Key Priorities for Federally-facilitated Exchange Compliance Reviews for the 2025 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 (FFEs). For purposes of this document, a reference to QHPs includes stand-alone dental plans (SADPs) offered on the FFEs, unless otherwise indicated. Compliance reviews focus on FFE requirements for QHP certification under 45 CFR Part 156, and other key FFE operational standards, including FFEs where states perform plan management functions. CMS will review data at both the issuer-and QHP-level (plan-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 new standards may be incorporated into the compliance reviews.

Table A below documents revised regulatory standards governing QHP certification. Table B below lists the regulatory standards governing QHP certification anticipated as part of the FFE compliance reviews for the 2025 plan year. This list is intended to help QHP issuers understand CMS' key priorities for 2025 FFE compliance reviews. For example, the network adequacy standards requirement that QHP issuers 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.

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). This document provides illustrative examples in Table C of regulatory standards that fall into this second category of requirements that will be monitored for compliance through other CMS review and oversight mechanisms. The examples in Table C are also not intended to be an exhaustive list.

The information provided is intended as a general informal summary of technical legal standards. It is not intended to take the place of the statutes, regulations, or formal policy guidance upon which it is based. The tables below summarize current policy and operations as of the date of publication. Stakeholders should refer to the applicable statutes, regulations, and formal guidance for complete and current information.

Table A: 2025 Revisions to the Regulatory Standards That May Be Included in FFE Compliance Reviews

Regulatory Standard	Federal Regulation
QHP Issuer Participation Standards The QHP issuer must meet Exchange participation standards by: ▪ Not discriminating based on race, color, national origin, disability, age, and sex (which includes discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes)[1]	**45 CFR § 156.200** ▪ § 156.200(e)
Access to and Exchange of Health Data and Plan Information The QHP issuer must comply with access to and exchange of health data and plan information by: ▪ Making all data classes and data elements maintained by the QHP issuer including but not limited to claims data, encounter data from capitated providers, and clinical data (including laboratory results) (if the QHP issuer maintains clinical data) accessible to its current enrollees or the enrollee's personal representative through the API no later than one business day after processing claims data, receiving encounter data or clinical data, or receipt of any data	**45 CFR § 156.221** ▪ § 156.221(b)

[1] *CMS will conduct compliance reviews consistent with federal nondiscrimination law, as applicable. In light of ongoing litigation regarding enforcement of certain provisions in the 2024 Final Rule implementing Section 1557 (89 FR 37522), we will not conduct compliance reviews for discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes. See Fla. V. Dep't Health & Human Servs., No: 8:24-cv-1080-WFJ-TGW (M.D. Fla.); Tenn. V. Becerra, No: 1:24cv161-LG-BWR (S.D. Miss.); Tex. V. Becerra, No: 6:24-cv-211-JDK (E.D. Tex.).*

Table AB: Regulatory Standards That May Be Included in FFE Compliance Reviews for 2025

Regulatory Standard	Federal Regulation
QHP Issuer Participation Standards The QHP issuer must meet Exchange participation standards by: ▪ 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 sex (which includes discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes)[2] ▪ Providing the same agent/broker compensation for similar coverage offered inside and outside the FFEs	**45 CFR § 156.200** ▪ § 156.200(c) ▪ § 156.200(e) ▪ § 156.200(f)
QHP Rate and Benefit Information The QHP issuer must report rates by: ▪ 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 ▪ Complying with rate requirements for SADPs beginning on or after January 1, 2024, that allow premium rates to vary by determining the enrollee's age on effective date of the policy issuance or renewal	**45 CFR § 156.210** ▪ § 156.210(c) ▪ § 156.210(c) ▪ § 156.210(d)
Transparency in Coverage The QHP issuer must comply with transparency in coverage standards by: ▪ 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	**45 CFR § 156.220** ▪ § 156.220(a)(1) ▪ § 156.220(b) ▪ § 156.220(c)

[2] *See supra* note 1.

Regulatory Standard	Federal Regulation
QHP Marketing and Benefit Design The QHP issuer must not discourage enrollment of individuals with significant health needs or include misleading content by: ▪ Not employing marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in QHPs ▪ Offering plans and plan variations with marketing names that include correct information, without omission of material fact and do not include content that is misleading	**45 CFR § 156.225** ▪ § 156.225(b) ▪ § 156.225(b)
Delegated and Downstream Entities The QHP issuer must comply with Federal standards applicable to delegated and downstream entities, such as: ▪ 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)	**45 CFR § 156.340** ▪ § 156.340(a)(1) ▪ § 156.340(b)
Agent/Broker Standards The QHP issuer must ensure compliance by its appointed agents/brokers as downstream/delegated entities, including in the following areas: ▪ 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	**45 CFR §§ 155.220 & 156.340** ▪ §§ 155.220(d) & 156.340(a)(2) ▪ §§ 155.220(e) & 156.340(a)(2) ▪ §§ 155.220(c)(3)(i)(A), (G) & 156.340(a)(2)
Network Adequacy Standards A QHP issuer that uses a provider network must meet the following standards related to its provider network by: ▪ Making its provider directory for a QHP available to the FFE for publishing online, and providing a hard copy to potential enrollees 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	**45 CFR § 156.230** ▪ § 156.230(b)(1) ▪ § 156.230(b)(2) ▪ § 156.230(c)

Regulatory Standard	Federal Regulation
Essential Community Providers A QHP issuer that uses a provider network must ensure access to Essential Community Providers (ECPs) by: ▪ 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 eight (8) ECP categories 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 plan type	**45 CFR § 156.235** ▪ § 156.235(a)-(b) ▪ § 156.235(a)(2)(ii)(A) ▪ § 156.235(a)(2)(ii)(B)
Meaningful Access to QHP Information The QHP issuer must ensure the readability of plan forms and notices by: ▪ Making these documents accessible for individuals in accordance with the Americans with Disabilities Act and for individuals with limited English proficiency	**45 CFR § 156.250** ▪ § 156.250
Rating Variations The QHP issuer must provide parity with respect to the cost of coverage offered inside and outside the Exchange by: ▪ 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)	**45 CFR §§ 156.255 & 147.102** ▪ § 156.255(b) ▪ § 147.102(a)(1)
Enrollment Periods for Qualified Individuals The QHP issuer must follow a defined enrollment process for the individual market by: ▪ 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	**45 CFR § 156.260** ▪ § 156.260(a) ▪ § 156.260(b)

Regulatory Standard	Federal Regulation
Enrollment Process for Qualified Individuals The QHP issuer must adhere to the required enrollment processes for the individual market by: ▪ 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)	**45 CFR §§ 156.265 & 156.1250** ▪ § 156.265(c) ▪ § 156.265(d) ▪ § 156.265(e) ▪ § 156.265(f) ▪ § 156.1250
Termination of Coverage for Qualified Individuals The QHP issuer must adhere to termination-of-coverage processes in the individual market by: ▪ 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 and must provide such within 10 business days of the date the issuer should have discovered the delinquency ▪ Maintaining termination-of-coverage records in accordance with Exchange standards ▪ Complying with the rules for effective dates of termination of coverage	**45 CFR § 156.270** ▪ § 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
Renewal and Discontinuation of QHPs The QHP issuer must follow renewal and discontinuation processes by: ▪ 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	**45 CFR §§ 156.290 & 156.1255** ▪ § 156.290(b) ▪ § 156.1255
Prescription Drug Formulary The QHP issuer, other than for SADPs, must comply with essential health benefits (EHB) requirements for prescription drugs by: ▪ 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	**45 CFR §§ 156.200(b)(3) & 156.122** ▪ § 156.122(a)(1) ▪ § 156.122(a)(3) ▪ § 156.122(c) ▪ § 156.122(d)(2)
Maintenance of Records The QHP issuer must follow maintenance of records processes by: ▪ 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	**45 CFR § 156.705** ▪ § 156.705(a) ▪ § 156.705(c)

Regulatory Standard	Federal Regulation
Handling of Health Insurance Casework System (HICS) The QHP issuer must follow standard processes for cases by: ▪ 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	**45 CFR § 156.1010** ▪ § 156.1010(b) ▪ § 156.1010(d) ▪ § 156.1010(f)
Other Notices for Special Enrollment Periods (SEPs) 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: ▪ Notifying affected enrollees within 30 calendar days after being notified by the FFE that the error has been fixed, if directed to do so	**45 CFR § 156.1256** ▪ § 156.1256
Patient Safety Standards for QHP Issuers The QHP issuer must establish patient safety standards by: ▪ 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	**45 CFR § 156.1110** ▪ § 156.1110(a)(2) ▪ § 156.1110(b)(2) ▪ § 156.1110(c)
Quality Rating System The QHP issuer must follow quality rating system (QRS) processes including: ▪ Submitting data validated in a form and manner specified by HHS, to ensure the integrity of the data required to calculate the QRS ▪ Only referencing the quality ratings for its QHPs in its marketing materials in a manner specified by HHS	**45 CFR § 156.1120** ▪ § 156.1120(a)(2) ▪ § 156.1120(c)

Regulatory Standard	Federal Regulation
Enrollee Satisfaction Survey System The QHP issuer must follow enrollee satisfaction survey (ESS) system processes including: ▪ Collecting data for each QHP, with more than 500 enrollees in the previous year that has been offered in an Exchange for at least one year and following an HHS survey sampling methodology ▪ Submitting data validated in a form and manner specified by HHS and submitting this data to its contracted ESS vendor to ensure the integrity of the data required to conduct the survey ▪ Only referencing the quality ratings for its QHPs in its marketing materials in a manner specified by HHS	**45 CFR § 156.1125** ▪ § 156.1125(b)(1) ▪ § 156.1125(b)(2) ▪ § 156.1125(c)
Quality Improvement Strategy The QHP issuer must follow quality improvement strategy (QIS) processes including: ▪ Implementing and reporting on a QIS after participating in an Exchange for 2 or more consecutive years. The QIS must include a payment structure providing increased reimbursement or other market-based incentives in accordance with the health care topic areas defined in section 1311(g)(1) of the ACA, for each QHP offered in an Exchange, consistent with HHS guidelines ▪ Submitting data validated in a manner and timeframe specified by the Exchange to support the evaluation of quality improvement strategies in accordance with 45 CFR § 155.200(d)	**45 CFR § 156.1130** ▪ § 156.1130(a) ▪ § 156.1130(b) and (c)

Regulatory Standard	Federal Regulation
Access to and Exchange of Health Data and Plan Information The QHP issuer must comply with access to and exchange of health data and plan information by:	**45 CFR § 156.221**
▪ Implementing and maintaining a standards-based Application Programming Interface (API) that permits third-party applications to retrieve, with the approval and at the direction of a current individual enrollee or the enrollee's personal representative, data specified in 45 CFR § 156.221(b) through the use of common technologies and without special effort from the enrollee	▪ § 156.221(a)
▪ Making all data classes and data elements maintained by the QHP issuer including but not limited to claims data, encounter data from capitated providers, and clinical data (including laboratory results) (if the QHP issuer maintains clinical data) accessible to its current enrollees or the enrollee's personal representative through the API no later than one business day after processing claims data, receiving encounter data or clinical data, or receipt of any data.	▪ § 156.221(b)
▪ Implementing the API by complying with certain standards under 45 CFR § 170.213, 45 CFR § 170.215, 45 CFR part 162, and 42 CFR § 423.160	▪ § 156.221(c)
▪ Implementing and maintaining privacy and security features including but not limited to those required to comply with HIPAA privacy and security requirements in 45 CFR parts 160 and 164, 42 CFR parts 2 and 3, and other applicable law protecting privacy and security of individually identifiable data	▪ § 156.221(c)(2)
▪ Making publicly accessible, by posting directly on its website and/or via publicly accessible hyperlink(s), complete accompanying documentation that contains information about certain parameters/components necessary to search and retrieve responses/data	▪ § 156.221(d)

Regulatory Standard	Federal Regulation
▪ Denying or discontinuing any third-party application's connection to the API if QHP issuer reasonably determines unacceptable level of risk, consistent with its security risk analysis under 45 CFR part 164 subpart C and makes this determination using objective, verifiable criteria	▪ § 156.221(e)
▪ Providing enrollee resources regarding privacy and security in an easily accessible location on its public website and through other appropriate mechanisms through which it ordinarily communicates with current and former enrollees seeking to access their health information held by the QHP issuer, educational resources in simple and easy-to-understand language	▪ § 156.221(g)
▪ Providing a narrative justification, as part of its QHP application, describing the reasons why the plan cannot reasonably satisfy the requirements in 45 CFR 156.221 (a) - (g) for the applicable plan year if issuer believes it cannot satisfy the requirement, which should include the impact of non-compliance upon enrollees, the current or proposed means of providing health information to enrollees, and solutions and a timeline to achieve compliance with the requirements	▪ § 156.221(h)(1)
▪ Complying with 45 CFR 156.221(a) through (e) and (g) beginning with plan years beginning on or after January 1, 2021, and with 45 CFR 156.221(f) beginning with plan years beginning on or after January 1, 2026: with regard to data with a date of service on or after January 1, 2016; and that are maintained by the QHP issuer for enrollees in QHPs	▪ § 156.221(i)

Table BC: 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 use disorder services, are accessible without unreasonable delay.	45 CFR § 156.230(a)(ii)
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 comply with applicable state laws prohibiting abortion coverage in QHPs and must follow financial standards for the segregation and collection of funds for specified abortion services.	45 CFR § 156.280