



---

**January 28, 2019**

**Frequently Asked Questions (FAQs) Regarding Participation Requirements for Enhanced Direct Enrollment (EDE) Entities Serving Consumers in States with Federally-facilitated Exchanges (FFE)**

The following FAQs detail the requirements and submission timeline for prospective EDE Entities that plan to use the EDE pathway in calendar year 2019 for plan years (PYs) 2019 and 2020 to offer and enroll consumers in qualified health plans (QHPs) through the FFEs and state-based Exchanges on the Federal Platform (SBE-FPs). The Centers for Medicare & Medicaid Services (CMS) will release further guidance on program and audit submission requirements prior to the audit submission window described below.

**1. When can prospective EDE Entities pursue EDE for calendar year 2019?**

CMS is continuing to implement EDE, an optional program allowing EDE Entities (QHP issuers and web-brokers may seek to participate in EDE) in the FFEs and SBE-FPs (also known as the Marketplace) to host an application for Marketplace coverage on their own websites. For a summary of the EDE program, please refer to this FAQ document, [Frequently Asked Questions \(FAQs\) for Enhanced Direct Enrollment](#). For more information on basic EDE program requirements and details, refer to the [Third-party Auditor Operational Readiness Reviews for the Enhanced Direct Enrollment Pathway and Related Oversight Requirements](#).

To pursue EDE, prospective EDE Entities must build their EDE environments and submit audits consisting of two parts (a Business Requirements Audit and a Privacy and Security Audit) within the submission windows established by CMS.

The primary audit submission window for prospective EDE Entities interested in implementing EDE in calendar year 2019 for PY 2019 and 2020 is April 1, 2019 to June 30, 2019.<sup>1</sup> CMS will not accept audits outside of this submission window. There is no guarantee that every prospective EDE Entity that submits a complete audit in the submission window will receive approval unless and until the Entity meets all program requirements. CMS will release future guidance about the next annual audit submission window after the PY 2020 open enrollment period (OEP).

**Note:** If a prospective EDE Entity submits an audit and resubmits it before hearing from CMS about its original submission, CMS will only consider the date of the latest submission for purposes of determining review priority. CMS will conduct an initial high-level review of each audit to evaluate the quality and completeness of the audit.

---

<sup>1</sup> A preliminary audit submission window is in effect from December 15, 2018 to January 31, 2019 for those prospective EDE Entities that had substantially completed development of their EDE environments and their related audits in calendar year 2018.

### April 1, 2019 to June 30, 2019 Audit Submission Window and Notice of Intent

If a prospective EDE Entity intends to submit its audit during the April 1, 2019 to June 30, 2019 submission window, it must send its notice of intent to [directenrollment@cms.hhs.gov](mailto:directenrollment@cms.hhs.gov) by February 15, 2019. Once the prospective EDE Entity has a confirmed Auditor(s) who will complete its audit(s), the Entity must notify CMS that it intends to use the EDE pathway for PY 2019 and PY 2020 prior to initiating the audit. CMS is only requesting notices of intent from prospective primary EDE Entities (defined below) developing an EDE environment, contrary to last year; prospective upstream EDE Entities should notify CMS of their intent to participate in EDE when or after their prospective primary EDE Entity submits its audit. The subject line of a notice of intent email must read “Enhanced DE: Intent” and the information below must be included in the body of the email:

- Prospective EDE Entity Name;
- Auditor Name(s) and Contact Information (Business Requirements and Privacy and Security, if different);
- EDE Phase (1, 2, or 3);
- Prospective EDE Entity Primary Point of Contact (POC) name, email, and phone number;
- Prospective EDE Entity Technical POC name, email, and phone number;
- Prospective EDE Entity Emergency POC name, email, and phone number; and
- CMS-issued Hub Partner ID.

CMS will conduct an initial high-level review of all audit submissions in the order they are received and based on available resources. If a prospective EDE Entity submits an incomplete audit, CMS will communicate the missing elements to the Entity based on the initial high-level review, and the audit will not enter the review queue. Once the prospective EDE Entity resubmits a complete audit, CMS will consider that resubmitted audit to be at the end of the review queue based on the date of submission. CMS does not guarantee any approval timelines.

### Upcoming Guidance and Program Materials

CMS expects to issue updated requirements, trainings (required for both Auditors and representatives of prospective EDE Entities), agreements, and baseline toolkits for the April 1, 2019 to June 30, 2019 submission window in early 2019. CMS expects to primarily use the same content and requirements as in the materials released in 2018 for PY 2019. Accordingly, prospective EDE Entities can begin developing their EDE environments based on the existing toolkits and privacy and security documentation that are located on [CMS zONE](#).<sup>2</sup> Prospective EDE Entities should also refer to the initial EDE guidelines that were released in 2018 for PY 2019 until new guidelines are released.<sup>3</sup>

---

<sup>2</sup> Note that prospective EDE Entities must set up a CMS Enterprise Portal account and request zONE access to view the zONE website. Prospective EDE Entities must share all EDE audit resources with their Auditors; CMS zONE site access is restricted to prospective and approved EDE Entities (participating web-brokers and issuers) only.

<sup>3</sup> *Third-party Auditor Operational Readiness Reviews for the Enhanced Direct Enrollment Pathway and Related Oversight Requirements* (February 21, 2018): <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Third-party-Direct-Requirements.pdf>

CMS will separately provide further information about requirements for EDE Entities that were approved to use EDE for PY 2019 prior to the April 1, 2019 to June 30, 2019 submission window.

**2. What constitutes a complete Business Requirements Audit?**

CMS will review each audit submission for completeness. CMS will not accept incomplete audits.

A complete business requirements audit submission meets the following criteria, at a minimum:

Toolkit & Template	Minimum Requirements for a Complete Audit
<u>All Toolkits</u>	<ul style="list-style-type: none"> <li>▪ Complete Auditor documentation (i.e., columns indicated for Auditor results) with no ambiguous language about the audit process or potential unmitigated risks</li> <li>▪ All required rows of all toolkits are completed</li> <li>▪ Risks identified during the course of the audit must be documented</li> </ul>
<u>Communications Toolkit</u>	<ul style="list-style-type: none"> <li>▪ Screenshots that demonstrate compliance (in English and Spanish, if applicable) with the requirements in rows 2, 3, 7, and 17 under the Requirements tab in the Toolkit</li> </ul>
<u>Application User Interface (UI) Toolkit</u>	<ul style="list-style-type: none"> <li>▪ Clear and adequate assessment of the Spanish-language application, if applicable</li> <li>▪ <i>Note: The Application UI Toolkit must be reviewed in full. The Eligibility Results Test Cases do not cover all questions in the Application UI Toolkit</i></li> </ul>
<u>Eligibility Results Toolkit(s)</u>	<ul style="list-style-type: none"> <li>▪ Screenshots of the entire application flow for each test case</li> <li>▪ Correct eligibility results and eligibility determination notices (EDNs) for each test case</li> </ul>
<u>Application Program Interface (API) Functional Integration Toolkit</u>	<ul style="list-style-type: none"> <li>▪ Correct results and successful completion of each test case</li> </ul>
<u>EDE Business Audit Report Template</u>	<ul style="list-style-type: none"> <li>▪ Complete descriptions of each requirement; Auditors must not exclude key aspects of each requirement</li> </ul>
<u>Supplemental Documentation</u>	<ul style="list-style-type: none"> <li>▪ CMS will not review supplemental documentation that CMS has not requested</li> <li>▪ Auditors and prospective EDE Entities must not provide unrequested, supplemental documentation to communicate risks that are not otherwise appropriately documented in the Business Audit Report Template or Toolkits</li> </ul>

An incomplete business requirements audit does not meet the completeness criteria described above. The Auditor must complete incomplete audits in accordance with the standards described above. CMS will require that incomplete audits be resubmitted in their entirety and will prioritize its review of these resubmitted audits based on the date the complete audit is submitted.

Business requirements audits should not include comments that describe the Auditor’s process for verifying the requirement unless there is a specific issue or concern regarding the requirement that warrants raising a concern.

**3. What constitutes a complete Privacy and Security Audit?**

CMS will review each audit submission for completeness. CMS will not accept incomplete audits.

A complete privacy and security audit submission meets the following criteria, at a minimum:

Document	Minimum Requirements for a Complete Audit
<p><u><i>Security Assessment Report (SAR)</i></u></p>	<ul style="list-style-type: none"> <li>▪ The SAR is not a living document; findings should not be added/removed unless CMS's initial review of the final draft discovers deficiencies or inaccuracies that need to be addressed</li> <li>▪ The SAR should contain a summary of findings that includes ALL findings from the assessment to include documentation reviews, control testing, scanning, penetration testing, interview(s), etc.</li> <li>▪ Explain if and how findings are consolidated</li> <li>▪ Ensure risk level determination is properly calculated, especially when weaknesses are identified as part of the Center for Internet Security (CIS) Top 20 and/or Open Web Application Security Project (OWASP) Top 10</li> <li>▪ Only one final SAR should be submitted to CMS. Once the SAR has been submitted and CMS has no additional comments or edits on the SAR, the prospective EDE Entity should not submit additional SARs</li> </ul>
<p><u><i>Plan of Action and Milestones (POA&amp;M)</i></u></p>	<ul style="list-style-type: none"> <li>▪ Ensure all open findings from the SAR have been incorporated into the POA&amp;M</li> <li>▪ Explain if and how findings from the SAR were consolidated on the POA&amp;M; include SAR reference numbers, if applicable</li> <li>▪ Ensure the weakness source references each source in detail to include type of audit/assessment and applicable date range</li> <li>▪ Ensure the weakness description is as detailed as possible to include location/server/etc., if applicable</li> <li>▪ Monthly reviews and updates are REQUIRED until all the findings are resolved based on the findings from security controls assessments, security impact analyses, and continuous monitoring activities described in the EDE SSP controls CA-5 and CA-7. EDE Entities can schedule their own time for monthly submissions of the POA&amp;M, but must submit an update monthly</li> </ul>

An incomplete privacy and security audit does not meet the completeness criteria described above. The Auditor must complete incomplete audits in accordance with the standards described above. CMS will require that incomplete audits be resubmitted in their entirety and will prioritize its review of these resubmitted audits based on the date the complete audit is submitted.

#### 4. How can prospective EDE Entities implement EDE for calendar year 2019?

Prospective EDE Entities have two main options to consider in determining how and to what extent to pursue participation in EDE during calendar year 2019:

- Participate as a primary EDE Entity that has developed its own EDE environment and contracted with an Auditor to audit the environment,<sup>4</sup> or
- Participate as an upstream EDE Entity partner of an approved primary EDE Entity, which may not require an independent audit of the upstream entity's systems (i.e.,

<sup>4</sup> CMS is offering prospective EDE Entities three phases for hosting applications using the EDE pathway. A prospective EDE Entity may choose to implement Phase 1, 2, or 3 for the PY 2019 and PY 2020. For additional information on basic EDE program requirements and details, please refer to the *Third-party Auditor Operational Readiness Reviews for the Enhanced Direct Enrollment Pathway and Related Oversight Requirements* (February 21, 2018): <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Third-party-Direct-Requirements.pdf>

primary EDE Entities may provide an EDE environment to another entity [e.g., an issuer or web-broker]).

All upstream EDE Entities must have a legal relationship with a primary EDE Entity. The list of EDE Entities (both primary and upstream) that are approved to use the EDE pathway is available [here](#).<sup>5</sup> CMS will release more information about upstream EDE Entities prior to the audit submission window. Prospective EDE Entities that are interested in learning more about upstream partnerships (either participating as a primary EDE Entity partnering with upstream EDE Entities or as an upstream EDE Entity) are encouraged to review the forthcoming guidance.

---

<sup>5</sup> This list is updated frequently, but it may not immediately reflect EDE Entities most recently approved to use the EDE pathway.