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



Date: May 7, 2020

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

Title: Final 2021 Letter to Issuers in the Federally-facilitated Exchanges

The Centers for Medicare & Medicaid Services (CMS) is releasing this 2021 Final Letter to Issuers in the Federally-facilitated Exchanges (2021 Final Letter). This Letter provides updates on operational and technical guidance for the 2021 plan year for issuers seeking to offer qualified health plans (QHPs), including stand-alone dental plans (SADPs), in the Federally-facilitated Exchanges (FFEs) or the Federally-facilitated Small Business Health Options Programs (FF-SHOPs). It also describes how parts of this Letter apply to issuers in State-based Exchanges on the Federal platform (SBE-FPs). Issuers should refer to these updates to help them successfully participate in any such Exchange in 2021. Unless otherwise specified, references to the FFEs include the FF-SHOPs.

The 2021 Final Letter focuses on guidance that has been updated for the 2021 plan year, and refers issuers to the 2017 Letter to Issuers in the Federally-facilitated Exchanges (2017 Letter to Issuers), 2018 Letter to Issuers in the Federally-facilitated Exchanges (2018 Letter to Issuers), 2019 Letter to Issuers in the Federally-facilitated Exchanges (2019 Letter to Issuers), or 2020 Letter to Issuers in the Federally-facilitated Exchanges (2020 Letter to Issuers) in all instances where CMS guidance has not changed. CMS notes that the policies articulated in this Letter apply to the QHP certification process for plan years beginning in 2021.

Throughout this Letter, CMS identifies the areas in which states performing plan management functions in the FFEs have flexibility to follow an approach different from that articulated in this guidance.

_

¹ Center for Consumer Information and Insurance Oversight, CMS, 2017 Letter to Issuers in the Federally-facilitated Marketplaces (Feb. 29, 2016), available at: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2017-Letter-to-Issuers 022916.pdf. Center for Consumer Information and Insurance Oversight, CMS, Addendum to 2018 Letter to Issuers in the Federally-facilitated Marketplaces (Feb. 17, 2017), available at: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2018-Letter-to-Issuers-in-the-Federally-facilitated-Marketplaces (April 9, 2018), available at: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2019-Letter-to-Issuers.pdf; Center for Consumer Information and Insurance Oversight, CMS, 2020 Letter to Issuers in the Federally-facilitated Marketplaces (April 18, 2019), available at:

 $[\]underline{https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2020-Letter-to-Issuers-in-the-Federally-facilitated-Exchanges.pdf.}$

² Plan years in the FF-SHOPs will not always align with calendar year 2021.

Previously published rules concerning market-wide and QHP certification standards, eligibility and enrollment procedures, and other Exchange-related topics are set out in 45 CFR Subtitle A, Subchapter B. Unless otherwise indicated, regulatory references in this Letter are to Title 45 of the Code of Federal Regulations (CFR). CMS finalized additional standards in the rule titled, "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Final Rule," CMS-9916-F, which went on display on May 7, 2020 (2021 Payment Notice Final Rule). While certain parts of the Final Letter explain associated regulatory requirements, the 2021 Final Letter is not a complete list of regulatory requirements for issuers.

³ Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Final Rule (on display May 7, 2020).

CHAPTER 1: CERTIFICATION PROCESS FOR QUALIFIED HEALTH PLANS	1
Section 1. QHP Certification Process and Timeline	1
Section 2. QHP Application Data Submission	3
Section 3. QHP Data Changes	5
Section 4. QHP Review Coordination with States	6
Section 5. Plan ID Crosswalk	7
Section 6. Value-based Insurance Design	7
Section 7. Issuer Participation for the Full Plan Year	8
CHAPTER 2: QUALIFIED HEALTH PLAN AND STAND-ALONE DENTAL PLAN CERTIFICATION STANDARDS	8
Section 1. Licensure and Good Standing	8
Section 2. Service Area	8
Section 3. Network Adequacy	8
Section 4. Essential Community Providers	9
Section 5. Accreditation	9
Section 6. Patient Safety Standards for QHP Issuers	9
Section 7. Quality Reporting	9
Section 8. Quality Improvement Strategy	10
Section 9. Review of Rates	10
Section 10. Discriminatory Benefit Design	10
Section 11. Prescription Drugs	10
Section 12. Third Party Payment of Premiums and Cost Sharing	10
Section 13. Cost-sharing Reduction Plan Variations	10
Section 14. Data Integrity Review	11
CHAPTER 3: CONSUMER SUPPORT TOOLS AND PUBLIC INFORMATION	11
Section 1. Consumer Support Tools	11
Section 2. Transparency in Coverage Reporting	11
Section 3. Medical Cost Scenarios	11
CHAPTER 4: STAND-ALONE DENTAL PLANS: 2021 APPROACH	12
Section 1. SADP Annual Limitation on Cost Sharing	12
Section 2. SADP Actuarial Value Requirements	12
CHAPTER 5: QUALIFIED HEALTH PLAN PERFORMANCE AND OVERSIGHT	12
Section 1. Oversight Mechanisms	12
Section 2. Standards for Direct Enrollment Entities and for Third Parties to Perform Audits of Direct Enrollment Entities	
Section 3. Agent/Broker Non-Compliance	12

CHAPTER 6: FF-SHOPS	13
CHAPTER 7: CONSUMER SUPPORT AND RELATED ISSUES	13
Section 1. Coverage Appeals	13
Section 2. Consumer Case Tracking	13
Section 3. Meaningful Access	13
Section 4. Summary of Benefits and Coverage	13
CHAPTER 8: TRIBAL RELATIONS AND SUPPORT	15
CHAPTER 9: STATE-BASED EXCHANGES ON THE FEDERAL PLATFORM	15

CHAPTER 1: CERTIFICATION PROCESS FOR QUALIFIED HEALTH PLANS

The Patient Protection and Affordable Care Act (PPACA) and applicable regulations provide 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 Exchanges. The remaining standards are specific to health plans seeking QHP certification from the Exchanges.

This chapter provides an overview of the QHP certification process. This process applies to all states in which an FFE operates, which include 1) states performing plan management functions and making QHP certification recommendations to CMS, 2) states where CMS is performing all plan management functions and certifying QHPs while the state is enforcing the market-wide standards under the PPACA, and 3) direct enforcement states where CMS is performing plan management functions and enforcing market-wide standards under the PPACA (but the state continues to enforce state law requirements with which issuers must comply). Additional information and instructions about the process for issuers to complete a QHP application can be found at https://www.qhpcertification.cms.gov.

Section 1. OHP Certification Process and Timeline

As in prior years, issuers will submit a complete QHP application for all plan year 2021 plans they intend to have certified in a state in which an FFE is operating. Through an iterative process as shown in Table 1.1, CMS will review OHP applications for current and new issuers applying for QHP certification in an FFE⁵ and notify issuers of any need for corrections after each round of review. After CMS notifies issuers of all corrections, CMS will conduct outreach to issuers with CMS or state-identified data errors, and then issuers will submit corrections during the limited data correction window submission dates in Table 1.1. An issuer must follow the plan withdrawal process provided by CMS to withdraw a plan from QHP certification consideration, or to change an on-Exchange SADP under certification consideration to an off-Exchange SADP for certification consideration. As reflected in Table 1.1, CMS will also post a list of plans received and reviewed during the OHP application process in each issuer's profile in the CCIIO Plan Management Community (PM Community). Each issuer will access the plan list and confirm their plans within the PM Community. An issuer's submission of the final plan confirmation list to CMS is generally the last opportunity for an issuer to withdraw a plan from certification consideration for the upcoming plan year. Finally, issuers intending to offer OHPs, including SADPs, in the FFEs, 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. 6 CMS

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

⁵ 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 FFEs. CMS will not conduct QHP certification reviews of plans that are submitted for offering only outside of the FFEs, except for SADPs seeking off-Exchange certification. 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 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. FFEs 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 FFEs will only offer QHPs, including SADPs.

⁶ The documents will apply to all of the QHPs offered by a single issuer in an FFE at the Health Insurance Oversight System (HIOS) Issuer ID level or designee company. Issuers should ensure that the legal entity information listed in

will sign the QHP Certification Agreement and return it to issuers along with a final list of certified QHPs, completing the certification process for the upcoming plan year. After receiving the QHP Certification Agreement signed by CMS, issuers may begin marketing their plans as certified QHPs, including providing information about the plans to FFE registered agents and brokers.

Table 1.1 lists key plan year 2021 dates for QHP certification applications. Issuers may have their QHP application denied if they fail to meet the deadlines in Table 1.1 or if their applications are not accurate or complete after the deadline for issuer submission of changes to the QHP application.⁷

Table 1.1 includes key dates for an "Early Bird" QHP Application submission window, Transparency in Coverage data submission and resubmission, and Machine Readable file posting. Additional information about each requirement is found in Chapter 3, Section 2 (Transparency in Coverage Reporting) and Chapter 3, Section 1 (Consumer Support Tools), respectively. The Quality Rating System (QRS) and QHP Enrollee Experience Survey (QHP Enrollee Survey) reporting requirements for Plan Year (PY) 2021 have been suspended due to the COVID-19 public health emergency. The "Early Bird" QHP Application submission window is an optional submission window for issuers wishing to submit application data prior to the first formal submission deadline. CMS will review and return results on this data as available prior to the first submission deadline, and if the identified corrections are corrected, CMS will not flag it as a correction in the full review round.

-

https://www.cms.gov/files/document/covid-qrs-and-marketplace-quality-initiatives-memo-final.pdf.

HIOS under the Issuer General Information section is identical to the legal entity information that will be used when executing the documents.

⁷ Regulations at 45 CFR 155.1000 provide Exchanges with broad discretion to certify QHPs that otherwise meet the QHP certification standards specified in Part 156, and afford Exchanges 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.

⁸ As part of the Administration's efforts to combat COVID-19, CMS adopted a temporary policy of relaxed enforcement and directed QHP issuers to discontinue collection of clinical quality measure data and survey measure data for the 2020 QRS and 2020 QHP Enrollee Survey to calculate ratings for PY 2021.See the COVID-19 Marketplace Quality Initiatives memo posted on April 18, 2020 available at:

Table 1.1. Timeline for QHP Certification in the FFEs^{9,10}

Activity	Dates
Initial QHP Application submission window	4/23/20
Optional Early Bird QHP Application submission deadline	5/19/20
CMS reviews Early Bird QHP Application data and releases results in	5/20/20 - 6/10/20
the Plan Management Community	
Initial QHP Application deadline	6/17/20
CMS reviews initial QHP Applications and releases results in the Plan	6/18/20 - 8/12/20
Management Community	
Initial deadline for QHP Application Rates Table Template	7/22/20
Service area data change request deadline	8/11/20
Issuers complete final plan confirmation and submit final Plan ID	8/12/20 - 8/26/20
Crosswalk Templates in the PM Community	
Transparency in Coverage data submission deadline	8/26/20
Deadline for issuers to change QHP Application	8/26/20
CMS reviews QHP Applications and releases results in the PM	8/27/20 - 9/16/20
Community	
CMS sends QHP Certification Agreements to issuers	9/15/20
Issuers return signed QHP Certification Agreements to CMS	9/15/20 - 9/23/20
States send CMS final plan recommendations	9/15/20 - 9/23/20
Limited data correction window	9/17/20 - 9/18/20
Machine Readable file posting deadline	9/18/20
Transparency in Coverage data resubmission deadline	9/18/20
CMS releases certification notice to issuers and states	10/5/20 - 10/6/20
Open Enrollment begins	11/1/20

Section 2. QHP Application Data Submission

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 June 17, 2020,¹¹ and to make necessary updates to the QHP application prior to the last deadline for issuer submission on August 26, 2020.¹² Additionally, issuers in direct enforcement states must comply with any CMS requirements related to form and rate filings, in addition to any applicable state requirements.

_

⁹ QHP applications, application rates table template, service area data change request, and final plan confirmation data submissions are covered in the QHP certification Paperwork Reduction Act (PRA) package (OMB control number 0938-1187). Transparency in coverage data submissions are covered in the transparency in coverage PRA package (OMB control number 0938-1310). QRS clinical data and enrollee survey data submissions are covered in the Marketplace operations PRA package (OMB control number 0938-1249).

¹⁰ All dates are subject to change.

¹¹ The initial deadline for submission of the QHP Rates Table Template only is July 22, 2020.

¹² All issuers must submit required URLs by the last deadline for issuer submission. All URLs must be active and accessible by the deadline for issuers to return signed agreements to CMS, with the exception of the Transparency in Coverage URL, which must be active upon submission, including early bird submission.

All issuers must obtain Health Insurance Oversight System (HIOS) product and plan IDs using HIOS. ¹³ All issuers must also register for the PM Community to receive correction and certification notices, as well as other relevant communications regarding their QHP applications. ¹⁴

Issuers applying for QHP certification in FFEs, excluding those in states performing plan management functions, must submit their QHP applications in HIOS. While some FFE states use the National Association of Insurance Commissioners' System for Electronic Rate and Form Filing (SERFF) to collect plan data, which may include copies of the QHP templates, any data submitted into SERFF by issuers applying for QHP certification in FFEs where the state does not perform plan management functions will not be transferred to CMS and must be submitted in HIOS. Issuers in states performing plan management functions, however, should submit QHP applications in SERFF in accordance with state and CMS review deadlines. In FFEs where the state performs plan management functions, issuers should work directly with the state to submit all QHP issuer application data in accordance with state guidance. ¹⁵ For all states, issuers seeking to offer QHPs must also submit the Unified Rate Review Template (URRT) to CMS via the Unified Rate Review module in HIOS.

All issuers applying for QHP certification will access the Plan Preview environment to review plan benefit data and identify and correct data submission errors before the QHP application data submission deadline. Issuers can use Plan Preview to check plan data display for most enrollment scenarios, including service areas, cost sharing for benefits and URLs (including payment redirect). Issuers will use the Plan Preview environment to verify that their plan display reflects their state-approved filings. Issuers in states performing plan management functions in the FFEs will be able to view their plan data after the state transfers QHP data from SERFF to HIOS.

Discrepancies between an issuer's QHP application and approved state filings may result in a plan not being certified or if CMS has already certified a plan as a QHP, decertification or other appropriate compliance or enforcement action. 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.

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

Resources/index.html#Content%20Requirements%20for%20Plan%20Finder. CMS expects issuers to use the same HIOS plan identification numbers for plans submitted for certification for plan year 2021 that are the same plans certified as QHPs, including SADPs, for plan year 2020, as defined in 45 CFR 144.103 and pursuant to 45 CFR 147.106. While 45 CFR 147.106 is not applicable to issuers of SADPs, CMS expects SADP issuers to use the same HIOS plan identification numbers for plans submitted for certification for plan year 2021 as SADPs for plan year 2020 that have been modified, to the extent the modification(s) are made uniformly and solely pursuant to the removal of the requirement for SADPs to offer the pediatric dental EHB at a specified actuarial value. The same definition of "plan" also will apply to re-enrollment of current enrollees into the same plan, pursuant to §155.335(j). If an issuer chooses to not seek certification of a plan for a subsequent, consecutive certification cycle in the Exchange, or fails to have a plan certified for plan year 2021 that had been certified for plan year 2020, it is subject to the standards outlined in 45 CFR 156.290.

¹⁴ CMS will make instructions available in spring 2020 on how to enroll to receive information for the plan year 2021 QHP application period for issuers not currently participating in the PM Community.

¹⁵ CMS will work with states performing plan management functions in an FFE to ensure that such guidance is consistent with federal regulatory standards and operational timelines.

Section 3. QHP Data Changes

During the certification process for plan year 2021, 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 identifies during its review of QHP applications.

Table 1.2. Key Dates for QHP Data Changes in the FFEs¹⁶

Activity	Dates
Initial application submission	4/23/20 - 6/17/20
QHP review and modification	6/18/20 - 8/26/20
Data changes after QHP application deadline	8/27/20 - 10/6/20
After final data submission	Onward

Issuers may make changes to their QHP applications without state or CMS authorization until the deadline for initial application submission. After the close of the initial QHP application submission window, issuers may not add new plans to a QHP application or change an off-Exchange plan to be both on and off-Exchange. Issuers also may not change plan type(s) or market type and may not change QHPs, excluding SADPs, from a child-only plan to a non-child-only plan. Issuers may only change their service area after CMS approves the change. 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 deadline for issuer changes. For all other changes, issuers are also not required to submit data change requests or document state authorization to CMS. CMS will monitor all data changes and contact issuers if there are concerns about changes made.

To withdraw a plan from QHP certification consideration, an issuer must follow the plan withdrawal process as outlined by CMS at https://www.qhpcertification.cms.gov. 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-Exchange SADP under certification consideration to an off-Exchange SADP for certification consideration must submit a plan withdrawal request.

After the deadline for issuer changes to QHP applications, issuers will only make corrections directed by CMS or by their state. States may direct changes by contacting CMS with a list of requested corrections. Issuers whose applications are not accurate after the August 26, 2020, deadline for issuer submission of changes to the QHP application, and are then required to resubmit corrected data during the limited data correction window, may be subject to compliance action by CMS.¹⁷ Issuer changes made in the limited data correction window not approved by CMS and/or the state may result in compliance action by CMS, which could include decertification and suppression of the issuer's plans on HealthCare.gov.

After completion of the QHP certification process, CMS may offer additional data correction windows. 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. CMS will offer

¹⁶ All dates are subject to change.

¹⁷ See 45 CFR 156.805(a)(5).

windows for SHOP quarterly rate updates. Administrative data changes such as URL updates should be made in HIOS Plan Finder or the QHP Supplemental Submission Module and do not require a data change request to CMS, however, URL changes still require State Authorization prior to being updated. A request for a data change after August 26, 2020, excluding administrative changes or SHOP quarterly rate updates, 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 suppressed from display on HealthCare.gov until the data is corrected and refreshed for consumer display.

Section 4. QHP Review Coordination with States

Each state will define the relevant submission window for state-level reviews as well as dates and processes for corrections and resubmissions. CMS will rely on states' reviews of issuer-submitted policy forms and rate filings 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 FFE operational timelines. ¹⁸ States that have an Effective Rate Review Program should consult guidance from CMS regarding timelines for rate filings for 2021 plan year coverage. ¹⁹

When states perform QHP certification reviews, ²⁰ they may exercise reasonable flexibility in their application of CMS' 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 what is required for QHP certification through the FFEs, 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

^{. .}

¹⁸ States are the primary regulators of health insurers and are responsible for enforcing the market reform provisions in title XXVII of the PHS Act both inside and outside the Exchanges. 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/cciio/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.

¹⁹ Center for Consumer Information and Insurance Oversight, CMS, Bulletin: Timing of Submission of Rate Filing Justifications for the 2020 Filing Year for Single Risk Pool Coverage Effective on or after January 1, 2021.https://www.cms.gov/files/document/2020-final-rate-review-timeline-bulletin.pdf (March 27, 2020).

²⁰ States performing plan management functions will conduct certification reviews. In addition, all states, regardless of whether they perform plan management functions, will conduct certification reviews for certain review areas, as detailed in Chapter 2.

procedures are consistent with applicable federal law and operational deadlines. Issuers must meet all applicable obligations under state law to be certified for sale on the FFEs.

In states performing plan management functions, the state will also 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 QHP certification decisions, and load certified QHP plans on HealthCare.gov. CMS will work closely with states performing plan management functions to coordinate this process. 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.

For states performing plan management functions, the SERFF data transfer deadlines will align with the HIOS submission deadlines, as was the case for plan year 2020 submissions. These state transfers should include all plans submitted to the state for certification, including SADPs for off-Exchange sale. ²¹ 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.

All 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 PPACA certification requirements, as early in the certification process as practicable. For CMS to ensure this information is taken into account for certification, states must provide all of their recommendations and relevant information to CMS in a timely manner and no later than the state plan confirmation 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. CMS will work with all state regulators to confirm by the state plan confirmation deadline that all potential QHPs meet applicable state and federal standards, and are approved for sale in the state.

Section 5. Plan ID Crosswalk

Issuers are required to submit plan ID crosswalk data for each medical QHP and SADP that was certified for the 2020 plan year. Please refer to the 2018 Letter to Issuers for more information regarding submission requirements pertinent to the Plan ID Crosswalk. The approach for 2021 certification with regard to alternate enrollments also remains unchanged from 2018 and later years for QHPs that are not SADPs. SADPs, as plans that offer excepted benefits, are not subject to the guaranteed renewability standards specified at 45 CFR 147.106. However, CMS aims to apply the processes established for the 2020 plan ID Crosswalk Template to SADPs in order to support automatic re-enrollment for plans offered during the 2021 plan year.

Section 6. Value-based Insurance Design

In the 2021 Payment Notice Final Rule, we note that we are pursuing strategies that will assist in the uptake and offering of value-based insurance design by QHP issuers. We outline a "value-based" model QHP that contains consumer cost-sharing levels aimed at driving utilization of high value services and lowering utilization of low value services. Offering a value-based

²¹ SBE-FPs should not transfer off-Exchange SADPs.

insurance design QHP is voluntary, and issuers are encouraged to select services and cost sharing that work best for their consumers.

We also note in the 2021 Payment Notice Final Rule that for issuers in FFEs and SBE-FPs, we are not offering preferential display for value-based QHPs on HealthCare.gov. We did not finalize any additional recommendations in the 2021 Payment Notice Final Rule and are not instructing issuers to incorporate any additional changes with regard to this policy.

Section 7. Issuer Participation for the Full Plan Year

The approach for 2021 remains unchanged from 2018 and later years. Please refer to the 2018 Letter to Issuers for more information.

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 FFEs, including those in states performing plan management functions, and how CMS or the state will evaluate and conduct reviews of 2021 QHPs and SADPs for compliance.

Section 1. Licensure and Good Standing

The approach for licensure and good standing remains unchanged from 2018 and later years. Please refer to the Guidance to States on Review of Qualified Health Plan Certification Standards in Federally-facilitated Marketplaces for Plan Years 2018 and Later ("State Guidance on QHP Reviews") for more information. ²² As noted in the State Guidance on QHP Reviews, CMS does not review issuers' compliance with licensure and good standing standards. In FFEs, including in states performing plan management functions, states will continue to ensure issuer compliance with 45 CFR 156.200(b)(4).

Section 2. Service Area

The approach for reviews of service area remains unchanged from 2018 and later years. Issuers will not be permitted to change their plans' service area after their initial data submission except via a data change request to CMS. Please refer to the 2018 Letter to Issuers for more information.

Section 3. Network Adequacy

The approach for network adequacy remains unchanged from 2020. Please refer to the 2020 Letter to Issuers for additional information. For plan year 2020, CMS found all States participating in FFEs to have the required network adequacy means and authority. For plan year 2021, CMS does not anticipate any changes in its assessment of States with the means and authority for network adequacy review. HHS will support State efforts to encourage use of telehealth services, and also strongly encourages all issuers to consider increasing the use of

²² Center for Consumer Information and Insurance Oversight, CMS, Guidance to States on Review of Qualified Health Plan Certification Standards in Federally-facilitated Marketplaces for Plan Years 2018 and Later (April 13, 2017) *available at:* https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/QHP-Certification-Reviews-Guidance-41317.pdf.

telehealth services as part of their networks to ensure all consumers have access to all covered services.

Section 4. Essential Community Providers

The ECP standard and the approach for reviews of the ECP standard remain unchanged from 2020.²³ Please refer to the 2020 Letter to Issuers for more information. HHS encourages issuers to consider increasing use of telehealth services as part of their contingency planning to ensure access to adequate care for enrollees who might otherwise be cared for by relevant ECP types that may be missing from the issuer's provider network.

Section 5. Accreditation

The approach for reviews of the accreditation standard remains largely unchanged from 2020. However, in consideration of the announcements by HHS-recognized accrediting entities making modifications to accreditation standards due to the COVID-19 public health emergency, ²⁴ CMS may provide flexibilities with regard to health plan accreditation reviews, as appropriate.

Section 6. Patient Safety Standards for QHP Issuers

The approach for QHP patient safety annual certification standards remains unchanged from 2017 and later years. Please refer to the 2017 Letter to Issuers for details regarding guidance for QHP issuers who contract with a hospital with more than 50 beds. CMS will continue to assess these standards and any related burden for issuers and hospitals.

Section 7. Quality Reporting

The approach for review of QHP issuer compliance with quality reporting standards related to the QRS and QHP Enrollee Survey will follow the memo posted on April 18, 2020 which states that, to help curb the spread of COVID-19, CMS suspended activities related to the collection of clinical quality measures for the QRS and survey measures for the QHP Enrollee Survey for the 2021 plan year (2020 ratings year). CMS intends to continue to require display of the QHP quality rating information for all Exchanges, including the FFEs (including FFEs where states perform plan management functions) and State-based Exchanges (SBEs) (including SBE-FPs). and, consistent with prior years, will release subsequent guidance regarding the display guidelines for quality rating information beginning with the 2021 individual market open enrollment period. CMS encourages QHP issuers to continue to use clinical quality measures and survey measure data for internal quality improvement purposes.

At this time, QRS and QHP Enrollee Survey reporting requirements do not apply to SADPs or to child-only plans offered on Exchanges.

²³ See web-based ECP Petition for the 2021 plan year, available at: https://data.healthcare.gov/cciio/ecp_petition.

²⁴ See announcements, *available at*: https://www.urac.org/press-room/urac-responds-coronavirus, and https://www.aaahc.org/what-you-need-to-know/.

²⁵ COVID-19 Marketplace Quality Initiatives Memo *available at:* https://www.cms.gov/files/document/covid-qrs-and-marketplace-quality-initiatives-memo-final.pdf.

Section 8. Quality Improvement Strategy

The approach for QHP certification reviews for quality improvement strategy (QIS) reporting will follow the memo posted on April 18, 2020,²⁶ which states that, due to the COVID-19 public health emergency, CMS suspended reporting of QIS data such that QHP issuers eligible to submit QIS submissions are not required to make such submissions for the PY 2021 QHP certification period for participation in the FFEs. States with SBEs are encouraged to adopt a similar approach for QIS submission requirements by their respective QHP issuers for the PY 2021 QHP certification period. CMS also encourages QHP issuers to continue to use QIS information for internal quality improvement purposes.

At this time, the QIS requirements do not apply to SADPs or to child-only plans offered on Exchanges.

Section 9. Review of Rates

The approach for 2021 remains unchanged from the 2020 Letter to Issuers. Please refer to the Unified Rate Review Instructions for the 2021 plan year for more information.²⁷

Section 10. Discriminatory Benefit Design

The approach to discriminatory benefit design remains unchanged from 2018 and later years. Please refer to the 2018 Letter to Issuers for more information regarding discriminatory benefit design, QHP discriminatory benefit design, and the treatment protocol calculator.

Section 11. Prescription Drugs

The approach for reviewing issuers' prescription drug benefit offerings remains unchanged from 2019 and later years. Please refer to the 2019 Letter to Issuers for more information.

Section 12. Third Party Payment of Premiums and Cost Sharing

Requirements related to QHP and SADP issuers' acceptance of third party payments of premiums and cost sharing on behalf of QHP enrollees remain unchanged from 2018. Please refer to the 2018 Letter to Issuers for more information.

Section 13. Cost-sharing Reduction Plan Variations

The approach for issuers to provide cost-sharing reductions (CSRs) to consumers through CSR plan variations remains unchanged from 2018 and later years. Please refer to the 2018 Letter to Issuers for more information. Eligible consumers can enroll in these plan variations for the 2021 plan year and will continue to receive cost-sharing reductions provided by the issuers. Beginning October 2017 and beyond, CMS has not made and will not make CSR payments to issuers,

https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/2021-URR-Instructions.pdf.

²⁶ COVID-19 Marketplace Quality Initiatives Memo *available at:* https://www.cms.gov/files/document/covid-qrs-and-marketplace-quality-initiatives-memo-final.pdf.

²⁷ The 2021 Unified Rate Review Instructions are available under "Review of Insurance Rates: Forms" *available at:* https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/index.html#Review%20of%20Insurance%20Rates., and at the following link:

unless Congress appropriates funds for these payments.

Section 14. Data Integrity Review

The approach for conducting data integrity reviews remains unchanged from 2018 and later years. Please refer to the 2018 Letter to Issuers for more information.

CHAPTER 3: CONSUMER SUPPORT TOOLS AND PUBLIC INFORMATION

Section 1. Consumer Support Tools

CMS developed several decision support tools and publishes certain plan data to empower patients to understand their insurance options and select a plan through an FFE or SBE-FP, including through an FF-SHOP. Please see the 2018 Letter to Issuers for more information on these features, including provider and formulary search functions and the out-of-pocket cost comparison tool.

Section 2. Transparency in Coverage Reporting

This section provides an overview of the transparency reporting requirements for all QHP issuers, including SADP issuers, in the FFEs, including in states that are performing plan management functions.

Pursuant to 45 CFR 156.220, issuers are required to annually report transparency in coverage data to CMS. CMS submitted its information collection, CMS-10572, "Transparency in Coverage Reporting by Qualified Health Plan Issuers," Paperwork Reduction Act (PRA) to OMB. In April 2019, OMB approved it for an additional 3-year collection period. The data collection elements that QHP issuers reported from 2016 to 2019 remain part of the collection. Beginning with plan year 2020, issuers were required to report the following plan level data reporting: claims received, claims denied, claims denied due to prior authorization or referral required, claims denied due to an out-of-network provider/claim, claim denied due to an exclusion of service, claims denied due to lack of medical necessity (including and excluding behavioral health), and claims denied for "other" reasons. Finally, starting with the 2021 plan year, the transparency in coverage data collection is integrated into the QHP certification data submission process, such that issuers will submit the transparency template in the same manner as other QHP certification templates. Submissions will no longer be collected outside of the QHP certification timeline via an email box. Transparency in Coverage URL submissions should be made in the QHP Supplemental Submission Module. As reflected in Table 1.1, the final deadline for the initial Transparency in Coverage submission is August 26, 2020.

Section 3. Medical Cost Scenarios

Consumer testing of the summary of benefits and coverage (SBC) shows that hypothetical medical scenarios illustrating the consumer portion of medical costs, such as those found on the SBC, help consumers understand and compare health plan coverage options. Similar to SBC cost scenarios, medical cost scenarios on HealthCare.gov could provide valuable information to consumers about potential medical costs based on hypothetical conditions. In order to provide consumers greater cost transparency for future plan years, CMS will continue analyzing ways to provide additional medical cost scenarios to QHP customers on HealthCare.gov, but will not implement this feature for plan year 2021.

CHAPTER 4: STAND-ALONE DENTAL PLANS: 2021 APPROACH

The approach for submitting applications for certification of SADPs remains unchanged from 2020. Please refer to the 2018 and 2020 Letters to Issuers for more information.

Section 1. SADP Annual Limitation on Cost Sharing

For plan year 2021, the SADP annual limitation on cost sharing for one covered child is \$350 increased by the 6.646 percentage point increase of the Consumer Price Index (CPI) for dental services for 2019 of 488.792 over the CPI of 458.330 for dental services for 2016, increasing the annual limitation on cost-sharing for SADPs by \$23.26. Because this amount is less than \$25, and the regulation at 45 CFR 156.150(d) requires incremental increases to be rounded down to the next lowest multiple of \$25, the annual limitation on cost sharing for SADPs for plan year 2021 will remain \$350 for one child and \$700 for two or more children. For more information on how this limitation is determined, please refer to \$156.150 and to the 2018 Letter to Issuers.

Section 2. SADP Actuarial Value Requirements

The approach to actuarial value requirements and certification for SADP coverage of the pediatric EHB remains unchanged from 2020. For plan year 2021, SADP issuers may offer the pediatric dental EHB at any actuarial value. SADP issuers will be required to certify the actuarial value of each SADP's coverage of pediatric dental EHB.

CHAPTER 5: QUALIFIED HEALTH PLAN PERFORMANCE AND OVERSIGHT

Section 1. Oversight Mechanisms

Guidance on QHP issuer account management, issuer compliance monitoring, issuer compliance reviews, FFE oversight of agents and brokers, and issuer participation for the full plan year generally remains unchanged from 2018 and later years. Please refer to the 2018 Letter to Issuers for more information. As detailed in the 2020 Letter to Issuers, CMS established several changes to FFE oversight mechanisms for QHP issuers and web-brokers participating in direct enrollment (DE entities). DE entities participating in direct enrollment should review 45 CFR §§ 155.220, 155.221 and 155.415, as well as the 2020 Payment Notice Final Rule, for further details. CMS will provide further guidance about FFE oversight of DE entities, as necessary.

Section 2. Standards for Direct Enrollment Entities and for Third Parties to Perform Audits of Direct Enrollment Entities

The approach regarding oversight remains unchanged from the previous year. Please refer to 2020 Letter to Issuer regarding changes to standards for DE entities and for third-parties to perform audits of DE entities.

Section 3. Agent/Broker Non-Compliance

The approach for agent/broker non-compliance remains unchanged from that used in 2020. Please refer to the 2020 Letter to Issuers for more information.

CHAPTER 6: FF-SHOPS

CMS guidance regarding FF-SHOPs remains unchanged from the 2020 plan year. Please refer to the 2020 Letter to Issuers for more information on FF-SHOP changes for prior plan years.

CHAPTER 7: CONSUMER SUPPORT AND RELATED ISSUES

Section 1. Coverage Appeals

The approaches to coverage appeals remain unchanged from 2018 and later years. Please refer to the 2018 Letter to Issuers for more information.

Section 2. Consumer Case Tracking

The approach to consumer case tracking remains unchanged from 2018 and later years. Please refer to the 2018 Letter to Issuers for more information.

Section 3. Meaningful Access

Guidance on meaningful access remains unchanged from 2018 and later years. Please refer to the 2018 Letter to Issuers for more information.

Section 4. Summary of Benefits and Coverage

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

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 Public Health Service Act, as added by the PPACA. Specifically, issuers must fully comply with the requirements of 45 CFR 147.200(a)(3), which requires issuers to "provide an SBC in the form, and in accordance with the instructions for completing the SBC, that are specified by the Secretary in guidance."

On November 7, 2019, CMS released an updated SBC coverage examples Calculator, Guide and Narratives for coverage examples, SBC Template, and other associated resources (the 2021 SBC) for SBCs describing plans or policies effective on or after January 1, 2021. On February 3, 2020, the Departments of Health and Human Services, Labor, and the Treasury released updated versions of the 2021 SBC Template and related materials, following the identification of minor formatting issues, typographical errors, and inconsistencies across documents. These versions replace the versions released on November 7, 2019. These updates ensure consistency across 2021 SBC materials and do not impact SBC guidelines and instructions. CMS also released a set of FAQs pertaining to the applicability date of the updated SBC Template, Calculator, and related materials. ²⁹

The SBC Calculator is used by plans and issuers to generate cost-sharing estimates for coverage to treat three hypothetical medical scenarios (maternity care, type II diabetes, and a simple foot

²⁸ Available at: https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-

Resources#Summary_of_Benefits_and_Coverage_and_Uniform_Glossary. ²⁹ The FAQs about the applicability date of the updated SBC are *available at:*

https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/SBC-FAQ-1-2020.pdf.

fracture) that are required to be included in the SBC. The Departments of Health and Human Services, Labor, and the Treasury updated the Calculator, Guide, and Narratives based on feedback from stakeholders in order to improve its functionality, flexibility, and accuracy. The updates replace 2013 Truven Health MarketScan® data with 2016 data, update some of the treatment protocols for the SBC coverage examples, and make changes to the Calculator's logic to better align its underlying assumptions with how most plans and issuers apply cost sharing rules.

Use of the Calculator is not required. Plans and issuers may create their own calculator using the Guide and Narratives provided by HHS, or modify the logic of the Calculator to provide their own method of calculating estimated out-of-pocket-costs for the Coverage Examples, which may be more accurate based on their particular plan or policy design.

The 2021 SBC Template and Instructions update the 2017 SBC Template and Instructions to remove the statement after the Minimum Essential Coverage (MEC) disclosure, "If you don't have Minimum Essential Coverage for a month, you'll have to make a payment when you file your tax return unless you qualify for an exemption from the requirement that you have health coverage for that month." The new statement reads "Minimum Essential Coverage generally includes plans, health insurance available through the Marketplace or other individual market policies, certain Medicare and Medicaid coverage, CHIP, TRICARE, and certain other coverage. If you are eligible for certain types of Minimum Essential Coverage, you may not be eligible for the premium tax credit." This statement was updated because, starting January 1, 2019, the tax payment required for not having MEC or a coverage exemption was reduced to zero. The Uniform Glossary is updated as well to remove the definition of "Individual Responsibility Requirement" and update the definition of "Minimum Essential Coverage" to reflect this change. The update also adds the "Total Example Costs" for each of the three coverage examples to the template.

Additionally, the 2021 SBC Template and Instructions have been updated to include an additional option for plans and issuers completing the minimum value disclosure on the SBC. As explained in the 2019 Letter to Issuers, the concept of minimum value is not relevant with respect to individual market coverage and such coverage cannot meet or fail to meet minimum value standards. In the 2019 Letter to Issuers, we stated that the Departments would not take enforcement action against issuers of individual market coverage that indicated "Not Applicable" or "N/A" for their response to the minimum value disclosure on the 2017 SBC Template. The 2021 SBC Template and Instructions update the Template to add "Not Applicable" as a response option on the SBC Template, such that the disclosure reads: "Does this plan meet the Minimum Value Standards? [Yes/No/Not Applicable]." The 2021 Instructions indicate that issuers of individual market coverage should answer 'Not Applicable.""

Plans and issuers will be required to use the 2021 SBC Template and Instructions, the 2021 Guide and Narratives, and the 2021 Calculator, should they choose to use the Calculator, beginning on the first day of the first open enrollment period for any plan years (or, in the individual market, policy years) that begin on or after January 1, 2021, with respect to coverage for plan or policy years beginning on or after that date.³⁰

OHPs offered through the individual market Exchanges must use the 2021 SBC, the 2021 Guide

14

³⁰ See all SBC materials *available at*: https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/index.html#Summary%20of%20Benefits%20and%20Coverage%20and%20Uniform%20Glossary.

and Narratives, and, should they choose to use the Calculator, the 2021 Calculator for SBCs prepared for the open enrollment period for the 2021 plan year, which runs from November 1, 2020 through December 15, 2020.

For direct enforcement states, ³¹ SBCs are considered forms by HHS. Therefore, SBCs should be submitted to HHS for review in accordance with the form filing instructions in SERFF. Issuers operating in direct enforcement states are required to use the 2021 SBC, the 2021 Guide and Narratives, and, if the issuer chooses to use the Calculator, the 2021 Calculator for SBCs prepared for the open enrollment period for the 2021 plan year, and should submit their SBC materials to HHS in accordance with the form filing instructions in SERFF for the 2021 plan year. For issuers in other states, because states differ in their review of SBCs (e.g., some review them during form review, others may consider them to be marketing materials), issuers should follow applicable state guidelines for state enforcement activity with respect to SBCs where the state is enforcing SBC requirements.

Issuers must conform to the sample SBCs for American Indian/Alaska Native (AI/AN) zero and limited cost sharing plans. ³² Additionally, CMS encourages QHP issuers to make SBCs for these plans available on the public portion of their websites, and encourages Exchanges that do not use the HealthCare.gov platform to provide pre-enrollment access to the SBCs for these plans.

CHAPTER 8: TRIBAL RELATIONS AND SUPPORT

CMS guidance concerning Indian health care providers remains unchanged from 2018 and later years. For more information, please refer to the 2018 Letter to Issuers.

CHAPTER 9: STATE-BASED EXCHANGES ON THE FEDERAL PLATFORM

SBE-FPs leverage existing federal assets and operations to support certain functions of their Exchange and enforce rules governing their QHP issuers. Current SBE-FPs renewed the federal platform agreement for a term of five (5) years from January 1, 2018, to January 1, 2023. States that are newly transitioning to the SBE-FP model for plan year 2021 are required to execute the federal platform agreement with CMS prior to open enrollment. For more information on this agreement and its implementation, please refer to the 2018 Letter to Issuers.

The approach to the QHP issuer requirements that are applicable to, and enforceable by, SBE-FPs has not changed from that laid out in the 2019 Letter to Issuers, as generally noted in the 2020 Letter to Issuers. ³³ Likewise, the approach to authorities and responsibilities for plan management functions that are applicable to SBE-FPs has not changed from that laid out in the 2019 Letter to Issuers. ³⁴ Finally, the approach to SHOP requirements and limitations applicable

³¹ Currently, the states in which HHS is directly enforcing the SBC requirements are Missouri, Oklahoma, Texas, and Wyoming.

³² Sample SBCs for AI/AN zero and limited cost sharing plans are available as a resource to issuers *available at*: https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/index.html#Summary%20of%20Benefits%20and%20Coverage%20and%20Uniform%20Glossary.

³³ These include the two requirements under 45 CFR 155.200(f)(2) that remained after eliminating those related to network adequacy, essential community providers, and federal meaningful difference, as laid out in the 2020 Letter to Issuers.

³⁴ These include the SBE-FPs retaining authority and primary responsibility for plan management functions, including performing plan data review for QHP certification standards.

to SBE-FPs and their issuers has not changed from that laid out in the 2019 Letter to Issuers.³⁵ Please refer to the 2019 Letter to Issuers for more information.

Issuers offering QHPs through an SBE-FP will be assessed a federal user fee rate equal to a percentage of the monthly premium charged by the issuer for each policy under plans offered through an SBE-FP. The SBE-FP user fee rate, and the user fee rate applicable to FFE issuers, are as finalized in the 2021 Payment Notice Final Rule.

³⁵ Beginning on January 1, 2018, issuers offering QHPs for SHOP in SBE-FPs were no longer required to send enrollment/enrollment reconciliation files or meet other requirements related to the enrollment process. Additionally, new SHOP SBE-FPs were no longer recognized although existing SBE-FPs for SHOP could maintain that status.