

Key Priorities for Federally-facilitated Exchange Compliance Reviews for the 2021 Plan Year

Consistent with the Centers for Medicare & Medicaid Services' (CMS) authority under 45 CFR 155.1010(a)(2) and 156.715, CMS will perform compliance reviews of issuers offering Qualified Health Plans (QHPs) in the Federally-facilitated Exchanges (FFE). For purposes of this document, a reference to QHPs includes stand-alone dental plans (SADPs), unless otherwise indicated. We intend for these compliance reviews to focus on FFE requirements for QHP certification under 45 CFR Part 156, and other key FFE operational standards for FFEs, including FFEs where states perform plan management functions. CMS will review data at both the issuer- and the QHP-level. Policies, protocols, standard operating procedures, or other similar manuals and any other applicable documentation may be requested as part of the compliance review process to show compliance with applicable standards. As new regulations and operational guidance are published, those standards may be included as part of the compliance reviews.

Table A below lists the regulatory standards governing QHP certification that we anticipate including as part of the FFE compliance reviews for the 2021 plan year. This list is intended to help QHP issuers understand the key priorities for CMS' 2021 FFE compliance reviews. For example, the network adequacy standards requirement for QHP issuers to publish an up-to-date, accurate, and complete provider directory is included because it is critical information for enrollees to make educated choices about their care. We note that this list should not be construed as a comprehensive listing of all standards applicable to QHP issuers in the FFEs, nor a limitation on CMS' authority or ability to review compliance with any standards not appearing on this list. The compliance reviews that are the subject of this document are separate from other audits and reviews that may be conducted to ensure compliance with the Patient Protection and Affordable Care Act (e.g., Medical Loss Ratio [MLR] audits, and policy and rate filing reviews). We have provided illustrative examples in Table B of regulatory standards that fall into this second category of requirements that will be monitored for compliance through other review and oversight mechanisms. It is not intended to be an exhaustive list.

Table A: Regulatory Standards That May Be Included in FFE Compliance Reviews for 2021

Regulatory Standard	Federal Regulation
<p>QHP Issuer Participation Standards The QHP issuer must meet Exchange participation standards by:</p> <ul style="list-style-type: none"> ▪ For QHPs other than SADPs, offering at least one gold QHP and one silver QHP throughout each service area in which it offers coverage through the Exchange, and, if offering individual market QHPs, one child-only plan at the same level of coverage as any QHP offered through the individual market Exchange ▪ Not discriminating based on race, color, national origin, disability, age, and sex¹ ▪ Providing the same agent/broker compensation for similar coverage offered inside and outside the FFEs 	<p>45 CFR § 156.200</p> <ul style="list-style-type: none"> ▪ § 156.200(c) ▪ § 156.200(e) ▪ § 156.200(f)
<p>QHP Rate and Benefit Information The QHP issuer must report rates by:</p> <ul style="list-style-type: none"> ▪ Submitting justifications of rate increases to the Exchange prior to the implementation of the rate increases ▪ Prominently posting justifications of rate increases on the QHP issuer’s website 	<p>45 CFR § 156.210</p> <ul style="list-style-type: none"> ▪ § 156.210(c) ▪ § 156.210(c)
<p>Transparency in Coverage The QHP issuer must comply with transparency in coverage standards by:</p> <ul style="list-style-type: none"> ▪ Providing information on claims payment policies and practices ▪ Submitting data/information described in 45 CFR 156.220(a) in an accurate and timely manner to the Exchange, HHS, and the State insurance commissioner, and make the information available to the public ▪ Using plain language as defined in 45 CFR 155.20 when providing the required information 	<p>45 CFR § 156.220</p> <ul style="list-style-type: none"> ▪ § 156.220(a)(1) ▪ § 156.220(b) ▪ § 156.220(c)
<p>QHP Marketing and Benefit Design The QHP issuer must not discourage enrollment of individuals with significant health needs by:</p> <ul style="list-style-type: none"> ▪ Not employing marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in QHPs 	<p>45 CFR § 156.225</p> <ul style="list-style-type: none"> ▪ § 156.225(b)
<p>Delegated and Downstream Entities The QHP issuer must comply with standards applicable to delegated and downstream entities, such as:</p> <ul style="list-style-type: none"> ▪ Ensuring that its delegated/downstream entities comply with the standards of 45 CFR Part 156, Subpart C ▪ Ensuring that a delegation agreement includes the specified elements in accordance with 45 CFR 156.340(b) 	<p>45 CFR § 156.340</p> <ul style="list-style-type: none"> ▪ § 156.340(a)(1) ▪ § 156.340(b)

¹ Consistent with Executive Order 13988, the Office of Civil Rights at the Department of Health and Human Services is reviewing Section 1557 of the Patient Protection and Affordable Care Act (PPACA) and its applicability to the language in this regulation.

Regulatory Standard	Federal Regulation
<p>Agent/Broker Standards</p> <p>The QHP issuer must ensure compliance by its appointed agents/brokers, as downstream/delegated entities, including in the following areas:</p> <ul style="list-style-type: none"> ▪ Satisfying applicable FFE registration and training requirements ▪ Maintaining licensure in each state in which the agent/broker participates in an FFE ▪ If an agent/broker non-FFE website is used to complete QHP selection, the website must prominently display the required disclaimers 	<p>45 CFR §§ 155.220 & 156.340</p> <ul style="list-style-type: none"> ▪ §§ 155.220(d) & 156.340(a)(3) ▪ §§ 155.220(e) & 156.340(a)(3) ▪ §§ 155.220(c)(3)(i)(A),(G) & 156.340(a)(3)
<p>Network Adequacy Standards</p> <p>A QHP issuer that uses a provider network must meet the following standards related to its provider network by:</p> <ul style="list-style-type: none"> ▪ Making its provider directory for a QHP available to the FFE for publishing online, and providing a hard copy upon request ▪ Publishing 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 ▪ Making the provider directory publicly available on the QHP issuer's website in a machine-readable file and also providing it upon request by HHS in a format and manner specified by HHS ▪ Counting the cost sharing paid by an enrollee for an essential health benefit (EHB) provided by an out-of-network ancillary provider in an in-network setting towards the annual limitation on cost sharing, or providing written notice by the longer of the issuer's typical response to a prior authorization request or 48 hours before the provision of the benefit, that additional costs may be incurred for an EHB, including balance billing charges, unless prohibited under state law, and that any additional charges may not count toward the in-network annual limitation on cost sharing. 	<p>45 CFR § 156.230</p> <ul style="list-style-type: none"> ▪ § 156.230(b)(1) ▪ § 156.230(b)(2) ▪ § 156.230(c) ▪ § 156.230(e)

Regulatory Standard	Federal Regulation
<p>Essential Community Providers A QHP issuer that uses a provider network must ensure access to Essential Community Providers (ECPs) by:</p> <ul style="list-style-type: none"> ▪ Including a sufficient number and geographic distribution of ECPs, where available, to ensure reasonable and timely access to a broad range of such providers for low-income, medically underserved individuals in the QHP’s service area ▪ Offering contracts to all available Indian health care providers in the service area ▪ Offering contracts to at least one ECP in each of the ECP categories in each county in the service area, where an ECP in that category is available and provides services that are covered by the plan type 	<p>45 CFR § 156.235</p> <ul style="list-style-type: none"> ▪ § 156.235(a)-(b) ▪ § 156.235(a)(2)(ii)(A) ▪ § 156.235(a)(2)(ii)(B)
<p>Meaningful Access to QHP Information The QHP issuer must ensure the readability of plan forms and notices by:</p> <ul style="list-style-type: none"> ▪ Making these documents accessible for individuals in accordance with the Americans with Disabilities Act and for individuals with limited English proficiency 	<p>45 CFR § 156.250</p> <ul style="list-style-type: none"> ▪ § 156.250
<p>Rating Variations The QHP issuer must provide parity with respect to the cost of coverage offered inside and outside the Exchange by:</p> <ul style="list-style-type: none"> ▪ Charging the same premium rate without regard to whether the plan is offered through an Exchange, directly from the issuer, or through an agent/broker ▪ Varying the rate of a plan only with respect to rating area, individual or family coverage, age, and tobacco use (means use of tobacco on average four or more times per week within no longer than the past six months). 	<p>45 CFR §§ 156.255 & 147.102</p> <ul style="list-style-type: none"> ▪ § 156.255(b) ▪ § 147.102(a)(1)
<p>Enrollment Periods for Qualified Individuals The QHP issuer must follow a defined enrollment process for the individual market by:</p> <ul style="list-style-type: none"> ▪ Complying with the rules governing effective dates of coverage, as established by the Exchange ▪ Providing accurate information on effective dates of coverage to qualified individuals 	<p>45 CFR § 156.260</p> <ul style="list-style-type: none"> ▪ § 156.260(a) ▪ § 156.260(b)

Regulatory Standard	Federal Regulation
<p>Enrollment Process for Qualified Individuals</p> <p>The QHP issuer must adhere to the required enrollment processes for the individual market by:</p> <ul style="list-style-type: none"> ▪ Safeguarding enrollment information with respect to personally identifiable information ▪ Complying with premium payment rules established by the Exchange ▪ Providing new enrollees with an enrollment information package that meets readability and accessibility standards for individuals with disabilities or limited English proficiency ▪ Reconciling enrollment files with the Exchange in a format specified by the Exchange and resolving assigned updates no less than once a month, using the most recent enrollment information available ▪ Accepting premium and cost-sharing payments from certain third-party entities on behalf of plan enrollees (the QHP issuer’s downstream entities must also comply to the extent they routinely collect premiums or cost-sharing payments) 	<p>45 CFR §§ 156.265 & 156.1250</p> <ul style="list-style-type: none"> ▪ § 156.265(c) ▪ § 156.265(d) ▪ § 156.265(e) ▪ § 156.265(f) ▪ § 156.1250
<p>Termination of Coverage for Qualified Individuals</p> <p>The QHP issuer must adhere to termination-of-coverage processes in the individual market by:</p> <ul style="list-style-type: none"> ▪ Terminating coverage only under certain permitted circumstances ▪ Providing termination-of-coverage notices promptly to affected enrollees under applicable circumstances ▪ Establishing a policy for handling terminations of coverage due to nonpayment of premium ▪ Following the special termination guidelines for recipients of the advance payment of the premium tax credits ▪ Providing payment delinquency notices to affected enrollees ▪ Maintaining termination-of-coverage records in accordance with Exchange standards ▪ Complying with the rules for effective dates of termination of coverage 	<p>45 CFR § 156.270</p> <ul style="list-style-type: none"> ▪ § 156.270(a) ▪ § 156.270(b) ▪ § 156.270(c) ▪ § 156.270(c)-(e),(g) ▪ § 156.270(f) ▪ § 156.270(h) ▪ § 156.270(i)

Regulatory Standard	Federal Regulation
<p>Renewal and Discontinuation of QHPs The QHP issuer must follow renewal and discontinuation processes by:</p> <ul style="list-style-type: none"> ▪ Providing written notice to affected enrollees when the QHP issuer elects not to seek certification for a subsequent certification cycle ▪ Providing written notice that contains specific information to affected enrollees when the QHP issuer is renewing coverage under one or more QHPs or not renewing coverage under one or more QHPs, but automatically enrolling individuals into another of its QHPs 	<p>45 CFR §§ 156.290 & 156.1255</p> <ul style="list-style-type: none"> ▪ § 156.290(b) ▪ § 156.1255
<p>Prescription Drug Formulary The QHP issuer, other than for SADPs, must comply with essential health benefits (EHB) requirements for prescription drugs by:</p> <ul style="list-style-type: none"> ▪ Covering at least the greater of one drug in every United States Pharmacopeia (USP) category and class or the same number of prescription drugs in each USP category and class as the applicable EHB-benchmark plan ▪ Using a pharmacy and therapeutics committee that meets required membership standards, meets at least quarterly, establishes and manages the formulary drug list, as well as documents procedures and decisions related to formulary development and revision ▪ Having procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not covered by the health plan ▪ Making the formulary publicly available on the QHP issuer’s website in a machine-readable file and format specified by HHS 	<p>45 CFR §§ 156.200(b)(3) & 156.122</p> <ul style="list-style-type: none"> ▪ § 156.122(a)(1) ▪ § 156.122(a)(3) ▪ § 156.122(c) ▪ § 156.122(d)(2)
<p>Maintenance of Records The QHP issuer must follow maintenance of records processes by:</p> <ul style="list-style-type: none"> ▪ Maintaining all FFE-related documents and records and evidence of accounting procedures and practices necessary for HHS to periodically audit financial records and conduct compliance reviews ▪ Retaining FFE-related records for a period of 10 years 	<p>45 CFR § 156.705</p> <ul style="list-style-type: none"> ▪ § 156.705(a) ▪ § 156.705(c)
<p>Handling of Health Insurance Casework System (HICS) The QHP issuer must follow standard processes for cases by:</p> <ul style="list-style-type: none"> ▪ Investigating and resolving cases forwarded to the QHP issuer by HHS ▪ Resolving non-urgent cases received by a QHP issuer from HHS within 15 calendar days of receipt of the case, and urgent cases no later than 72 hours after receipt of the case ▪ Notifying enrollees regarding the disposition of cases received from HHS within the required timeframes and format 	<p>45 CFR § 156.1010</p> <ul style="list-style-type: none"> ▪ § 156.1010(b) ▪ § 156.1010(d) ▪ § 156.1010(f)

Regulatory Standard	Federal Regulation
<p>Other Notices for Special Enrollment Periods</p> <p>The QHP issuer must comply with notice requirements related to material plan or benefit display errors and the enrollees' eligibility for an SEP, included in 45 CFR 155.420(d)(12) by:</p> <ul style="list-style-type: none"> ▪ Notifying affected enrollees within 30 calendar days after being notified by the FFE that the error has been fixed, if directed to do so 	<p>45 CFR § 156.1256</p> <ul style="list-style-type: none"> ▪ § 156.1256
<p>Segregation of Funds for Abortion Services</p> <p>If the QHP issuer has any QHPs offering abortion services for which federal funding is prohibited, the QHP issuer must comply with requirements related to the segregation of funds intended to pay for abortion services for which public funding is prohibited by:</p> <ul style="list-style-type: none"> ▪ Establishing separate allocation accounts to store payments for the portion of premium attributable to the abortion services benefit apart from payments for the portion of premium not attributable to abortion services ▪ Notifying enrollees, only as part of the summary of benefits and coverage explanation, at the time of enrollment, of coverage of abortions for which federal funding is prohibited ▪ Submitting an annual assurance statement to the State insurance commissioner attesting that the plan has complied with section 1303 of the Affordable Care Act and applicable regulations 	<p>45 CFR § 156.280</p> <ul style="list-style-type: none"> ▪ § 156.280(e)(2)(iii) ▪ § 156.280(f) ▪ § 156.280(e)(5)(iii)
<p>Patient Safety Standards for QHP Issuers</p> <p>The QHP Issuer must establish patient safety standards by:</p> <ul style="list-style-type: none"> ▪ Verifying that its contracted hospitals with greater than 50 beds either utilize a patient safety evaluation system as defined in 42 CFR 3.2028 and have implemented a comprehensive person-centered discharge program to improve care coordination and health care quality for each patient; or have implemented an evidence-based initiative to improve health care quality through the collection, management, and analysis of patient safety events that reduces all cause-preventable harm, prevents hospital readmission, or improves care coordination. ▪ Collecting information from each of its contracted hospitals with greater than 50 beds to demonstrate that those hospitals meet the applicable patient safety standards ▪ Making available to the Exchange the documentation referenced in 45 CFR 156.1110(b) upon request by the Exchange, in a time and manner specified by the Exchange 	<p>45 CFR § 156.1110</p> <ul style="list-style-type: none"> ▪ § 156.1110(a)(2) ▪ § 156.1110(b)(2) ▪ § 156.1110(c)

Regulatory Standard	Federal Regulation
<p>Quality Rating System The QHP issuer must follow quality rating system processes including:</p> <ul style="list-style-type: none"> ▪ Only referencing the quality ratings for its QHPs in its marketing materials in a manner specified by HHS. 	<p>45 CFR § 156.1120</p> <ul style="list-style-type: none"> ▪ § 156.1120(c)
<p>Enrollee Satisfaction Survey System The QHP issuer must follow enrollee satisfaction survey system processes including:</p> <ul style="list-style-type: none"> ▪ Only referencing the quality ratings for its QHPs in its marketing materials in a manner specified by HHS. 	<p>45 CFR § 156.1125</p> <ul style="list-style-type: none"> ▪ § 156.1125(c)

Table B: Examples of Regulatory Standards Monitored Through Other Oversight Mechanisms

Example of Regulatory Standard	Federal Regulation
The QHP issuer must comply with benefit design standards, including provision of Essential Health Benefits and following cost-sharing limits, with respect to each of its QHPs.	45 CFR § 156.200(b)(3)
The QHP issuer must pay applicable user fees to HHS.	45 CFR § 156.200(b)(6)
The QHP issuer, other than for SADPs, must comply with the standards related to the risk adjustment program.	45 CFR § 156.200(b)(7)
The QHP issuer must adhere to any requirements imposed by a state in connection with its Exchange.	45 CFR § 156.200(d)
The QHP issuer must set rates for the entire benefit or plan year.	45 CFR § 156.210(a)
The QHP issuer must submit rate and benefit information to the Exchange.	45 CFR § 156.210(b)
The QHP issuer must meet the standards related to the administration of cost-sharing reductions and advance payments of the premium tax credit.	45 CFR § 156.215(a)
The QHP issuer must comply with any applicable state laws and regulations regarding marketing of health insurance coverage.	45 CFR § 156.225(a)
The QHP issuer, other than for SADPs, must ensure that services, including mental health and substance abuse services, are accessible without unreasonable delay.	45 CFR 156.230(a)(2)
The QHP issuer must demonstrate consistent application of premium variations by geographic rating areas.	45 CFR § 156.255(a)
The QHP issuer, other than for SADPs, must be accredited on the basis of local performance of its QHPs by an HHS-recognized accrediting entity in the applicable categories.	45 CFR § 156.275
The QHP issuer, other than for SADPs, must submit quality rating data to HHS and the Exchanges, contract with an HHS-approved enrollee satisfaction survey vendor, and implement and report on a quality improvement strategy.	45 CFR §§ 156.200(b)(5), 156.1120, 156.1125, 156.1130