



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

2021 Plan Year Federally-Facilitated Exchange Issuer Compliance Review Summary Report

April 5, 2023

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1. EXECUTIVE SUMMARY

In accordance with the Patient Protection and Affordable Care Act, as amended, and pursuant to 45 CFR § 155.1010(a)(2) and § 156.715, the Centers for Medicare & Medicaid Services (CMS) conducts Qualified Health Plan (QHP) issuer oversight and compliance monitoring activities in Federally-facilitated Exchanges (FFEs) including those in states performing plan management functions. Oversight and monitoring activities help protect consumers by ensuring QHP issuers are compliant with FFE standards. FFE compliance reviews also help QHP issuers identify opportunities for improvement and provide insight to CMS on areas where additional guidance may be helpful.

This report summarizes the results from FFE compliance review activities related to plans certified for Plan Year (PY) 2021.¹ By sharing this report, CMS can provide insights on identified areas of noncompliance in 2021 and help QHP issuers ensure their processes, procedures, and activities comply with CMS regulations and guidance.

Per 45 CFR § 155.1010(a)(2) and § 156.715, CMS may conduct compliance reviews of QHP issuers offering QHPs, including stand-alone dental plans (SADPs), in the FFEs to ensure ongoing compliance with QHP certification standards and FFE requirements. CMS selected 19 QHP issuer identification numbers (IDs) from 14 FFE states² for compliance reviews of plans certified for PY 2021. These compliance reviews focused on QHP issuer processes and operational testing related to the following areas: prescription drug benefits, QHP issuer participation standards, access to and exchange of health data and plan information, transparency in coverage, rate and benefits information, marketing and benefit design, network adequacy, special enrollment period notices, enrollment processes for qualified individuals (privacy and security), termination of coverage for qualified individuals, QHP issuer oversight of delegated and downstream entities including affiliated agents and brokers, rating variations, health insurance casework system (HICS), maintenance of records, quality standards, renewal and re-enrollment notices, and compliance plans.

The results from compliance reviews are categorized as "findings" or "observations." Findings may result from discovery of evidence suggesting noncompliance, in addition to cases of confirmed noncompliance. Observations may result from identification of areas for improvement when there is no evidence of actual noncompliance.

The compliance reviews further divide results by methodology. Process findings or observations were primarily issues identified with a QHP issuer's underlying process to complete a required activity. Performance findings or observations were primarily included when a QHP issuer's process included all of the required elements, but operational testing indicated that those elements were not followed consistently. In some cases, a combination of findings or observations were discovered due to a QHP issuer having problems with both its process and performance of a required activity.

¹ For the purposes of this report, CMS defines Plan Year 2021 as the period between January 1, 2021, and December 31, 2021.

² The 14 FFE states were AZ, FL, IL, LA, MT, NC, NH, OH, SC, SD, TX, UT, WI, and WY.

The following review areas were the most likely to produce findings and observations during the compliance review process:

- <u>Network Adequacy</u>: CMS identified issues regarding network adequacy including: QHP issuers did not make contract offers to Essential Community Providers (ECPs) and Indian health care providers as required by 45 CFR § 156.235(a)(2)(ii); and provider directories or machinereadable files that contained specific data elements were not up-to-date, complete, and accurate as required by 45 CFR § 156.230(b).
- <u>Downstream and Delegated Entities*</u>: CMS identified QHP issuer downstream and delegated entity contracts that did not include the Exchange-specific language required by 45 CFR § 156.340(b).
- <u>Casework</u>: CMS identified issues with the timely resolution, documentation, and complainant notification of HICS casework as required by 45 CFR § 156.1010.
- <u>Termination Notices for Qualified Individuals*</u>: CMS identified issues with the timeliness or accuracy of notices sent to enrollees, specifically termination notices that were not sent timely or did not include all required information as required by 45 CFR § 156.270(b).
- Enrollment Process for Qualified Individuals (Privacy and Security Policies)*: CMS identified issues with QHP issuers' privacy and security policies, or in some cases, specific incidents where the QHP issuer did not comply with, or were not consistently aware of, requirements to report any breach or security incidents to the CMS IT help desk either by email or phone call within the timeframes required under the FFE privacy and security policies pursuant to 45 CFR § 155.260 and § 156.265(b)(3)(iii).
- <u>Agent and Broker Oversight*</u>: CMS identified issues with inadequate monitoring of affiliated agents and brokers (i.e., QHP issuers did not consistently confirm whether their respective affiliated agents and brokers had completed the required FFE registration and training before assisting Exchange consumers) as required by 45 CFR § 156.340(a)(3).

CMS recommends QHP issuers review the results summarized in this report and use this information to identify opportunities for improvement in their own policies, procedures, and processes. CMS expects QHP issuers to be familiar with FFE standards and processes and to have mechanisms in place to self-monitor compliance. Figure 1 displays the percentage of reviewed QHP issuers with findings and observations in each review area; QHP issuers may have had multiple results in an area.

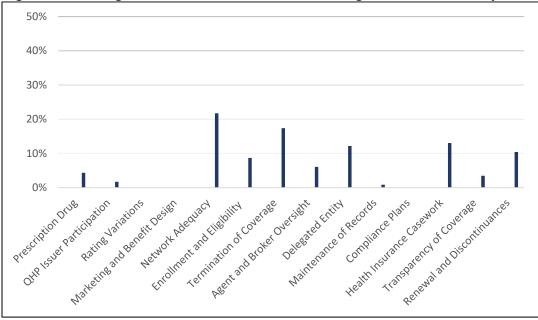


Figure 1: Percentage of QHP Issuers Reviewed with Findings and Observations by Area³

2. COMPLIANCE REVIEW PROCESS

The compliance review is a multi-phase process beginning with QHP issuer selection and culminating in a compliance review report. This section provides an overview of the compliance review process. Figure 2 depicts the steps in the FFE compliance review process. CMS also released *Key Priorities for Federally-facilitated Exchange Compliance Reviews for the 2021 Plan Year,* which sets forth a list of regulatory standards that CMS considers to be of the highest priority in the PY 2021 compliance reviews. This document is available at: https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/2021-Key-Priorities-Table-Final.pdf.



CMS selects QHP issuers for compliance reviews based on criteria related to performance data and ongoing monitoring activities. For PY 2021, CMS conducted compliance reviews of 19 QHP issuers' identification numbers. Beginning in March 2021, CMS issued notifications to the selected QHP issuers and conducted kick-off calls to discuss each QHP issuer's selection and the compliance review process,

as well as to inform the QHP issuer of any documentation needed prior to start of the review. After receiving and reviewing the requested documentation, CMS performed testing and validation on the

³ These statistics represent the percentage of QHP issuers reviewed with Findings or Observations attributed to a particular review area. Scoring may represent multiple Findings attributed to the same area, as seen under Network Adequacy which includes Findings or Observations for provider directory, machine-readable data files, ECP contracting areas tested under one combined heading, which resulted in more than one Finding or Observation in several review areas.

information submitted. CMS then conducted interviews with each QHP issuer's staff about its FFE operations. Figure 3 shows a breakdown of the QHP issuer characteristics for PY 2021 compliance reviews.

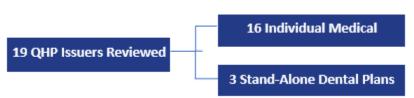


Figure 3: QHP Issuer Characteristics for PY 2021 Compliance Reviews⁴

The PY 2021 compliance reviews consisted of 19 desk reviews (encompassing 16 QHPs and 3 SADPs).⁵ During each review, CMS: 1) reviewed QHP issuers' policies, procedures, and processes for all 17 review areas within the scope of the review, and 2) performed testing for 15 of the 17 review areas to assess compliance with FFE regulations.

The next section details the results of the PY 2021 compliance reviews by review area. The compliance reviews continued to focus more on QHP issuers' processes and performance, and less on their written policies and procedures than prior years. Written policies and procedures were requested and reviewed as part of the compliance review to aid CMS in determining whether a QHP issuer's processes complied with FFE requirements.

3. COMPLIANCE REVIEW RESULTS

Findings and observations contained in this report align with the 17 review areas noted in the Executive Summary and associated regulatory standards. Tables 1-17 present findings and observations for each of the 17 review areas. Findings result from the discovery of evidence suggesting noncompliance, in addition to cases of confirmed or admitted noncompliance. Observations result from the discovery of evidence of practices or procedures which represent a compliance risk, but for which there was no evidence of noncompliance, in addition to identification of areas for improvement.

CMS classified findings and observations⁶ based on the type of review methodology⁷ employed:

• **Process Review:** This included review of QHP issuers' written processes and procedures for review areas within the scope of the PY 2021 compliance reviews. Throughout the reviews, CMS requested and examined applicable policies and procedures established and provided by the QHP issuers.

⁴ The 16 Individual Medical included a target compliance review of one parent company covering five different states.

⁵ CMS conducted desk reviews using zoom interviews, website research, and email to collect the necessary information and documents for review.

⁶ Review areas may contain findings, observations, or both, depending on testing results.

⁷ Information about the CMS review methodologies is provided as a high-level overview of the review processes completed for each area under review. This information is not sufficiently detailed to complete a similar review and replicate CMS' results.

• **Performance Testing:** This included testing to assess QHP issuers' compliance with FFE regulations for review areas within the scope of the PY 2021 compliance reviews. CMS completed testing using either 100% of available data (e.g., contracts, cases, notices) or a random sample of data. The decision of which sampling methodology to use was based on the test being performed.

Results by Review Area

This section describes the standards and requirements for each of the 17 review areas, the methodology CMS used to review QHP issuer compliance, any associated findings and observations, and suggested best practices for review areas that produced findings or observations.

3.1 Prescription Drug Formulary

Pursuant to 45 CFR § 156.200(b)(3), a QHP issuer must ensure that each QHP complies with benefit design standards, defined at § 156.20 to mean the essential health benefits (EHB) package. Pursuant to 45 CFR § 156.122, a QHP issuer's health plan provides EHB with respect to prescription drugs if it, among other things:

- Covers at least the greater of one drug in every United States Pharmacopeia category and class or the same number of prescription drugs in each category and class as the EHB-benchmark plan;
- Submits its formulary drug list to the FFE, the State, or the Office of Personnel Management (OPM);
- Uses a pharmacy and therapeutics committee that meets specific membership standards;
- Has procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not covered by its health plan; and
- Provides an up-to-date, accurate, and complete listing of all covered drugs on its formulary list in a manner that is easily accessible on its website.

3.1.1 CMS Review Methodology

CMS reviewed prescription drug formularies available on the QHP issuers' websites against those submitted as part of the PY 2021 QHP certification process to determine whether there were significant changes to the formularies since certification that could be prohibited by non-discrimination requirements specified at 45 CFR § 156.125 and § 156.225(b). In addition, CMS reviewed the QHP issuer's drug formularies to determine if the number of specific drugs available met minimum threshold requirements of 45 CFR § 156.122(a)(1) across a broad range of therapeutic classes and recommended drug treatment regimens. CMS also reviewed the QHP issuers' exception request process to determine if the evaluation and notification process is completed in a manner consistent with the requirements of 45 CFR § 156.122(c).

3.1.2 Results

Table 1 lists findings or observations related to this review area.

Review Methodology	Findings or Observations	Findings Count	Observations Count
Performance Testing	 Non-formulary drug exception request policy is not complete (e.g., policy does not include all of the standards for making a determination and notifying an enrollee of the coverage determination on non-formulary drug exceptions). 	5	N/A*

Table 1: Prescription Drug Findings or Observations

*Compliance review protocols do not allow observations for this type of finding.

3.1.3 Best Practices

- Regularly review all formularies, especially when they are managed by a third party, to ensure that any mid-year changes conform to applicable regulations.
- Regularly review published formularies to ensure they include a current and complete list of all covered drugs, including any tier structure that has been adopted, and any restrictions to obtaining a drug.
- Regularly review implementation of the drug exception request process to ensure that requests are being evaluated, decisions are made, and notifications are sent as required and within the applicable timeframes.

3.2 QHP Issuer Participation General Standards

Pursuant to 45 CFR § 156.200, Exchange participation standards require a QHP issuer to, among other things:

- Have each QHP certified by the Exchange in which it is being offered;
- Comply with Exchange processes, procedures, and requirements under Title 45, Part 155, Subpart K and, in the small group market, 45 CFR § 155.706;
- Not discriminate based on race, color, national origin, disability, age, or sex; and
- Provide the same agent and broker compensation for similar coverage offered inside and outside the Exchanges.

3.2.1 CMS Review Methodology

CMS reviewed non-discrimination policies to ensure that the policies were in place and available to employees and that the policy included all classes identified under the regulation.⁸ CMS also reviewed agent and broker compensation policies, comparing amounts paid for on- and off-Exchange coverage, subscriber agreements, and lists of the QHPs (by type) offered under the participating QHP issuer IDs.

3.2.2 Results

Table 2 lists findings or observations related to this review area.

⁸ The evaluation of the non-discrimination policies was modified in 2019 to deem the QHP issuer's policy as compliant if it mirrored the statutory language in Section 1557 of the ACA.

Review Methodology	Findings or Observations	Findings Count	Observations Count
Process Testing	 Non-discrimination policies, procedures, protocols, standard operating procedures, or other similar manuals omitted protected classes. 	0	1

Table 2: QHP Issuer Participation General Standards Findings or Observations

3.2.3 Best Practices

- Review written policies, procedures, and notification documents to ensure they are consistent with regulatory requirements related to non-discrimination.
- Develop and monitor compensation practices to ensure that Exchange status is not considered when determining the rate of compensation for an agent or broker.

3.3 QHP Rate and Benefit Information

Pursuant to 45 CFR § 156.210(c), a QHP issuer must submit to the Exchange a justification for a rate increase prior to the implementation of the increase and prominently post the justification on its website.

3.3.1 CMS Review Methodology

CMS reviewed QHP issuers' websites to determine if applicable rate increase justifications, or links to them, were available on their websites.

3.3.2 Results

Table 3 lists findings or observations related to this review area.

Review Methodology	Findings or Observations	Findings Count	Observations Count
Performance Testing	 No findings were identified in this review area. 	0	N/A*

Table 3: QHP Rates and Benefits Findings or Observations

*Compliance review protocols do not allow observations for this review area.

3.3.3 Best Practices

• Establish an annual process to ensure a justification is posted to the QHP issuer's website, consistent with FFE regulations.

3.4 Transparency in Coverage

Pursuant to 45 CFR § 156.220, a QHP issuer must provide specific information in accordance with the regulation to the Exchange, the Department of Health and Human Services (HHS), and their State insurance commissioner, and make the information available to the general public, in plain language. A QHP issuer also must make available the amount of enrollee cost sharing under the individual's plan or

coverage with respect to the furnishing of a specific item or service by a participating provider in a timely manner upon the request of the individual through a website or other means for individuals without access to the internet.

3.4.1 CMS Review Methodology

CMS reviewed QHP issuer websites to determine if the QHP issuer provided links to required information, either on a single page or within multiple webpages that may be accessible from a landing page. CMS also accesses the QHP Issuer's Claims Payment Policies & Other Information URL to ensure it includes the minimum requirements of:

- Out-of-network liability and balance billing;
- Enrollee claims submission;
- Grace periods and claims pending;
- Retroactive denials;
- Recoupment of overpayments;
- Medically necessity and prior authorization timeframes and enrollee responsibilities;
- Drug exception timeframes and enrollee responsibilities (not required for SADPs);
- Explanation of benefits; and
- Coordination of benefits.

3.4.2 Results

Table 4 lists findings or observations related to this review area.

Review Methodology	Findings or Observations	Findings Count	Observations Count
Performance Testing	 Claims transparency information was not provided or did not include all required information. 	3	N/A*
	 Claims transparency information URL was not easily accessible. 	1	0

Table 4: Transparency in Coverage Findings or Observations

*Compliance review protocols do not allow observations for this type of finding.

3.4.3 Best Practices

- Establish an annual process to ensure the required information is posted to the QHP issuer website and the links provided are active.
- Ensure the QHP issuer's Claims Payment Policies & Other Information URL includes the minimum requirements.

3.5 Marketing and Benefit Design

Pursuant to 45 CFR § 156.225(b), a QHP issuer may not employ marketing practices or benefit designs that have the effect of discouraging enrollment of individuals with significant health needs.

3.5.1 CMS Review Methodology

CMS reviewed FFE QHP issuers' processes related to marketing and benefit design to determine whether they included processes intended to prevent discriminatory practices in the development of plan benefits, including coverage standards and limitations.

3.5.2 Results

Table 5 lists findings or observations related to this review area.

Table 5: Marketing and Benefit Design Findings or Observations

Review Methodology	Findings or Observations	Findings Count	Observations Count
Performance Testing	 No findings or observations were identified in this review area. 	0	0

3.5.3 Best Practices

- Establish and use a process that evaluates and monitors the design of each plan's benefits to ensure that plans are not designed with potentially discriminatory benefits or requirements.
- Establish and use a process that evaluates and monitors the marketing plan for each product to ensure that the marketing practices will not have the effect of discouraging the enrollment of individuals with significant health needs.

3.6 Network Adequacy

Pursuant to 45 CFR § 156.230(a)(2), (a)(3), and (b), a QHP issuer with QHPs that use provider networks are required to maintain a sufficient provider network by:

- Maintaining a network that is sufficient in number and types of providers, including providers that specialize in mental health and substance abuse services, to ensure that all services will be accessible without unreasonable delay, and that is consistent with the network adequacy provisions of Section 2702(c) of the Public Health Service Act;
- Making an accurate and up-to-date provider directory available to the Exchange for publication online and providing a hard copy to potential enrollees upon request; and
- Identifying which providers are not accepting new patients in their provider directories.

Pursuant to 45 CFR § 156.235(a), a QHP issuer's networks must also have 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 individuals or individuals residing in Health Professional Shortage Areas within the QHP's service area. An ECP is a provider that serves predominantly low-income, medically underserved individuals. A QHP issuer must satisfy the following criteria, among other requirements:

- Offer contracts in good faith to all available Indian health care providers in the service area; and
- Offer contracts in good faith to at least one ECP in each ECP category 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 QHP issuer plan type.

3.6.1 CMS Review Methodology

CMS evaluated the QHP issuer's provider directory to determine if 1) a provider directory is available to enrollees both online and in hard copy upon request, 2) online and printed directories clearly identify providers that are not accepting new patients, and 3) demographic and other required information is included and is accurately recorded in the provider directory.

CMS accessed the QHP issuer's online and machine-readable provider directory data files and selected a sample of providers from different specialty groups from each source. Each provider office in the sample was analyzed using the provider's website, other internet resources, or telephone calls to confirm that the demographic information published in the directory was up-to-date, accurate, and complete. The information gathered during this internet search was documented and compared against the source data to confirm that the location, telephone number, specialty, medical group, institutional affiliations, and reported status of the provider as not accepting new patients were correct. In cases where the QHP issuer also created a stand-alone hard copy directory, CMS determined if the information contained within it was consistent with the online directory.

CMS' testing of this review area also included a comparison of the QHP issuer's ECP lists against the *HHS* 2021 Non-Exhaustive List of ECPs to identify if there were any counties and/or specialties within the QHPs' services areas which did not meet the FFE requirements for ECPs. In those counties where QHPs did not meet ECP requirements, CMS requested documentation that the QHP issuer had extended a good faith offer to contract to all Indian health care providers within the QHPs' service areas and at least one ECP provider in each category in each county in the QHPs' service areas.

3.6.2 Results

Table 6 lists findings or observations related to this review area.

Review Methodology	Findings or Observations	Findings Count	Observations Count
Performance Testing	 Provider directories contained incorrect information pertaining to one or more of the following details: medical group affiliation, specialty, address, phone number, and status of accepting new patients (e.g., some sampled providers were no longer in practice and/or had incorrect contact information). 	16	1
	 Provider directory URL requires an individual to login or create an account. 	1	0
	 QHP issuer's ECP list did not meet all ECP contract-offer requirements (e.g., some QHP issuers did not offer contracts to one or more Indian health care providers in their service area or could not provide documentation proving such contract offers were made). 	7	0

Table 6: Network Adequacy Findings or Observations⁹

3.6.3 Best Practices

- Regularly verify data in provider directories to ensure the accuracy of the information and make process improvements, when necessary, to ensure the data is as accurate, complete, and up to date as possible.
- Use provider data within claims submission and payment processing systems to evaluate possibly incorrect data elements.
- Create a process to evaluate network adequacy that includes procedures to remedy deficiencies that are identified.
- Annually identify all ECPs, including Indian health care providers, in each service area and develop a process to ensure that contract offers are made to ECPs as required by the regulation and documentation of those offers is maintained in accordance with applicable FFE record-retention requirements.

3.7 Premium Rate Variations

Pursuant to 45 CFR §§ 147.102(a) and 156.255(b), a QHP issuer is required to charge the same premium rate without regard to whether the plan is offered through an Exchange, directly from the QHP issuer, or through an agent. Premium variations are not permitted on the basis of the method of sale or the offering of a plan through an Exchange.

⁹ The total of 25 findings in this area for 19 QHP issuers reviewed is accurate as several QHP issuers had multiple findings and every QHP issuer received at least one finding in this review area.

3.7.1 CMS Review Methodology

CMS performed comparisons of the premiums for QHPs sold on- and off-Exchange to determine if the rates being charged were comparable¹⁰ for similar plans.

3.7.2 Results

Table 7 lists findings or observations related to this review area.

Table 7: Premium Rate Variation Findings or Observations

Review Methodology	Findings or Observations	Findings Count	Observations Count
Performance Testing	 No findings were identified related to this review area. 	0	N/A*

*Compliance review protocols do not allow observations for this review area.

3.7.3 Best Practices

• Monitor pricing strategies and actuarial data across plans to ensure that QHPs will not have pricing differences related to being offered on Exchange or directly through the QHP issuer.

3.8 Other Notices for Special Enrollment Periods for Qualified Individuals

Pursuant to 45 CFR § 156.1256, a QHP issuer offering coverage through an FFE must notify enrollees of material plan or benefit display errors and the enrollees' eligibility for a special enrollment period within 30 calendar days after being notified by an FFE or CMS that the error has been fixed, if directed to do so by an FFE or CMS.

3.8.1 CMS Review Methodology

CMS reviewed certification records to determine if a QHP issuer had been required to make a notification to its enrollees. If the QHP issuer had been required to make the appropriate notifications, CMS selected a sample of impacted enrollees. The letters were reviewed to determine if they had been sent within the appropriate timeframes and that they used the approved notification template.

3.8.2 Results

Table 8 lists findings or observations related to this review area.

Table 8: Other Notices for Special Enrollment Periods Findings or Observations

Review Methodology	Findings or Observations	Findings Count	Observations Count
Performance Testing	 No findings were identified related to this review area. 	0	N/A*

¹⁰ The definition of "comparable" for this evaluation was determined to be a variance between similar QHPs of less than one dollar per month.

*Compliance review protocols do not allow observations for this review area.

3.8.3 Best Practices

- Actively monitor plan submissions and plan displays to ensure that errors are not included.
- Should errors be identified, the QHP issuer should actively review the errors and make all required notifications within the timeframes required.

3.9 Enrollment Process for Qualified Individuals

Pursuant to 45 CFR § 156.265, a QHP issuer must adhere to the required enrollment processes for the individual market FFE, including:

- Enrolling a qualified individual through the Exchanges if they receive an eligibility determination from the Exchange;
- Accepting enrollment information consistent with applicable Exchange privacy and security requirements;
- Ensuring the process used to complete the eligibility application complies with all Exchange standards, including applicable privacy and security requirements;
- Providing new enrollees with enrollment information packages that meet readability and accessibility standards for individuals with disabilities or limited English proficiency;
- Reconciling enrollment files with the Exchange no less frequently than once a month; and
- Verify to the Exchange that the enrollment information has been received.

Within this review area, CMS also reviewed requirements related to acceptance of certain third-party payments (see 45 CFR § 156.1250). This regulation requires QHP issuers in the individual market to accept premium and cost-sharing payments for the QHPs from certain third parties on behalf of enrollees, including Indian tribes, tribal organizations, and urban Indian organizations; Ryan White HIV/AIDS Programs; as well as local, state, and federal government programs and their grantees.

3.9.1 CMS Review Methodology

CMS reviewed enrollment processes, new enrollment packages, and processes for reconciling enrollment files with the FFEs. To evaluate QHP issuer compliance with FFE privacy and security standards, CMS reviewed privacy and security policies, materials for privacy and security training provided to employees and delegated and/or downstream entities, and records of individuals who completed the training. To evaluate QHP issuer compliance with FFE third-party payment acceptance requirements, CMS reviewed the QHP issuers' premium acceptance policy, and through written and verbal communication, identified the QHP issuers' processes related to the acceptance of third-party payments for patient premiums.

3.9.2 Results

Table 9 lists findings or observations related to this review area.

Review Methodology	Findings or Observations	Findings Count	Observations Count
Performance Testing	 QHP issuer did not have a process for, was not aware of, or had not been compliant with the FFE incident or breach reporting requirements as required by section II.c.7 of the Qualified Health Plan Certification Agreement and Privacy and Security Agreement. 	4	0
	 QHP issuer did not have a process for, was not aware of, or had not been compliant with the FFE incident or breach reporting requirements as required by section II.c.7 of the Qualified Health Plan Certification Agreement and Privacy and Security Agreement. 	0	6
	 Renewal or re-enrollment notices did not include the required Paper Reduction Act (PRA) disclosure statement 	12	0

Table 9: Enrollment Process Findings or Observations

3.9.3 Best Practices

- Evaluate and update policies and procedures related to incident and breach reporting with respect to QHPs offered through the FFEs and include the required notification timeframes and a reporting process as appropriate.
- Evaluate and update notification processes to monitor all mailings and document the timeframes for them to be sent.
- Monitor all mailings to ensure that letters or notifications are sent to enrollees as required and contain all required information.

3.10 Termination of Coverage for Qualified Individuals

Pursuant to 45 CFR § 156.270, a QHP issuer must adhere to termination-of-coverage processes in the individual market FFEs. These processes require QHP issuers to:

- Terminate coverage only under certain permitted circumstances;
- Provide termination-of-coverage notices promptly to affected enrollees, when applicable;
- Establish a policy for handling terminations of coverage due to nonpayment of premiums;
- Follow the special termination guidelines for recipients of Advance Payments of the Premium Tax Credit (APTC);
- Provide payment delinquency notices to affected enrollees;
- Maintain termination-of-coverage records in accordance with Exchange standards; and
- Comply with the rules for effective dates of termination of coverage.

3.10.1 CMS Review Methodology

CMS reviewed QHP issuers' termination-of-coverage written policies to determine if the policies contained the required elements. CMS also performed testing on a sample of enrollee termination notices from each QHP issuer to determine if enrollees were notified of their terminations without undue delay, the notices contained a coverage termination-effective date, and the reasons for the terminations. Additionally, CMS performed a review of QHP issuers' record maintenance written policies specific to termination of coverage. CMS also conducted performance testing on payment delinquency notices to determine whether QHP issuers sent them within appropriate timeframes.

3.10.2 Results

Table 10 lists findings or observations related to this review area.

Review Methodology	Findings or Observations	Findings Count	Observations Count
Performance Testing	 Termination-of-coverage policy is not complete. 	6	0
	 Enrollee did not have claims paid in the first month of the grace period. 	1	0
	 QHP issuer did not send termination/cancelation notices to all enrollees, or they were sent with undue delay. 	13	0
	 Termination notices did not include a reason for termination or the correct reason. 	3	0
	 Enrollees receiving APTC were not provided a 3 consecutive months' grace period. 	1	0
	 Termination notice did not include the termination effective date for termination. 	6	0
	 Delinquency notices were not sent. 	1	0

Table 10: Termination of Coverage Findings or Observations¹¹

3.10.3 Best Practices

- Regularly review termination-of-coverage policy to ensure all standards for the termination of enrollment due to non-payment of premium are included in the termination policy.
- Regularly review termination-of-coverage operations to ensure processes are working as intended, and notices are sent promptly and with the required content.

¹¹ A total of 31 findings recorded this area for 19 QHP issuers reviewed. Several findings had multiple elements contained within them resulting in the total represented in this chart.

3.11 Agent and Broker Oversight

Pursuant to 45 CFR § 156.340(a)(3), a QHP issuer must confirm that their affiliated agents and brokers are compliant with all applicable requirements such as:

• Satisfaction of applicable FFE registration and training requirements.

3.11.1 CMS Review Methodology

CMS reviewed QHP issuers' written policies and procedures related to affiliated agent and broker onboarding. CMS then cross-referenced QHP issuers' submitted lists of National Producer Numbers (NPNs) for affiliated agents and brokers who assisted with PY 2021 enrollments against the published *CMS Agent and Broker FFE Registration Completion List for Plan Year 2021*¹² to determine if each affiliated agent or broker had completed the required FFE registration and training for PY 2021. CMS also compared the registration completion dates of those registered agents or brokers with the date of the first enrollment they assisted with for PY 2021 to determine if the affiliated agents or brokers were assisting with enrollment prior to having completed the registration and training process.

3.11.2 Results

Table 11 lists findings or observations for this review area.

Review Methodology	Findings or Observations	Findings Count	Observations Count
Performance Testing	 NPNs for affiliated agents, brokers, or agencies did not match CMS's records, indicating that they had not completed the required FFE registration and training process for PY 2021. 	2	4
	 NPNs assisted with enrollments prior to having completed the required FFE registration and training process for PY 2021. 	1	2

Table 11: Agent and Broker Oversight Findings or Observations

3.11.3 Best Practices

- Regularly review CMS's agent and broker registration completion list and compare it with affiliated agents' and brokers' NPNs to ensure that affiliated agents and brokers have completed FFE registration, as required.
- Establish a process to educate affiliated agents and brokers if they are assisting consumers with FFE enrollments and found to be noncompliant with the FFE registration and training requirements.

¹² Available at <u>https://data.healthcare.gov/dataset/AB-Registration-Completion-List/wb6u-x2ny/data</u>.

3.12 Delegated and Downstream Entities

Pursuant to 45 CFR § 156.340, a QHP issuer must comply with standards applicable to delegated and downstream entities, including executing a delegation agreement/amendment that in part: 1) specifies delegated activities and reporting responsibilities; 2) provides for remedies if the delegated entity does not perform satisfactorily; and 3) otherwise conforms with the requirements in 45 CFR § 156.340(b).

3.12.1 CMS Review Methodology

CMS reviewed each contract (including any amendments) with a delegated or downstream entity submitted by the QHP issuer to determine if the contract:

- Specifies the delegated activities and reporting responsibilities;
- Provides for revocation of the delegation or other remedies when HHS or the QHP issuer determines that such parties have not performed satisfactorily;
- Requires compliance with all applicable statutes and regulations;
- Provides for access by HHS or its designees to the entity's books, contracts, computers, or other systems relating to the QHP issuer's obligations until 10 years from the final date of the agreement period; and
- Contained these provisions no later than January 1, 2015, for existing agreements, and no later than the effective date of the agreement for agreements that were newly entered into as of October 1, 2013.

3.12.2 Results

Table 12 lists findings or observations related to this review area.

Review Methodology	Findings or Observations	Findings Count	Observations Count
Performance Testing	 QHP issuer's downstream and delegated entity agreements (including any amendments thereto) did not include all of the language required by 45 CFR § 156.340. 	13	0

Table 12: Delegated and Downstream Entity Findings or Observations

3.12.3 Best Practices

- Review all contracts with downstream and delegated entities performing functions related to the FFEs to ensure that the language required under 45 CFR § 156.340 is incorporated (as applicable).
- Establish oversight processes for downstream and delegated entities to ensure they are in compliance with their contractual obligations and related FFE requirements.

3.13 Maintenance of Records

Pursuant to 45 CFR § 156.705, a QHP issuer is required to comply with the FFE standards for maintenance of records. This requirement includes maintaining FFE records for a period of 10 years.

Additionally, a QHP issuer must make available all records that are necessary for HHS to conduct financial audits and compliance reviews.

3.13.1 CMS Review Methodology

CMS reviewed written policies to determine QHP issuer record maintenance schedules and confirm compliance with the FFE 10-year record maintenance requirement. CMS also reviewed a variety of records or documents requested from QHP issuers.

Findings or observations related to this review area were identified if record retention timeframes did not meet requirements or if the QHP issuer was unable to supply a record or document requested as part of testing.

3.13.2 Results

Table 13 lists findings or observations related to this review area.

Review Methodology	Findings or Observations	Findings Count	Observations Count		
Process Review	 QHP issuer's record retention schedule and policy did not reflect the required record retention timeframe.¹³ 	0	1		

Table 13: Maintenance of Records Findings or Observations

3.13.3 Best Practices

• Update written record-retention policies, and provide applicable staff training, to ensure records are maintained and accessible upon request for the required 10-year period.

3.14 Compliance Plans

Pursuant to 45 CFR § 156.715, a QHP issuer is subject to compliance reviews and must provide CMS access to certain FFE records. Such records may include, but are not limited to:

- The QHP issuer's books and contracts, including policy manuals and other plan benefit information provided to enrollees;
- The QHP issuer's policies and procedures, protocols, standard operating procedures, or other similar manuals; and
- Any other information reasonably necessary for HHS to evaluate compliance with certification standards, assess adherence to an effective compliance plan, and determine the likelihood of fraud or abuse.

¹³ A finding of this type was most recently previously identified in 2018; policies and procedures regarding record retention were reviewed but no errors, findings, or observations were identified in this area for 2021.

3.14.1 CMS Review Methodology

To evaluate compliance with these standards, CMS reviewed compliance plans submitted by QHP issuers.

3.14.2 Results

Table 14 lists findings or observations related to this review area.

Review Methodology	Findings or Observations	Findings Count	Observations Count	
Performance Testing	 No findings or observations were identified related to this review area. 	0	0	

Table 14: Compliance Plan Findings or Observations

3.14.3 Best Practices

• Create and regularly evaluate the compliance plan to help demonstrate that the organization has established procedures consistent with 45 CFR 155.1000 (c), including an overall process of remaining compliant with each regulation as well as providing punitive and corrective actions should they be required.

3.15 Casework

Pursuant to 45 CFR § 156.1010, a QHP issuer must:

- Investigate and resolve, as appropriate, consumer cases forwarded by HHS¹⁴;
- Resolve non-urgent cases (for cases forwarded by HHS) no later than 15 calendar days after receipt of the case, and urgent cases no later than 72 hours after the case is received;
- Provide notice¹⁵ to the complainant of the disposition of a case as soon as possible upon resolution of the case, but in no event later than 3 business days after the case is resolved; and
- Record resolution summaries in the HICS within 7 days of completion with a clear and concise explanation of the how the case was resolved.

3.15.1 CMS Review Methodology

CMS reviewed the casework documentation submitted by each QHP issuer for a sample of cases selected by CMS for review. The submitted documentation included internal HICS case notes, written case narratives and screenshots of the resolution page in HICS, and written case dispositions.

Each case record was tested to determine if 1) the QHP issuer resolved the complaint within the applicable non-urgent or urgent timeframe; 2) the complainant was notified verbally or in writing within 3 business days of the resolution; 3) for complainants notified of the resolution verbally, written notice

¹⁴ CMS records casework in the Health Insurance Casework System (HICS), a web application that CMS requires QHP issuers operating in FFEs to use for casework intake and resolution activities.

¹⁵ To meet this requirement, notification may be verbal or written as determined most appropriate by the QHP issuer. In instances where notification is verbal, then a written notification must be provided in a timely manner to the consumer.

was also provided in a timely manner¹⁶; 4) a clear and concise narrative of how the case was resolved and how and when the complainant was notified was documented in HICS; and 5) the resolution narrative was uploaded to the HICS system within 7 business days after resolution.

3.15.2 Results

Table 15 lists findings or observations related to this review area.

Review Methodology	Findings or Observations	Findings Count	Observations Count		
Performance Testing	 HICS case records did not include information about how and when the complainant was notified of the resolution. 	5	0		
	 Written notifications were not sent to consumers either within 3 business days or in a timely manner¹⁸ in cases where the initial notification was made verbally. 	8	0		
	 HICS written notifications were not provided to the complainant. 	4	0		
	 Urgent cases were not resolved within 72 hours of receipt of the case. 	7	0		
	 Non-urgent cases were not resolved within 15 calendar days of receipt of the case. 	7	0		
	 HICS resolution summary did not contain how and when the notification was sent to the complaint. 	6	0		
	 Duplicate case was not closed per CMS guidance. No reference to the newer Case ID was identified in the duplicate case resolution summary. 	0	1		
	 Date of Resolution was not completed in the HICS system. 	0	1		
	 HICS complaint resolution summaries were not entered within 7 business days after the resolution of the case. 	2	0		

Table 15: Casework Findings or Observations¹⁷

¹⁶ For purposes of these compliance reviews, "timely manner" was considered to be within 2 weeks of the verbal notification, barring exceptional circumstances.

¹⁷ A total of 35 findings recorded this area for 19 QHP issuers reviewed. Several findings had multiple elements contained within them resulting in the total represented in this chart.

¹⁸ See supra note 14.

3.15.3 Best Practices

• Regularly review casework processes to ensure cases are reviewed, researched, and resolved and to ensure that all proper documentation and notifications are made consistent with FFE regulations.

3.16 Patient Safety Standards

Pursuant to 45 CFR § 156.1110, a QHP issuer that contracts with a hospital with greater than 50 beds must verify that the hospital meets the following patient safety standards:

- Adoption of a mechanism for comprehensive person-centered hospital discharge to improve care coordination and health care quality for each patient and utilizes a patient safety evaluation system as defined in 42 CFR § 3.20 (i.e., has a current agreement or other information demonstrating a partnership with a Patient Safety Organization (PSO)); or
- Establishment of 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.

3.16.1 CMS Review Methodology

CMS reviewed the QHP issuer's policy or process to ensure that contracted hospitals with more than 50 beds meet the patient safety standards. If the QHP issuer does not have a policy or process, CMS analyzes the hospital service contract to identify how the hospital demonstrates it meets the required patient safety standards.

3.16.2 Results

Table 16 lists findings or observations related to this review area.

Review Methodology	Findings or Observations	Findings Count	Observations Count	
Process Review	 No findings or observations were identified related to this review area. 	0	0	

Table 16: Patient Safety Findings or Observations

3.16.1 Best Practices

• Verify the contracted hospital has a partnership with a Patient Safety Organization or has established an evidence-based initiative to improve health care quality.

3.17 Quality Rating System, Marketing Requirement

Pursuant to 45 CFR § 156.1120(c), a QHP issuer may reference the quality ratings for its QHPs in its marketing materials, in a manner specified by HHS. Pursuant to 45 CFR § 156.1125(c), a QHP issuer may reference the survey results for its QHPs in its marketing materials, in a manner specified by HHS. Pursuant to 45 CFR § 156.1125(d), a QHP issuer must annually submit data necessary to conduct the survey to its contracted Enrollee Satisfaction Survey (ESS) vendor on a timeline and in a standardized form and manner specified by HHS.

3.17.1 CMS Review Methodology

CMS reviewed the QHP issuer's website and other marketing materials to determine whether marketing materials reference QRS and QHP Enrollee Survey results.

3.17.2 Results

Table 17 lists findings or observations related to this review area.

Table 17: Quality Rating System, Marketing Requirement Findings or Observations

Review Methodology	Findings or Observations	Findings Count	Observations Count		
Performance Testing	 No findings or observations were identified related to this review area. 	0	0		

3.17.3 Best Practices

• Verify if a QHP issuer references quality ratings for its QHPs in its marketing materials in a manner specified by HHS.

4. CONCLUSION

FFE compliance reviews in PY 2021 were conducted for 19 QHP issuers representing 19 distinct parent companies in 14 FFE states. This included 16 individual medical issuers and 3 SADPs. All of the reviews were completed through desk reviews.

Review areas that frequently included findings or observations included:

- Ensuring accurate and up-to-date provider directory information as required by 45 CFR § 156.230(b)(2);
- Contract offers were not extended to Essential Community Providers (ECPs) and/or Indian Health Providers (IHPs) in good faith as required by 45 CFR § 156.235;
- Reviewing agreements with downstream and delegated entities to ensure their compliance with 45 CFR § 156.340(b);
- Completing HICS casework as required by 45 CFR § 156.1010, including recording outcomes and making appropriate notifications in a timely manner;
- Termination-of-coverage notices did not consistently meet the standards established by the FFE as required by 45 CFR § 156.270;

- Incident and breach reporting process is not consistent with the QHP Certification Agreement as required by 45 CFR § 156.265(c); and
- QHP renewal and/or discontinuation notifications did not meet Exchange requirements as required by 45 CFR § 156.1255.

The FFE compliance review process evolves annually to coincide with updates to regulations and guidance. Between 2017 and 2021, CMS modified the compliance review process to further increase the focus on testing operations and data rather than reviewing documented procedures. CMS also refined existing methodologies to ensure the process continues to provide data about QHP issuer compliance while remaining efficient. The insights gained from FFE compliance reviews will continue to inform future guidance and regulatory updates.

5. APPENDIX – Finding or Observation Count by Review Area and De-Identified QHP Issuer

De-identified QHP Issuer Information	Agent and Broker	Casework	Delegated Entity	Enrollment and Eligibility	Network Adequacy	Operations	Prescription Drug	Renewal & Discontinuan ce	Termination of Coverage	Transparency of Coverage	Grand Total
2021-1		1	1	1	2	1	1		1		8
2021-2					1				1		2
2021-3					1				1		2
2021-4	1	1	2	1	2			1	2		10
2021-5		5									5
2021-6	1	1	1	1	3	1	1		1	1	11
2021-7			1	1	1			1	1		5
2021-8	1	1	1	1	1	1		1	1	2	10
2021-9	1				2				1		4
2021-10		1	1		2						4
2021-11					1			1	1	1	4
2021-12		1	1	1	1			1	2		7
2021-13			1		2			1	1		5
2021-14		1	1	1	1			1	2		7
2021-15			1	1	1		1	1	2		7
2021-16	1	1	1		1			1	1		6
2021-17	1	1	1		2		1	1	1		8
2021-18	1	1	1	1			1	1	1		7
2021-19				1	1			1			3
Grand Total	7	15	14	10	25	3	5	12	20	4	115

The appendix above contains the actual count of each finding or observation recorded by review area and by de-identified QHP issuer. The information in this chart represents only those review areas for which there was an identified finding or observation recorded; the remaining areas have been excluded for readability and space constraints.