggregation functions);
- The timeline for rate changes set forth at 45 CFR 155.705(b)(6)(i)(A) (for SBM-FPs using the Federal platform for SHOP enrollment or premium aggregation functions);
- Minimum participation rate requirements and calculation methodologies set forth at 45 CFR 155.705(b)(10) (for SBM-FPs using the Federal platform for SHOP enrollment functions);
- Employer contribution methodologies set forth at 45 CFR 155.705(b)(11)(ii) (for SBM-FPs using the Federal platform for SHOP enrollment or premium aggregation functions);
- Annual employee open enrollment period requirements set forth at 45 CFR 155.725(e)(2) (for SBM-FPs using the Federal platform for SHOP enrollment functions);

- Initial group enrollment or renewal coverage effective date requirements set forth at 45 CFR 155.725(h)(2) (for SBM-FPs using the Federal platform for SHOP enrollment functions); and
- Termination of SHOP coverage or enrollment rules set forth at 45 CFR 155.735 (for SBM-FPs using the Federal platform for SHOP eligibility, enrollment, or premium aggregation functions).

Finally, we proposed in the 2018 Payment Notice Proposed Rule that in order to participate in an SBM-FP using the Federal platform for SHOP enrollment functions, QHP issuers would be required to send enrollment reconciliation files on at least a monthly basis according to a process, timeline, and file format established by the FF-SHOPs, consistent with 45 CFR 156.285(c)(5). If the proposal is finalized as proposed, issuers offering small group market QHPs through an SBM-FP's SHOP would be required to follow the process applicable in the FF-SHOPs, as described in 45 CFR 156.285(c)(5).