Qualified Health Plan Issuer Application Instructions

Plan Year 2025

Extracted section:
Section 2B: Interoperability

Section 2B: Interoperability

The instructions for this section apply to the following issuer type:

- QHP

See Appendix D for additional information.

1. Introduction

Per the Interoperability and Patient Access Final Rule published on May 1, 2020, applicable QHP issuers must comply with all provisions detailed in 45 *Code of Federal Regulations* (CFR) 156.221, which requires the implementation and maintenance of a patient access application programming interface (API) and related documentation by July 1, 2021.

These requirements only apply to issuers on the Federally-facilitated Exchanges (FFEs), including FFEs in states which conduct plan management activities. Issuers in State-based Exchanges on the Federal Platform, or that only offer stand-alone dental plans (SADPs), or plans in the Federally-facilitated Small Business Health Options Programs are not required to respond to these questions.

In the Interoperability section of MPMS, regulated issuers are required to provide responses to four questions related to the requirements detailed in the regulation. Each question relates to a specific component of the regulation (see Table 2B.1 for additional information). If an issuer answers "No" to any question, they must download and complete the Interoperability Justification Form to explain the root cause for non-compliance, the impact on enrollees, and plans to achieve compliance.

2. Data Requirements

To complete this section, the following are needed:

1. Information confirming issuer compliance with the requirements specified at 45 CFR 156.221(a) through (g) on which the issuer can base its answers to Questions 1–4.
2. A live URL that links to the required content specified at 45 CFR 156.221(d).
3. A live URL that links to the required content specified at 45 CFR 156.221(g).
4. Information about why the issuer is not compliant with the requirements specified at 45 CFR 156.221(a) through (g) if the issuer answers "No" to any of the Interoperability Questions.
5. Interoperability Justification Form. Only required if the issuer responds "No" to any of the Interoperability Questions.

3. Quick Reference

Key Changes for 2025
◆ Revised Correction Codes for the Interoperability URLs related to the accessibility and required content specified at 45 CFR 156.221(d) and 45 CFR 156.221(g).
◆ Issuers can provide only one URL in response to Question 3.
◆ Issuers can provide only one URL in response to Question 4.
◆ Issuers must use the updated Interoperability Justification Form if answering "No" to any question.

Tips for the Interoperability Section
◆ Verify that URLs for Questions 3 and 4 are active and link to the required content. ◆ Ensure that the content available via the URL submitted for Question 3 meets the requirements of 45 CFR 156.221(d). The presence of keywords is not sufficient to meet the regulatory requirements. ◆ Ensure that the content available via the URL submitted for Question 4 meets the requirements of 45 CFR 156.221(g). ◆ Provide URLs that link directly to the required content for Question 3 and Question 4. ◆ Verify that any links within the URLs submitted for Questions 3 and 4 are active if the issuer relies on those links to meet regulatory requirements. ◆ Check that special effort, such as a sign-in or registration, is not required to access the content specified in Question 3 and Question 4. ◆ Submit the Interoperability Justification Form if answering "No" to any question.

Additional Resources
◆ There are supporting documents for this section. ◆ There are no instructional videos for this section. ◆ There are no templates for this section.

4. Detailed Section Instructions

Issuers are required to answer four "Yes" or "No" questions in the Interoperability section related to key provisions of the Interoperability and Patient Access Rule (45 CFR 156.221). Figures 2B-1 through 2B-4 show each question displayed in the Marketplace Plan Management System (MPMS).

Question 3 and Question 4 require the issuer to provide a URL that links to content specified at 45 CFR 156.221(d) and 45 CFR 156.221(g), respectively. CMS assesses both the accessibility and the content of the submitted URLs against the regulatory requirements. Therefore, it is critical that issuers ensure that each URL submitted is active, otherwise CMS will not be able to assess issuer compliance and a correction code will be assigned. Additionally, issuers must provide URLs that do not require special effort to access—issuers may not require a sign in, registration, username, or password to access the URLs. Issuers should also ensure that any links to required content within the submitted URLs remain functional.

Issuers that respond "No" to any question will be automatically directed to the Justification submission screen (see Figure 2B-5). Issuers directed to the Justification submission screen must download and complete the Interoperability Justification Form, to provide the following details required by 45 CFR 156.221(h):

- The reasons why the issuer cannot reasonably satisfy all the 45 CFR 156.221 requirements for the upcoming plan year (the root cause).
- The impact of non-compliance upon issuer's enrollees.
- The current or proposed means of providing the required 45 CFR 156.221 health information to issuer's enrollees.
- Issuer's solutions and a timeline to achieve compliance with all the 45 CFR 156.221 requirements.

Information about each question and the Justification Form is included in Table 2B-1, along with links to the detailed regulatory requirements and supporting information to help the issuer complete the Interoperability section.

Table 2B-1. Descriptions of Required Components and Supporting Information for Interoperability Submission

Interoperability Component	Supporting Information
Question 1: Has the issuer fully implemented a secure API that both:	• A secure API and its necessary features are detailed in 45 CFR 156.221(a) and 45 CFR 156.221 (c).

Interoperability Component	Supporting Information
• Allows all enrollees to access their claims and encounter information through a third-party application of the enrollee's choice, and • Meets the standards of Health Level 7 [HL7] Fast Healthcare Interoperability Resources [FHIR] Release 4.0.1?	• Issuers are urged to refer to the "Best Practices for Payers and App Developers" document, which can be found in CMS' Interoperability Guidance. Issuers' use of this document is not required. The document provides valuable implementation and testing guidance for issuers building secure, standards-based APIs. The document is subject to change; issuers using the document should check regularly for any updates.
Question 2: Has the issuer ensured inclusion of all information detailed in 45 CFR 156.221 (b) in the content made accessible via the API?	Issuer's URL must include the following content: a. Data concerning adjudicated claims, including claims data for payment decisions that may be appealed, were appealed, or are being appealed, and provider remittances and enrollee cost sharing pertaining to such claims, no later than 1 business day after a claim is processed. b. Encounter data from capitated providers, no later than 1 business day after data concerning the encounter is received by the QHP issuer. c. Clinical data, including laboratory results, if the QHP issuer maintains any such data, no later than 1 business day after data is received by the issuer.
Question 3: Has the issuer published on an easily accessible website and/or through publicly accessible hyperlink(s) information to support third party application use of the API, as detailed in 45 CFR 156.221(d)?	The issuer must demonstrate compliance by making, at minimum, the following information available on their website: a. API syntax, function names, required and optional parameters and their data types, return variables and their types/structures, and exceptions and exception handling methods and their returns. b. The software components and configurations an application must use to successfully interact with the API and process its responses. c. All applicable technical requirements and attributes for an application to be registered with any authorization server deployed in conjunction with the API. Issuers can demonstrate compliance by linking directly to the required standards on an external website, for example ALL the following required API Interoperability Standards: • USCDI, at 45 CFR 170.213 • FHIR Release 4.0.1 • HL7 FHIR US Core IG STU 3.1.1 • HL7 SMART App Launch Framework IG 1.0.0 • OpenID Connect Core 1.0. Issuers can also link directly to the recommended Implementation Guides (IGs), which include the following: • CARIN for Blue Button IG Version STU 2.0.0 • Da Vinci PDex IG Version STU 2.0.0 • Da Vinci PDex U.S. Drug Formulary IG Version STU 2.0.1. If the issuer chooses to link directly to a required standard or IG to demonstrate compliance with the interoperability requirements, the issuer must ensure that link remains active and points to the required content. More information about the required standards and recommended IGs is available here.

Interoperability Component	Supporting Information
Question 4: Has the issuer published educational resources about health information privacy and security, including the information detailed in 45 CFR 156.221(g), on a website easily accessible to enrollees?	Issuer's website's content must include educational resources about health information privacy and security, explaining at a minimum: 1. General information on steps the individual may consider taking to help protect the privacy and security of their health information, including factors to consider in selecting an application including secondary uses of data, and the importance of understanding the security and privacy practices of any application to which they entrust their health information; and 2. An overview of which types of organizations or individuals are and are not likely to be Health Insurance Portability and Accountability Act (HIPAA)–covered entities, the oversight responsibilities of the Office for Civil Rights and the Federal Trade Commission, and how to submit a complaint to the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) and the Federal Trade Commission (FTC) as described in 45 CFR 156.221. Issuers are urged to refer to the "Best Practices for Payers and App Developers" document, which can be found in CMS' Interoperability Guidance. Issuers' use of this document is not required. The document provides valuable implementation and testing guidance for issuers building secure, standards-based APIs. The document is subject to change; issuers using the document should check regularly for any updates.
Interoperability Justification Form	Issuers that answered "No" to any of the four Interoperability Questions must download the Interoperability Justification Form, complete the form in its entirety and upload it through MPMS to satisfy the requirements of 45 CFR 156.221(h).

Figures 2B-1 through 2B-6 display the Interoperability Questions and Justification Form.

Figure 2B-1. Interoperability Question 1

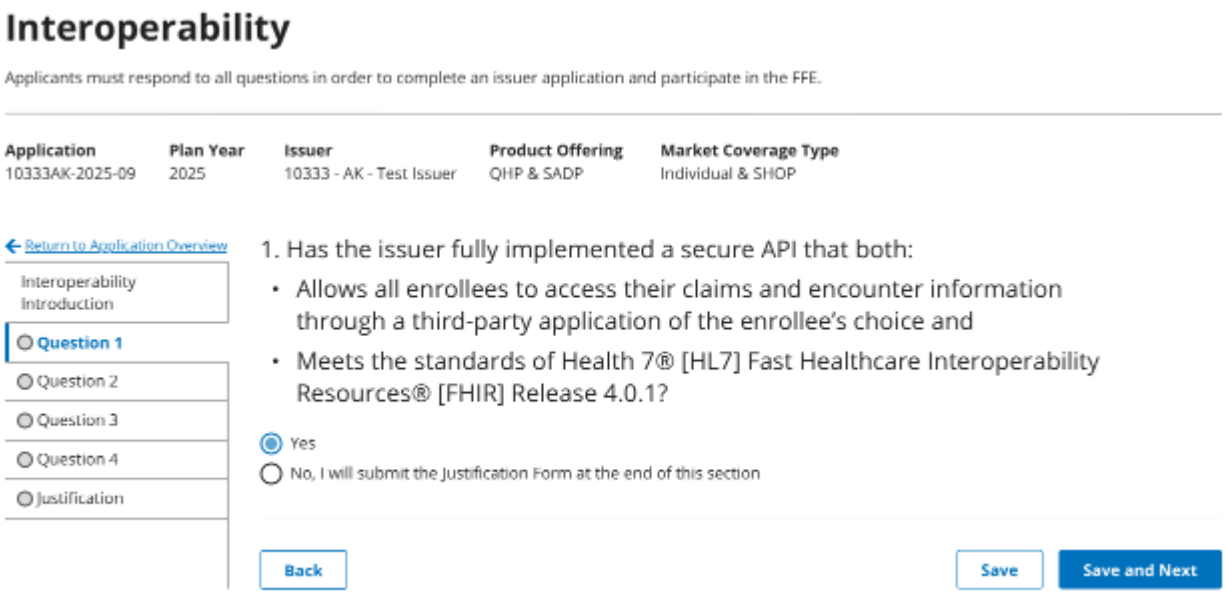


Figure 2B-2. Interoperability Question 2

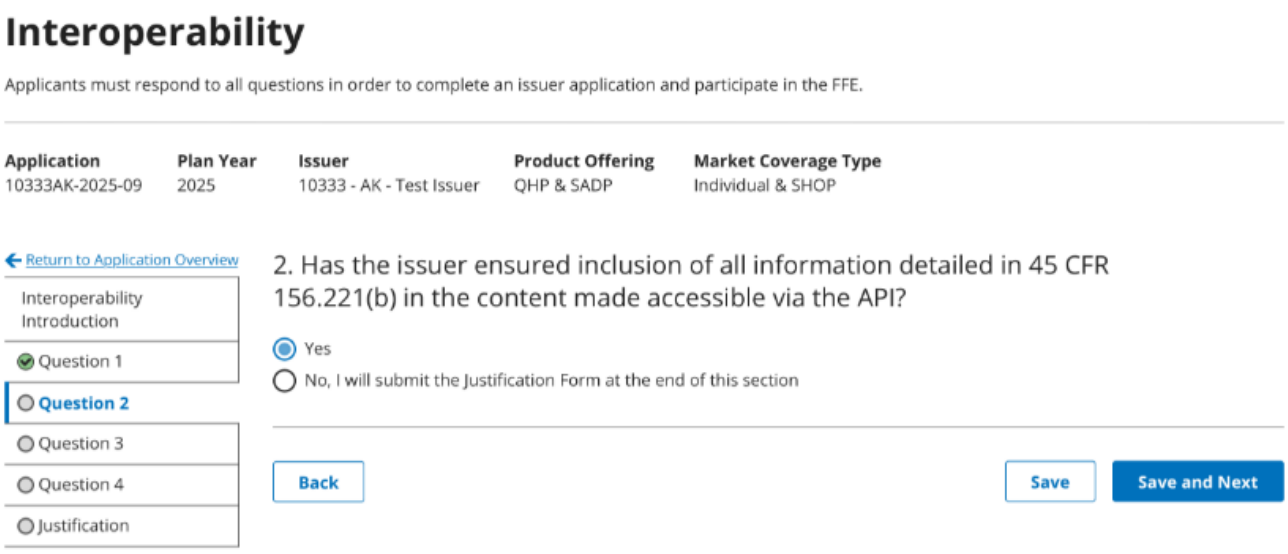


Figure 2B-3. Interoperability Question 3

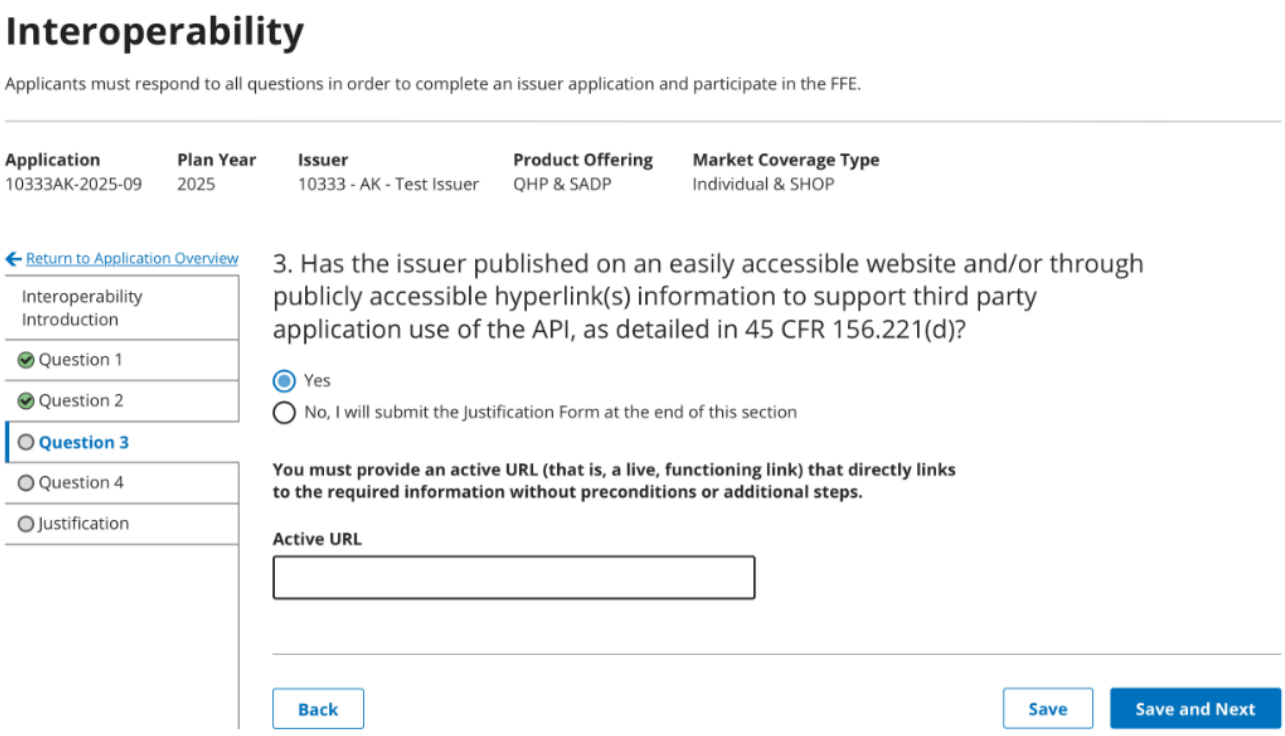


Figure 2B-4. Interoperability Question 4

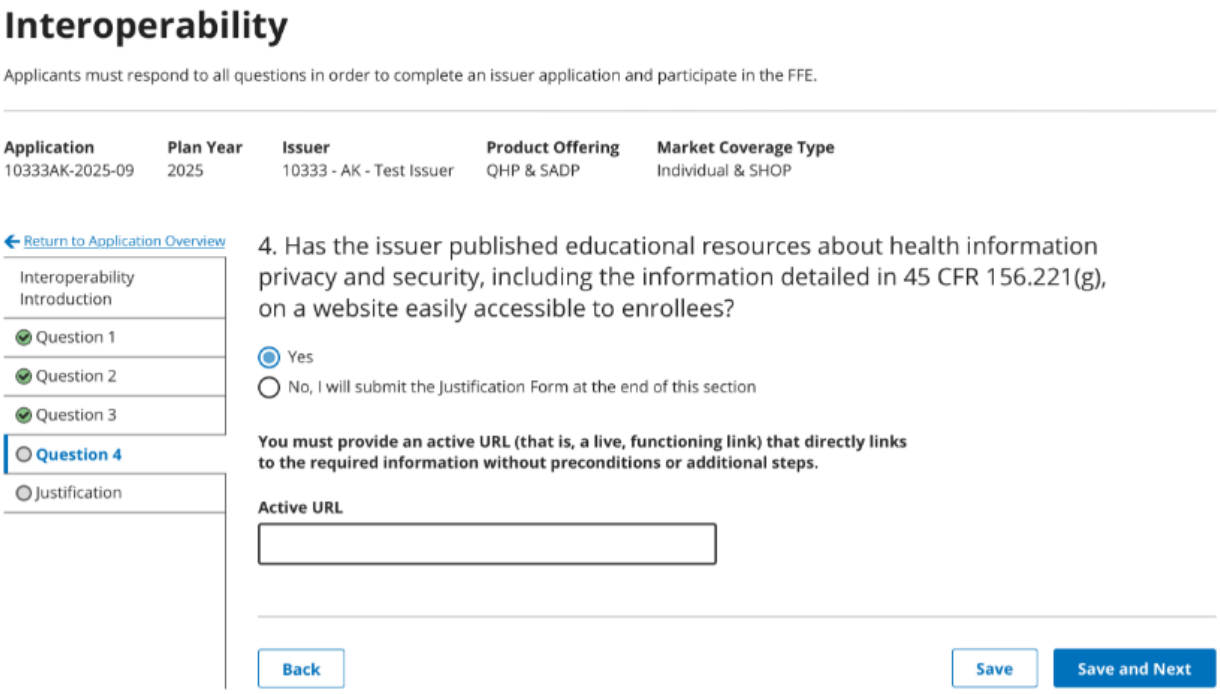
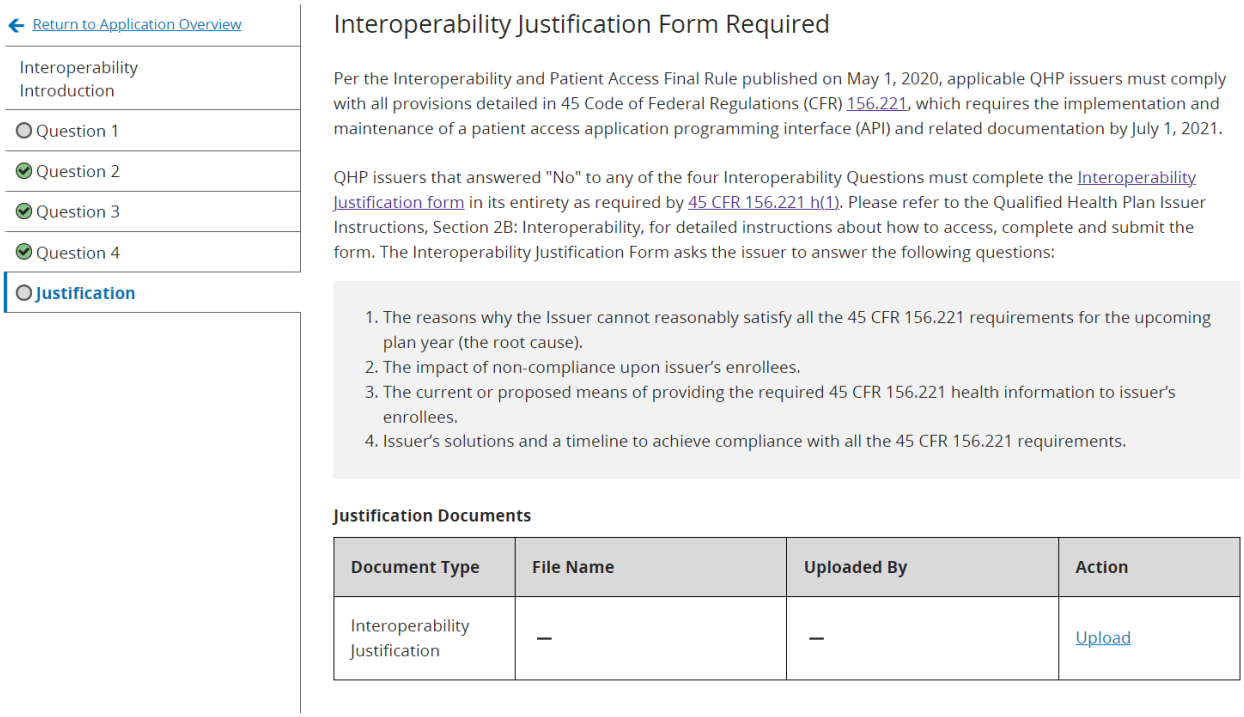


Figure 2B-5. Interoperability Justification Form Submission



Issuers can download the Interoperability Justification Form (Figure 2B-6) from the Interoperability page of the QHP certification website.

Figure 2B-6. Interoperability Justification Form

Interoperability Justification

Issuers must fill in the following Information.

Issuer Name:

HIOS ID:

Instructions: Per the Interoperability and Patient Access Final Rule published on May 1, 2020, applicable QHP issuers must comply with all provisions detailed in 45 *Code of Federal Regulations* (CFR) 156.221, which require the implementation and maintenance of a patient access application programming interface (API) and related documentation by July 1, 2021.

This form is not required for QHP issuers:

- Meeting the requirements above, by having answered "Yes" to all four Interoperability Questions in the Marketplace Plan Management System (MPMS).
- In State-based Exchanges on the Federal Platform.
- Offering only Stand-Alone Dental Plans.
- Only offering plans in the Federally-facilitated Small Business Health Options Program.

QHP issuers that answered "No" to any of the four Interoperability Questions in MPMS must complete the Interoperability Justification form in its entirety as required by 45 CFR 156.221 h(1) and upload it through MPMS. Please refer to the Qualified Health Plan Issuer Instructions, Section 2B: Interoperability, for detailed instructions about how to upload the form.

1. The reasons why the Issuer cannot reasonably satisfy all the 45 CFR 156.221 requirements for the upcoming plan year (the root cause).
2. The impact of non-compliance upon issuer's enrollees.

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3. The current or proposed means of providing the required 45 CFR 156.221 health information to issuer's enrollees.
4. Issuer's solutions and a timeline to achieve compliance with all the 45 CFR 156.221 requirements.

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This concludes the Interoperability section of the QHP Application Instructions.