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## I. Summary

The Centers for Medicare & Medicaid Services (CMS) is continuing to implement Enhanced Direct Enrollment (EDE), an optional program allowing approved EDE Entities<sup>1</sup> (e.g., Qualified Health Plan [QHP] issuers and web-brokers<sup>2</sup> approved to participate in EDE) registered with or utilizing the Federally-facilitated Exchange (FFE, also known as the Marketplace) and State-based Exchanges on the Federal Platform (SBE-FPs), to host an application for Exchange<sup>3</sup> coverage on their own websites. Participation in EDE requires integration with a suite of Exchange application programming interfaces (APIs). The APIs allow EDE Entities approved to participate in EDE to create, modify, submit, and retrieve Exchange data.

Based on the EDE implementation experience for the plan year (PY) 2020 open enrollment period (OEP), CMS is revising EDE program requirements for the remainder of PY 2020 and PY 2021, including the PY 2021 Open Enrollment Period, hereinafter referred to as Year 3 of EDE, effective on the publication date of these Guidelines. This set of Guidelines outlines EDE program and audit requirements that apply to Year 3 of EDE.

CMS offers an annual audit submission window when prospective<sup>4</sup> primary EDE Entities<sup>5</sup> may submit audits to apply for EDE participation or seek to change phases. Prospective primary EDE Entities are entities that are seeking approval to use their EDE environments for the first time and EDE Entities already approved to use the EDE pathway that are seeking to implement a new eligibility application phase (see Section XI, Processes for Changes to an Audited or Approved EDE Environment, for more information).

The audit submission window for prospective primary EDE Entities interested in implementing EDE or changing phases during Year 3 of EDE is from April 1, 2020 to June 30, 2020 at 3:00 AM ET. As detailed further in Section X.C, Completeness Requirements, CMS will conduct

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<sup>1</sup> References to “EDE Entity” or “EDE Entities” throughout these guidelines may apply to DE technology providers or other entities providing technology services on behalf of issuers or web-brokers to enable their participation in EDE if those entities are developing and/or maintaining an issuer’s or web-broker’s EDE technology platform. A DE technology provider, as defined in 45 C.F.R. § 155.20, means “a type of web-broker business entity that is not a licensed agent, broker, or producer under State law and has been engaged or created by, or is owned by an agent or broker, to provide technology services to facilitate participation in direct enrollment under [45 C.F.R.] §§ 155.220(c)(3) and 155.221.”

<sup>2</sup> The term “web-broker” is defined in 45 C.F.R. § 155.20 as “an individual agent or broker, group of agents or brokers, or business entity registered with an Exchange under §155.220(d)(1) that develops and hosts a non-Exchange website that interfaces with an Exchange to assist consumers with direct enrollment in qualified health plans offered through the Exchange as described in §§155.220(c)(3) and 155.221. The term also includes a direct enrollment technology provider.”

<sup>3</sup> Exchange has the meaning set forth in 45 C.F.R. § 155.20. However, the EDE program does not extend to State-based Exchanges (SBEs) or Small Business Health Options Program (SHOP) marketplaces. Therefore, as used in these Guidelines, the term “Exchange” does not include SBEs that do not rely on the Federal Platform or SHOP marketplaces.

<sup>4</sup> Prospective EDE Entity means an entity that has not received approval from CMS to use the EDE pathway or an existing EDE Entity that intends to submit a business requirements audit to receive CMS approval for an end-state eligibility application phase change (as detailed in Section XI.A, EDE Entity-initiated EDE Phase Change Requests), and therefore is prospective with respect to the new phase for which it is seeking approval.

<sup>5</sup> Primary EDE Entities and Upstream EDE Entities are described in more detail in Section IV.B, Providing an EDE Environment to Other Entities.

completeness reviews on all prospective primary EDE Entity audits submitted within the applicable submission window, however the Entity's opportunities to correct completeness deficiencies depends, in part, on when it submits its audit in the audit submission window. CMS will not review audits until the submission window begins. There is no guarantee that every prospective primary EDE Entity that submits a complete audit within the submission window will receive approval prior to the 2021 OEP or during the 2020 calendar year. CMS strongly encourages EDE Entities to submit complete audits as early as possible within the audit submission window. Please review Section X.B, Audit Submission Deadlines, for more detailed information on completeness reviews during the audit submission window. To aid in expediting the approval process, an upstream EDE Entity<sup>6</sup> should work with its primary EDE Entity to notify CMS of the proposed arrangement and submit the operational and oversight documentation to CMS for review.<sup>7</sup> Based on the documentation provided to CMS, CMS will determine if any additional audit requirements must be met prior to the upstream EDE Entity receiving approval. This approval will only occur with or after the primary EDE Entity's approval.

Developing and auditing an EDE environment may take considerable effort and time (e.g., it may take up to or more than a year). Once an Entity submits a complete audit, the approval process typically involves multiple resubmissions on behalf of the Entity. Resubmissions may stem from compliance findings in the audit submission and resubmissions, and issues and findings in the EDE environment and eligibility application. The number of resubmissions and back-and-forth communication also depends on how thoroughly and quickly Entities address issues and findings. Therefore, the EDE approval process typically takes several months, and may take up to a year depending on the selected end-state phase, the quality of the build of the EDE environment, the quality of the audit and documentation submitted to CMS, and the quality and timeliness of resubmissions. Based on CMS's experience with prior audits, prospective EDE Entities that submit complete audits later in the audit submission window (i.e., mid-to-late May through June), depending on the quality of the submission and phase (among other factors), have a low probability of going live before the OEP. No prospective EDE Entity will be approved unless and until the Entity meets all program requirements. CMS will not review audits received after June 30, 2020. CMS will release future guidance about the next annual audit submission window.

## **II. Background**

When using the EDE pathway, a primary EDE Entity will provide a full application,<sup>8</sup> enrollment, and post-enrollment support experience on its website, and must implement the full EDE API suite of required services, regardless of the EDE Entity's chosen application phase.<sup>9</sup> This suite of required services includes: Store ID Proofing, Person Search, Create App, Create App from Prior Year App, Store Permission, Revoke Permission, Get App, Add Member, Remove Member,

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<sup>6</sup> Upstream EDE Entities are described in more detail in Section IV.B, Providing an EDE Environment to Other Entities.

<sup>7</sup> Please refer to Section VI.A.i, Required Business Requirements Audit Documentation, for more information.

<sup>8</sup> An EDE Entity's EDE environment and application may not support all applicant eligibility scenarios or application changes depending on the EDE Entity's chosen phase, as described below in Section IV.A, Application Phase Options.

<sup>9</sup> Please refer to Section IV.A, Application Phase Options.

Update App, Delete App, Submit App, Get Data Matching Issue (DMI), Get Special Enrollment Period Verification Issue (SVI), Metadata Search, Notice Retrieval, Submit Enrollment, Document Upload, System and State Reference Data, Get Enrollment, and Payment Redirect.<sup>10</sup> This list excludes optional APIs.

The EDE Entity will be able to transfer information directly between its application and the Exchange by integrating its unique user interface (UI) with the EDE API suite. CMS will continue to be responsible for determining each consumer's eligibility and issuing Eligibility Determination Notices (EDNs).

CMS aims to foster a better consumer experience with the EDE pathway. EDE Entities and CMS will accomplish this objective by providing consumers in FFE and SBE-FP states with additional methods to shop and apply for Exchange individual market coverage and by allowing consumers to work with an EDE Entity to enroll in an individual market QHP without requiring consumers to log on to HealthCare.gov. Using the API suite, EDE Entities can innovate and implement improvements to the application and enrollment process. The EDE API suite will provide an EDE Entity with the data and tools necessary to fully manage customer relationships, including the ability to update applications and enrollments when necessary, as well as to assist consumers with various post-enrollment activities such as remedying open consumer DMIs/SVIs and payment issues. CMS anticipates the EDE pathway will result in increased effectuation rates.

These Guidelines define EDE program audit requirements, and discuss requirements and considerations for prospective EDE Entities' selection of an Auditor, as well as the scope of the operational readiness review (ORR) prospective EDE Entities must undertake to demonstrate they are prepared to provide EDE services through use of the EDE pathway.

To pursue EDE, prospective primary 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 window established by CMS.<sup>11</sup> Each prospective primary EDE Entity must engage one or more independent Auditors to perform these audits and certify that the Entity's website(s) and operations comply with the program requirements listed in Exhibit 2 (Business Requirements) and Exhibit 4 (Privacy and Security Requirements) or in Exhibit 10 (Business Audit Phase Change Requirements) of these Guidelines prior to CMS approving the Entity to use the EDE pathway or to change application phases (detailed further in Section XI.A, EDE Entity-initiated EDE Phase Change Requests). In addition, there may be audit submission requirements for certain upstream EDE Entities. See IV.B.iv, Privacy and Security Audit Requirements for Hybrid, Non-issuer Upstream EDE Entities, for more information.

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<sup>10</sup> CMS may release additional required or optional APIs during 2020. If CMS releases a required API, the change will be considered a CMS-initiated Change Request. Please refer to Section XI.B, CMS-initiated Change Requests for more information.

<sup>11</sup> For more information on the audit requirements for prospective primary EDE Entities, see the discussion of the Business Requirements Audit and Privacy and Security Audit Requirements in Sections VI, Business Audit Requirements and Scope, VII, Privacy and Security Audit Requirements and Scope, and XI.A, EDE Entity-initiated EDE Phase Change Requests. Additionally, there are separate audit requirements for some entities that are not primary EDE Entities (i.e., Hybrid, Non-issuer Upstream EDE Entities). For more information, please refer to Section IV.B., Providing an EDE Environment to Other Entities, and its subsections. Also see <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/EDE-2019-Non-Issuer-FAQ.pdf>.

The ORR process and CMS approval are necessary because of the effects an EDE Entity's processes may have on the HealthCare.gov information technology (IT) platform and consumers' eligibility applications.

CMS will conduct ongoing oversight of each EDE Entity in a manner consistent with that provided in previous plan years, including regular oversight of the Entity's applications in its production and testing environments for completeness and accuracy. Entities must ensure that testing environments used for CMS testing are secured with user access credentials. Consistent with the application requirements detailed in this document and the EDE Business Agreement, CMS requires each prospective and approved primary EDE Entity to maintain a testing environment that accurately represents its EDE production environment and integration with the EDE pathway, including functional use of all EDE APIs. The environment must reflect the EDE end-user experience.<sup>12</sup> This may require an Entity to develop a third environment for developing and testing new, unapproved changes. For more information on EDE Entity-initiated Change Requests, please refer to Section XI.C, Other EDE Entity-initiated Change Requests.

#### **A. Authority**

Pursuant to 45 C.F.R. §§ 155.220(c)(3)(ii), 155.221, 155.260, 156.265(b), and 156.1230, an EDE Entity must comply with applicable requirements, including demonstrating operational readiness to use the EDE pathway. Pursuant to 45 C.F.R. § 155.221(d), the Department of Health & Human Services (HHS) may immediately suspend the EDE Entity's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations, or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS' satisfaction.<sup>13</sup>

Pursuant to 45 C.F.R. § 155.221(e)-(g), a prospective primary EDE Entity must retain one or more independent third-party Auditors to perform an ORR to validate compliance with EDE program requirements (see Section V, Selection of an Auditor, for details pertaining to the selection of an Auditor). The prospective primary EDE Entity will identify the Auditor(s) it has selected for verifying program compliance in each of the two agreements the Entity must sign with CMS: an EDE Business Agreement, which sets forth consumer communication and operational requirements, and an Interconnection Security Agreement (ISA), which sets forth privacy and security requirements.<sup>14</sup> In addition, an existing primary EDE Entity that wants to change phases or add functionality or systems to its EDE environment must follow the processes for EDE Entity-initiated changes as detailed in Section XI, Processes for Changes to an Audited or Approved EDE Environment.

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<sup>12</sup> Please refer to Section IV.B, Providing an EDE Environment to Other Entities, for more information.

<sup>13</sup> Also see 45 C.F.R. § 155.220(k)(3).

<sup>14</sup> Generally, unless specifically indicated otherwise, references to the EDE Business Agreement or the ISA refer to the current, legally enforceable version of each agreement. As of the release of these Guidelines, CMS has released the PY2020 versions of both Agreements, which will remain in effect until October 31, 2020. The EDE Business Agreement and ISA are available on CMS zONE at the following link: <https://zone.cms.gov/document/enhanced-direct-enrollment>.

A primary EDE Entity may provide its approved EDE environment to upstream EDE Entities for use. Upstream EDE Entities that want to add functionality or systems to their respective primary EDE Entity's approved EDE environment beyond minor branding changes or QHP display changes<sup>15</sup> may also be required to complete an ORR that includes a privacy and security audit conducted by an independent, third-party Auditor.<sup>16</sup>

CMS considers Auditors to be downstream and delegated entities of the EDE Entity in accordance with 45 C.F.R. § 155.221(e). The EDE Entity is therefore responsible for its Auditor(s)'s performance and compliance with applicable EDE program requirements.

### **III. Information for Existing EDE Entities and Certain Prospective EDE Entities**

#### **A. EDE Entities That CMS Approved to Use the EDE Pathway**

For existing EDE Entities that are not changing their EDE phase for Year 3 of EDE or otherwise seeking to add new functionality or systems to their approved EDE environment, CMS aims to mitigate the burden of the audit renewal process.

##### *i. Business Requirements Audit*

Primary EDE Entities pursuing a different EDE phase from the phase CMS initially approved should refer to Section XI.A, EDE Entity-initiated EDE Phase Change Requests, for the requirements and process to implement an EDE Entity-initiated phase change request (CR). A primary EDE Entity that wants to add functionality or systems to an approved EDE environment should refer to Section XI.C, Other EDE Entity-initiated Change Requests for applicable requirements and processes. Existing EDE Entities that are not pursuing a different EDE phase or otherwise seeking to add functionality or systems to their approved EDE environment do not need to contract with an Auditor to conduct and submit a new business requirements audit. But, existing EDE Entities may need to implement CMS-initiated CRs as described in Section XI.B, CMS-initiated Change Requests, of these Guidelines.

##### *ii. Privacy and Security Audit*

Existing EDE Entities must adhere to the continuous monitoring reporting requirements in the *Information Security and Privacy Continuous Monitoring (ISCM) Strategy Guide* (ISCM Strategy Guide), which includes the completion of an annual assessment of security and privacy controls by an Auditor, as described in the ISCM Strategy Guide. A primary EDE Entity that intends to add functionality or systems to an approved EDE environment should refer to Section XI.C, Other EDE Entity-initiated Change Requests for applicable requirements and processes, which may include conducting a supplemental privacy and security audit.

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<sup>15</sup> QHP display changes are limited to issuer upstream EDE Entities. Please refer to Section IV.B, Providing an EDE Environment to Other Entities, for more information.

<sup>16</sup> Please refer to Section IV.B, Providing an EDE Environment to Other Entities, for more information. Additionally, refer to <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/EDE-2019-Non-Issuer-FAQ.pdf>.

*iii. Annual Agreement and Operational and Oversight Information Collection*

Annually, prior to the OEP, CMS will contact existing EDE Entities and prospective EDE Entities that have submitted audits to submit the EDE Business Agreement, the ISA (for primary EDE Entities only), and operational and oversight information.<sup>17</sup>

***B. EDE Entities That Have Completed Their Audits, But That CMS Has Not Approved***

*i. Business Requirements Audit*

For a prospective EDE Entity that has not been approved for PY 2020, but has submitted a complete business requirements audit prior to the release of these Guidelines and entered the audit queue, CMS will allow such a prospective EDE Entity to use its previously submitted and complete EDE Business Audit assuming it continues to seek approval for the phase indicated in its initial audit submission, and it does not otherwise seek to add new functionality or systems to its EDE environment prior to approval. A prospective primary EDE Entity that intends to add functionality or systems to an audited EDE environment should refer to Section XI.C, Other EDE Entity-initiated Change Requests for applicable requirements and processes, which may include conducting a supplemental audit. The prospective EDE Entity must implement any changes to the business requirements as detailed in Section XI.B, CMS-initiated Change Requests. CMS will only allow this approach to the extent that the previous audit accurately represents review of a prospective EDE Entity's currently configured EDE environment.

*ii. Privacy and Security Audit*

For a prospective EDE Entity that is not approved for PY 2020, but has submitted a complete privacy and security audit prior to the release of these Guidelines and entered the audit queue, CMS will allow such a prospective EDE Entity to use its previously submitted and complete EDE privacy and security audit assuming no significant changes have been made to its environment since the submission pursuant to the processes defined below in Section XI, Processes for Changes to an Audited or Approved EDE Environment. CMS will only allow this approach to the extent that the previous audit accurately represents review of a prospective EDE Entity's current compliance standing and configured EDE environment. Consistent with the ISCM Strategy Guide, prospective EDE Entities may need to provide updated privacy and security documentation to CMS to demonstrate the continued compliance of their environments.

**IV. Enhanced Direct Enrollment Critical Decision Factors**

EDE Entities have several options to consider in determining how and to what extent to participate in EDE during Year 3 of EDE. An Entity may seek to participate as a primary EDE Entity that has developed its own EDE environment or may participate as an upstream EDE Entity of an approved primary EDE Entity. Please see Section IV.B, Providing an EDE Environment to Other Entities, for more information. In addition, as detailed immediately below, there are three different application phase options for primary EDE Entities to consider for participation in EDE.

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<sup>17</sup> Please refer to Section VI.A.i, Required Business Requirements Audit Documentation for more information on the operational and oversight information that will be requested by CMS as part of this annual process.

### ***A. Application Phase Options***

CMS is offering the option of implementing one of three phases of the eligibility application using the EDE pathway. An EDE Entity may choose to implement Phase 1, 2, or 3 (described further below) for Year 3 of EDE. Phase 1 requires the lowest level of effort to implement and audit, and Phase 3 requires the highest level of effort to implement and audit. A prospective EDE Entity must commit to a phase and complete the phase implementation prior to initiating its audit because the audit must evaluate the compliance of the prospective EDE Entity's EDE environment with the requirements of the applicable phase. It is imperative that EDE Entities carefully evaluate the available application phases and select an appropriate phase for their clients and their organization's expertise and capacity. Once an Entity starts developing for its selected phase, it is recommended that the Entity not seek to change phases until the Entity is approved to go live with its originally selected phase. If an Entity has not completed its build, changing phases may require the Entity to modify elements of its implementation depending on how much of the system it has already built. Similarly, once an Entity begins its audit, it may need to re-audit elements of its implementation depending on the extent of the changes and how much of the system has already been audited. After conducting and submitting an audit, Entities must not modify their EDE environments to change phases without consulting CMS and must follow the processes defined below in Section XI, Processes for Changes to an Audited or Approved EDE Environment, which includes conducting an additional business requirements audit.

EDE Entities that implement Phases 1 or 2 are required to implement screening questions to redirect consumers whose eligibility circumstances the EDE Entities are unable to support to other supported application and enrollment channels. Please refer to Exhibit 1 for more information on the screening scenarios and Exhibit 2 for information on the screening question and communication requirements.

All EDE Entities, regardless of the phase chosen, are required to support consumer-reported changes in circumstances (CiCs) and special enrollment periods (SEPs) during and outside of the OEP. In addition, they are required to support re-enrollment application activities for any such actions that fall within the scenarios supported by the EDE Entity's chosen end-state phase. Furthermore, EDE Entities of all phases must support households that wish to enroll in more than one enrollment group. Exhibit 1 describes each of the three end-state phases and explains their benefits.



**Exhibit 1. Application End-state Phases**

End State Phases	Description	Benefits
<p><b>Phase 1: Host Simplified Application + EDE API Suite</b></p>	<p>EDE Entity hosts an application that cannot support all application scenarios, but will support only a subset of application scenarios.</p> <ul style="list-style-type: none"> <li>▪ Application filer (and others on application, if applicable) resides in the application state and all dependents have the same permanent address, if applicable</li> <li>▪ Application filer plans to file a federal income tax return for the coverage year; if married plans to file a joint federal income tax return with spouse</li> <li>▪ Application filer (and spouse, if applicable) is not responsible for a child 18 or younger who lives with the Application filer but is not on his/her federal income tax return</li> <li>▪ No household members are full-time students aged 18-22</li> <li>▪ No household member is pregnant</li> <li>▪ All applicants are U.S. citizens</li> <li>▪ All applicants can enter Social Security Numbers (SSNs)</li> <li>▪ No applicants are applying under a name different than the one on his/her Social Security cards</li> <li>▪ No applicants were born outside of the U.S. and became naturalized or derived U.S. citizens</li> <li>▪ No applicants are currently incarcerated (detained or jailed)</li> <li>▪ No household members are American Indian or Alaska Native</li> <li>▪ No applicants are offered health coverage through a job or COBRA</li> <li>▪ No applicants were in foster care at age 18 and are currently 25 or younger</li> <li>▪ All dependents are claimed on the Application filer's federal income tax return for the coverage year</li> <li>▪ All dependents are the Application filer's children who are single (not married) and 25 or younger</li> <li>▪ No dependents are stepchildren or grandchildren</li> <li>▪ No dependents live with a parent who is not on the Application filer's federal income tax return</li> </ul>	<p>Lowest level of effort to implement and audit. EDE development would be streamlined, since not all application questions would be in scope.</p>
<p><b>Phase 2: Host Expanded Simplified Application + EDE API Suite</b></p>	<p>EDE Entity hosts an application that cannot support all application scenarios. The scenarios supported include the following:</p> <ul style="list-style-type: none"> <li>▪ All scenarios covered by Phase 1</li> <li>▪ Full-time student</li> <li>▪ Pregnant application members</li> <li>▪ Non-U.S. citizens</li> <li>▪ Naturalized U.S. citizens</li> <li>▪ Application members who do not provide an SSN</li> <li>▪ Application members with a different name than the one on their SSN cards</li> <li>▪ Incarcerated application members</li> <li>▪ Application members who previously were in foster care</li> <li>▪ Stepchildren</li> </ul>	<p>Second lowest level of effort to implement and audit. EDE development would be streamlined, since not all application questions would be in scope.</p>

End State Phases	Description	Benefits
Phase 3: Host Complete Application + EDE API Suite	<p>EDE Entity hosts an application that supports all application scenarios (equivalent to existing HealthCare.gov):</p> <ul style="list-style-type: none"> <li>▪ All scenarios covered in Phase 2</li> <li>▪ American Indian and Alaskan Native household members</li> <li>▪ Application members with differing home addresses or residing in a state separate from where they are applying for coverage</li> <li>▪ Application members with no home address</li> <li>▪ Application members not planning to file a tax return</li> <li>▪ Married application members not filing jointly</li> <li>▪ Application members responsible for a child age 18 or younger who lives with them, but is not included on the Application filer's federal income tax return (parent/caretaker relative questions)</li> <li>▪ Application members offered coverage through their job, someone else's job, or COBRA</li> <li>▪ Application members with dependent children who are over age 25 or who are married</li> <li>▪ Application members with dependent children living with a parent not on their federal income tax return</li> <li>▪ Dependents who are not sons/daughters</li> </ul>	<p>Highest level of effort to implement and audit. EDE Entity would provide and service the full range of consumer scenarios. Additionally, the EDE Entity would no longer need to redirect consumers to alternative pathways for complex eligibility scenarios. Please note that the implementation of Phase 3 is comparatively more complex than the other phases and may require more time to audit and approve.</p>

In addition to the Application UI, EDE Entities are required to provide account management functions for consumers. EDE Entities must also provide required information in the UI and via email related to a consumer's application and enrollment status. These communications include, but are not limited to, providing status updates on the application and enrollment; providing information and updates on DMIs and SVIs, enrollment periods, and notices that are generated by the Exchange; facilitating document uploads for DMIs and SVIs; and updating and reporting changes to application and enrollment information. To review more detailed descriptions of communications requirements, please refer to the most recent version of the Communications Toolkit, which is available on CMS zONE.<sup>18</sup>

***B. Providing an EDE Environment to Other Entities<sup>19</sup>***

A primary EDE Entity is an entity that develops, designs, and hosts its own EDE environment for its own use or for use by others. A primary EDE Entity must have a third-party auditor complete the business requirement and privacy and security audits, sign the ISA and EDE Business Agreement, have its own Partner ID, and comply with all applicable requirements, including conducting oversight of upstream EDE Entity and downstream agent and broker users of its approved EDE environment. An upstream EDE Entity is an entity that uses an EDE environment provided by a primary EDE Entity.<sup>20</sup> All upstream EDE Entities must have a legal relationship with a primary EDE Entity reflected in a signed written agreement between the

<sup>18</sup> The Communications Toolkit is stored within the Business Report Template and Toolkits file available at the following link: <https://zone.cms.gov/document/business-audit>.

<sup>19</sup> This section does not address requirements related to non-issuer white-label users (also referred to as downstream agents and brokers) of a primary EDE Entity's EDE environment. Please refer to Section IV.D, Downstream Third-party Agent and Broker Arrangements, for more information on these types of arrangements.

<sup>20</sup> The list of EDE Entities (both primary and upstream) that are approved to use EDE is available at the following link: <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Web-brokers-in-the-Health-Insurance-Marketplace.html> (see "Enhanced Direct Enrollment Approved Partners").

upstream EDE Entity and the primary EDE Entity. There are three categories of upstream EDE Entities: white-label issuers; hybrid issuers; and hybrid, non-issuer entities. For all upstream arrangements, the “EDE end-user experience” consists of all aspects of the pre-application, application, plan shopping, plan selection, enrollment, and post-enrollment experience and any data<sup>21</sup> collected necessary for those steps or for the purposes of any Authorized Functions.<sup>22, 23</sup> CMS allows for unique white-label branding and logos within the primary EDE Entity’s environment for all upstream arrangements.<sup>24</sup> Only a primary EDE Entity can provide an EDE environment to a hybrid, non-issuer upstream EDE Entity or an upstream issuer (whether a white-label or hybrid upstream issuer EDE Entity); that is, upstream EDE Entities cannot provide an EDE environment to other upstream EDE Entities.

The primary EDE Entity must detail all arrangements with upstream EDE Entities by submitting a completed ISA Appendix B that details the arrangements and any data connections or exchanges. If a primary EDE Entity is unclear on whether an arrangement needs to be included, the primary EDE Entity should submit an Appendix B detailing the arrangement to CMS or contact CMS to discuss the arrangement to confirm if it needs to be reported. Furthermore, any arrangements involving web-brokers must be detailed in an Appendix B submission.<sup>25</sup>

#### *i.* White-label Issuer Upstream EDE Entities

White-label issuers are upstream EDE Entities that use a primary EDE Entity’s approved EDE environment, but make minor branding and QHP display changes to facilitate their use of the other Entity’s approved EDE environment. White-label issuers may add their logos and otherwise re-brand the EDE environment to present it as their own, and may limit their plan displays to their own QHP offerings consistent with 45 C.F.R. § 156.1230(a)(1)(ii).<sup>26</sup> White-label issuer upstream EDE Entities must otherwise use the primary EDE Entity’s environment without modification and cannot add any functionality or systems to the primary EDE Entity’s approved EDE environment.

White-label issuer upstream EDE Entities are not required to conduct and submit a business requirements audit or a privacy and security audit, but they must submit an Upstream EDE Entity Documentation Package (as described in VI.A, Audit Documentation), which includes the EDE Business Agreement, and they must also maintain a unique Partner ID.

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<sup>21</sup> All subsequent references to “data” collected in this document are inclusive of the data elements delineated in Section III.a, “Authorized Functions”, of the EDE Business Agreement, which is available on CMS zONE at the following link: <https://zone.cms.gov/document/business-audit>.

<sup>22</sup> Collectively, CMS considers these elements to constitute the EDE end-user experience whether the end-users are consumers or agents or brokers.

<sup>23</sup> For a list of Authorized Functions for which an EDE Entity may create, collect, disclose, access, maintain, store, and use a consumer’s personally identifiable information, please refer to Section III.a, “Authorized Functions”, of the EDE Business Agreement, which is available on CMS zONE at the following link: <https://zone.cms.gov/document/business-audit>.

<sup>24</sup> See Section IV.D, Downstream Third-party Agent and Broker Arrangements, for information on what types of branding is permitted in these downstream arrangements.

<sup>25</sup> As noted in Section IV.D, Downstream Third-party Agent and Broker Arrangements, any arrangements involving web-brokers must be detailed in an Appendix B submission for review by CMS even if they are believed to be pure white-label arrangements.

<sup>26</sup> Please refer to Section IV.E, QHP Shopping Experience in an EDE Environment for more information.

## *ii.* Hybrid Issuer Upstream EDE Entities

A hybrid issuer upstream EDE Entity is an issuer that implements—or has a primary EDE Entity implement on its behalf—additional functionality or systems to the primary EDE Entity’s EDE environment beyond minor branding changes or QHP display changes. CMS considers any changes to a primary EDE Entity’s approved EDE environment or the overall EDE end-user experience beyond minor branding changes or QHP display changes to be the addition of functionality or systems to an approved EDE environment. For example, additional functionalities or systems may include any redirect or connection to another entity’s system or website (e.g., the hybrid, issuer upstream EDE Entity’s system or website) as part of the EDE pre-application, application, plan shopping, plan selection, enrollment, or post-enrollment experience, including any data collection prior to initiating or after completing the Exchange application and/or submitting the QHP enrollment to the applicable Exchange.

If the primary EDE Entity intends to share data with a hybrid issuer upstream EDE Entity, this must be documented in the primary EDE Entity’s ISA Appendix B. This includes, for example, if the hybrid issuer upstream EDE Entity is hosting its own QHP shopping experience and collects and sends consumer data to, or receives consumer data from, the primary EDE Entity outside the boundaries of the primary EDE Entity’s approved EDE environment.

In the future, hybrid issuer upstream EDE Entities may be required to retain an Auditor to conduct a business requirements audit or privacy and security audit relevant to those functionalities or systems.

Hybrid issuer upstream EDE Entities must sign an EDE Business Agreement and maintain a unique Partner ID. Entities that have questions regarding hybrid issuer upstream EDE arrangements should contact DE Support at [directenrollment@cms.hhs.gov](mailto:directenrollment@cms.hhs.gov).

## *iii.* Hybrid, Non-Issuer Upstream EDE Entities

A hybrid, non-issuer upstream EDE Entity arrangement may be primarily characterized by the presence of additional functionality or systems that modify or represent additions to the primary EDE Entity’s EDE environment beyond minor branding changes or otherwise change the EDE end-user experience. The hybrid, non-issuer upstream EDE Entity arrangement may have split control or authority for creating and/or maintaining the systems and functionality that comprise the totality of the EDE environment or end-user experience. For example, additional functionalities or systems may include any redirect or connection to another entity’s system or website (e.g., the hybrid, non-issuer upstream EDE Entity’s system or website) as part of the EDE pre-application, application, plan shopping, plan selection, enrollment, or post-enrollment experience, including any data collection prior to initiating or after completing the Exchange application and/or submitting the QHP enrollment to the applicable Exchange.

One key criterion that CMS will consider in evaluating relationships between primary EDE Entities and potential hybrid, non-issuer upstream EDE Entities is the transference of a consumer’s experience or a consumer’s data outside of the boundaries of a primary EDE Entity’s approved environment. For example, CMS would consider any arrangement that sends a consumer or transmits a consumer’s data—either collected from the consumer for Exchange application and QHP enrollment purposes or provided by the Exchange pursuant to such activities— outside the system boundaries of a primary EDE Entity’s approved EDE

environment to constitute a hybrid, non-issuer upstream EDE Entity arrangement. The following examples illustrate situations that CMS would consider constituting a hybrid, non-issuer upstream EDE Entity relationship with a primary EDE Entity:

- Example Scenario 1: A hybrid, non-issuer upstream EDE Entity displays QHPs to the consumer separate from the primary EDE Entity's EDE environment and then may redirect the consumer and/or their data on a selected QHP to the primary EDE Entity for completing the eligibility application or submitting the enrollment transaction to the applicable Exchange.
- Example Scenario 2: A hybrid, non-issuer upstream EDE Entity provides a plan selection and enrollment process separate from the primary EDE Entity's EDE environment. This may involve any exchange of applicable consumer data (pre-application or post-application) between the hybrid, non-issuer upstream EDE Entity's system(s) and the primary EDE Entity's EDE environment to complete plan selection and enrollment. The consumer or the consumer's data may then be relayed back to the primary EDE Entity's EDE environment for further action, including enrollment, post-enrollment communications, and post-enrollment management action items.
- Example Scenario 3: A hybrid, non-issuer upstream EDE Entity retrieves, stores, transfers, or manages consumer data obtained or collected through the primary EDE Entity's EDE environment outside of that environment (e.g., data stored by customer relationship management software hosted or maintained outside of the primary EDE Entity's environment for the hybrid, non-issuer upstream EDE Entity's use).

These Guidelines do not provide examples of the full universe of possible hybrid, non-issuer upstream EDE Entity relationships or arrangements.<sup>27</sup> For example, any arrangement where a non-issuer upstream entity implements an EDE program requirement instead of the primary EDE Entity (e.g., privacy and security controls, business requirements, agent/broker identity proofing, etc.) would likely be a hybrid, non-issuer upstream EDE Entity arrangement.

For purposes of analyzing whether there is a hybrid, non-issuer upstream EDE Entity arrangement, the scope of the evaluation covers the full EDE end-user experience. This includes any data collected or received from the Exchange or Exchange consumers (directly or indirectly via an agent or broker), any implementation of the EDE requirements, any preliminary QHP shopping or eligibility information or estimates, and the QHP selection and enrollment experience.

If a non-issuer entity only redirects a consumer from its website to a primary EDE Entity's EDE environment to complete the EDE end-user experience, and the entity does not exchange any data or provide any Exchange-related information relevant to the EDE end-user experience, then it would not be considered a hybrid, non-issuer upstream entity relationship.<sup>28</sup>

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<sup>27</sup> Primary EDE Entities or hybrid, non-issuer upstream EDE Entities that have questions regarding permissible arrangements and the hybrid, non-issuer upstream EDE Entity model should contact DE Support at [directenrollment@cms.hhs.gov](mailto:directenrollment@cms.hhs.gov).

<sup>28</sup> Such an arrangement would be considered to be a downstream agent or broker arrangement. See Section IV.D, Downstream Third-party Agent and Broker Arrangements, for additional examples of the types of arrangements that

As detailed further below, hybrid, non-issuer upstream EDE Entities are required to retain an Auditor to conduct a privacy and security audit relevant to the additional functionalities or systems it seeks to add to the primary EDE Entity's approved EDE environment. Hybrid, non-issuer upstream EDE Entities must also sign an EDE Business Agreement and maintain a unique Partner ID.

*iv. Privacy and Security Audit Requirements for Hybrid, Non-issuer Upstream EDE Entities*

A prospective hybrid, non-issuer upstream EDE Entity must complete an ORR<sup>29</sup> that includes a privacy and security audit conducted by an Auditor. This audit must be conducted in compliance with the requirements for a primary EDE Entity conducting a privacy and security audit outlined in Sections V, Selection of an Auditor; VII, Privacy and Security Audit Requirements and Scope; VIII, Required Auditor and EDE Entity Training; and X, Approval Process and Audit Submission Window.<sup>30</sup> The Auditor must evaluate the prospective hybrid, non-issuer upstream EDE Entity's compliance with all applicable EDE privacy and security controls and requirements;<sup>31</sup> however, the Auditor does not need to independently evaluate the implementation of any inherited common controls implemented by the primary EDE Entity.<sup>32</sup> The Auditor must verify that all non-inherited and hybrid controls<sup>33</sup> are fully implemented and document any controls that have not been implemented. The Auditor must document any related mitigation steps the prospective hybrid, non-issuer upstream EDE Entity has taken. These requirements are consistent with the instructions in the EDE System Security and Privacy Plan (SSP) workbook.<sup>34</sup> For a list of all of the applicable privacy and security controls applicable to hybrid, non-issuer upstream EDE Entities (including the ones that may be inherited from the primary EDE Entity), please refer to Exhibit 11 and Exhibit 12 in the Appendix of these Guidelines.

After CMS approves a hybrid, non-issuer upstream EDE Entity, the EDE Entity must implement and maintain an ISCM program for its systems to maintain CMS approval. The ISCM requirements are detailed in the EDE Guidelines and the ISCM Strategy Guide (available on CMS zONE at the following link: <https://zone.cms.gov/document/privacy-and-security-audit>).

Hybrid non-issuer upstream EDE Entities must also comply with the business audit post-approval activities described in Section XI, Processes for Changes to an Audited or Approved EDE Environment, as applicable (e.g., if the hybrid, non-issuer upstream EDE Entity has implemented some portion of the EDE Business Requirements outside of the primary EDE

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would be considered downstream agent or broker arrangements, rather than hybrid, non-issuer upstream EDE Entity arrangements.

<sup>29</sup> See 45 C.F.R. § 155.221(b)(4) and (e).

<sup>30</sup> Hybrid, non-issuer upstream EDE Entity privacy and security audits and business requirements audits (if applicable) may be submitted on a rolling basis and, while the audit(s) must be complete for the Entity to enter the review queue, resubmission to provide missing elements not included in a previously submitted audit may similarly be submitted on a rolling basis.

<sup>31</sup> For a list of privacy and security controls that the Auditor must evaluate to ensure compliance by the hybrid, non-issuer upstream EDE Entity, please refer to Exhibit 11 in the Appendix of these Guidelines.

<sup>32</sup> For a list of inheritable common controls, please refer to Exhibit 12 in the Appendix of these Guidelines.

<sup>33</sup> Non-inherited controls include any inheritable common controls that have not been inherited from the primary EDE Entity's EDE environment.

<sup>34</sup> See page iv of the SSP available on CMS zONE at the following link: <https://zone.cms.gov/document/privacy-and-security-audit>.



Entity's EDE environment, such as the agent/broker identity proofing or post-eligibility application communications, it must adhere to the applicable CR requirements).

A primary EDE Entity that wants to enter into an arrangement with a hybrid, non-issuer upstream Entity must initiate the process for a category 3 EDE Entity-initiated Change Request as described in Section XI, Processes for Changes to an Audited or Approved EDE Environment. CMS recommends that a primary EDE Entity submit documentation for the category 3 EDE Entity-initiated Change Request before the hybrid, non-issuer upstream Entity initiates the audit. CMS will accept privacy and security audit submissions for hybrid, non-issuer upstream EDE Entities on a rolling basis.

*v. Additional Standards Regarding Primary EDE Entities and Upstream EDE Entities*

CMS requires written confirmation from both primary EDE Entities and their upstream Entities about any such relationships, as well as requires information and documentation from the upstream EDE Entities as requested, before allowing a connection to CMS for an upstream EDE Entity. Additionally, primary EDE Entities must identify inheritable common and hybrid security and privacy controls that their upstream EDE Entities should leverage. The common and hybrid security and privacy controls must be documented in the SSP workbook, and must also be documented as part of the written contract between primary EDE Entities and their upstream EDE Entities.

*vi. Unique Partner ID Requirements for Primary EDE Entities and Upstream Entities*

CMS requires primary EDE Entities with upstream EDE Entities to submit EDE API transactions using Partner IDs associated with the upstream EDE Entities when EDE applications/enrollments originate from an upstream EDE Entity.<sup>35</sup> This requirement applies to all types of upstream EDE Entities (including white-label and hybrid arrangements).

CMS requires this for the following reasons:

- For reporting and tracking purposes, the application/enrollment must reflect the EDE Entity that the transaction originated from.
- For purposes of suspension, if applicable, CMS can suspend specific Partner IDs. If only one Partner ID is used by the primary EDE Entity, a suspension of either the primary EDE Entity or any single upstream EDE Entity would result in the suspension of all activity from any EDE Entity using that Partner ID.

A primary EDE Entity that has upstream EDE Entities must update its Hub<sup>36</sup> Onboarding Form to include additional information for each of its upstream EDE Entities. The Hub Onboarding Form can be found on CMS zONE,<sup>37</sup> and when completed, must be emailed to the email address included on zONE and in the Hub Onboarding Form ([dsh.support@qssinc.com](mailto:dsh.support@qssinc.com)) as of January

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<sup>35</sup> CMS does not require a unique Partner ID for any downstream agent or broker arrangements. Please refer to Section IV.D, Downstream Third-party Agent and Broker Arrangements for more information on these types of arrangements.

<sup>36</sup> EDE Entities must connect to the Data Services Hub ("Hub") in order to access and use the Exchange APIs.

<sup>37</sup> The Hub Onboarding Form is available at the following CMS zONE webpage: <https://zone.cms.gov/document/hub-onboarding-form>.

2020). Each upstream EDE Entity must have a unique Partner ID and will receive its Partner ID when it (or its primary EDE Entity) submits or updates its Hub Onboarding Form.

### ***C. Data Collections***

An EDE Entity must perform data collections only within its approved EDE environment for purposes of the EDE pathway, except as approved by CMS through the EDE Entity-initiated Change Request process (see Section XI.C, Other EDE Entity-initiated Change Requests). Any and all websites that collectively make up the EDE environment used by the primary or upstream EDE Entity are subject to oversight by CMS. Any implementation or use of an EDE environment must be consistent with the audit(s) submitted to and approved by CMS.

### ***D. Downstream Third-party Agent and Broker Arrangements***

#### ***i. General Downstream Agent and Broker Requirements***

An EDE Entity may allow third-party agents and brokers who are validly registered with the FFE to use its respective approved EDE environment, either directly through the primary EDE Entity or by way of an arrangement with an upstream EDE Entity, to assist consumers in supported states (i.e., states in which the EDE Entity operates) with applying for coverage offered through an Exchange, as well as applying for advanced payments of the premium tax credit (APTC) and Cost-Sharing reductions (CSRs), and with selecting QHPs. This includes agents and brokers that are also web-brokers in the context of classic DE but that are operating solely as agents and brokers in the context of using the EDE pathway.<sup>38</sup>

#### ***ii. Downstream Agent and Broker White-label User Arrangement Requirements***

Downstream third-party agent and broker arrangements may be white-label arrangements for which a primary EDE Entity enables the downstream agent or broker to only make minor branding changes to the primary EDE Entity's EDE environment (i.e., adding an agent's or broker's logo or name to an EDE environment).

If a downstream agent or broker only redirects a consumer from its website to a primary EDE Entity's EDE environment to complete the EDE end-user experience, and the primary EDE Entity does not exchange any data or provide any Exchange-related information relevant to the EDE end-user experience to the downstream agent or broker, then it would not be considered a hybrid, non-issuer upstream entity relationship. However, a downstream agent or broker may collect limited data from a consumer on its own website and securely transmit it to an EDE Entity without necessarily making the arrangement a hybrid, non-issuer upstream entity relationship. The following are examples of the types of data that may be collected and transmitted by the downstream agent or broker consistent with this approach. Information may be collected:

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<sup>38</sup> In other words, web-brokers who currently participate in classic DE can enter into an arrangement to use a primary EDE Entity's environment.



- To determine if a consumer is (or should be) shopping for QHPs, such as basic information to assess eligibility for financial assistance, as well as to estimate premiums (e.g., household income, ages of household members, number of household members, and smoker status).<sup>39</sup>
- Related to the consumer's service area (e.g., zip code, county, and state).

The data noted above may be securely transmitted by the downstream agent or broker and used in the EDE end-user experience without making the arrangement a hybrid, non-issuer upstream entity relationship only if the data is transmitted in conjunction with the initial redirect of the consumer to the EDE end-user experience provided by the primary EDE Entity and the arrangement does not otherwise constitute a hybrid, non-issuer upstream entity relationship as described above. In any such arrangement, the data must be transmitted securely and in one direction only (i.e., from the downstream agent or broker to the primary EDE Entity's environment). This flexibility does not allow for a primary EDE Entity to send consumer data to the downstream agent or broker outside of the EDE end-user experience and does not allow for additional data exchanges beyond what is outlined above which takes place in conjunction with the initial redirect prior to the beginning of the EDE end-user experience on the primary EDE Entity's platform.

Any implementation consistent with what is described in this subsection (i.e., Section IV.D.ii, Downstream Agent and Broker White-label User Arrangement Requirements) must be documented within the primary EDE Entity's ISA Appendix B, including an identification of the data transferred with the redirect from the non-issuer entity's website, and submitted as an EDE Entity-initiated Change Request (see Section XI, Processes for Changes to an Audited or Approved EDE Environment), if CMS has already approved the primary EDE Entity's environment.

Downstream third-party agents and brokers will not sign an EDE Business Agreement or the ISA and will not be provided or allowed to use a unique Partner ID for EDE API transactions.

Finally, for details regarding any additional user interface customization beyond the white-label branding described above, please refer to the EDE Entity-initiated Change Request process in Section XI, Processes for Changes to an Audited or Approved EDE Environment.

### *iii. Oversight of Downstream Agents and Brokers*

An EDE Entity is responsible for ensuring compliance with applicable requirements, including the applicable terms and conditions of the EDE Business Agreement, by all downstream agents and brokers who access and use its approved EDE environment. An EDE Entity's environment must contain sufficient privacy and security safeguards and must be accessed consistent with its documented policies and procedures, to protect against noncompliance by any authorized downstream agents and brokers who are using its EDE environment or interacting with or managing any consumer applications associated with its EDE environment. For example, while CMS does not require downstream agents or brokers who use an EDE Entity's EDE environment to sign the ISA independently, CMS does require that the written agreement between the EDE

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<sup>39</sup> As discussed in Section IV.B.iii, Hybrid, Non-Issuer Upstream EDE Entities, providing a QHP shopping experience followed by a redirect would constitute a hybrid, non-issuer upstream EDE Entity relationship. See Example Scenario 1.

Entity and its downstream agents or brokers require the agent or broker to comply with the relevant and applicable privacy and security requirements contained within the Appendix A: Privacy and Security Standards and Implementation Specifications for Non-Exchange Entities to the Agreement between Agent or Broker and the Centers for Medicare & Medicaid Services for Individual Market Federally-Facilitated Exchanges and the State-Based Exchanges on the Federal Platform. Furthermore, a compliant EDE environment that is appropriately managed by an EDE Entity must protect against noncompliant use of the environment by downstream agents or brokers with respect to EDE privacy and security standards. Finally, web-brokers who are approved primary EDE Entities, or approved hybrid, non-issuer upstream EDE Entities, that allow the use of their EDE environments by downstream agents and brokers must comply with the requirements in 45 C.F.R. § 155.220(c)(4). Similarly, issuers that are approved primary or upstream EDE Entities and allow the use of their EDE Environments by downstream agents and brokers must comply with the requirements in 45 C.F.R. § 156.340.<sup>40</sup>

### ***E. QHP Shopping Experience in an EDE Environment***

#### ***i. QHP Shopping Experience***

EDE Entities must comply with the applicable QHP display requirements for web-brokers and issuers as defined in 45 C.F.R. §§ 155.220, 155.221, and 156.1230. In the case of a primary EDE Entity allowing the use of its EDE environment by a white-label issuer upstream EDE Entity consistent with the provisions in Section IV.B.i., Providing an EDE Environment to Other Entities, the primary EDE Entity can provide an EDE environment that meets the QHP display requirements applicable to the white-label issuer upstream EDE Entity.<sup>41</sup> If a primary EDE Entity allows the use of its EDE environment by downstream agents and brokers (i.e., not in the context of an upstream EDE Entity relationship), the EDE environment must comply with the QHP display requirements applicable to the primary EDE Entity.<sup>42</sup>

In addition, CMS strongly recommends that EDE Entities offer the QHP selection experience after consumers have completed the eligibility application, as opposed to offering the QHP selection experience prior to a consumer completing the eligibility application. CMS recommends this to minimize the risk of a consumer's eligibility or plan availability changing after the consumer completes the eligibility application. For example, offering QHP selection prior to the eligibility application may require an EDE Entity to estimate a consumer's eligibility for health insurance affordability programs (e.g., Medicaid, CHIP, APTC, and CSRs); however, the Exchange's eligibility determination may differ from the EDE Entity's estimate. As a result, consumers may be required to reassess their original QHP selections based on their official

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<sup>40</sup> Downstream agents and brokers that use the EDE environment of an approved primary or upstream issuer EDE Entity are a type of delegated or downstream entity under 45 C.F.R. § 156.340.

<sup>41</sup> For example, a web-broker primary EDE Entity can provide a white-label issuer upstream EDE entity with an issuer-branded, white-label EDE environment that only displays the QHP issuer's plans consistent with 45 C.F.R. § 156.1230(a)(1)(ii). In such situations, the issuer branded white-label EDE environment would also display the disclaimer required under 45 C.F.R. § 156.1230(a)(1)(iv).

<sup>42</sup> For example, a web-broker primary EDE Entity would be required to display all QHPs offered through the applicable Exchange consistent with 45 C.F.R. § 155.220(c)(3)(i)(A) and (B). This includes display of all QHP information provided by the Exchange or directly by the QHP issuer to the web-broker primary EDE Entity. The web-broker primary EDE Entity may only customize its website for a downstream agent or broker to include minor branding changes consistent with Section IV.D.ii, Downstream Agent and Broker White-label User Arrangement Requirements.

eligibility results from the Exchange. Additionally, if a consumer is completing a CiC, the consumer's plan availability may be restricted by Plan Category Limitations; however, the consumer and EDE Entity will not be aware of these potential limitations until the consumer has completed an eligibility application. As a result, consumers may not be eligible for the QHPs they initially selected.

#### ***F. Best Practices Prior to the Audit***

EDE Entities must complete development of their EDE environments and any related systems prior to initiating their audits, which includes integrating with all required APIs. Based on experience with previous audit submissions, it is strongly recommended that EDE Entities complete development of their environments prior to the start of the audit submission window.

CMS strongly encourages EDE Entities to test their environments using the supplemental EDE Partner Test Case Suite in addition to all applicable required test cases contained in the toolkits. Please note, while the Eligibility Results Toolkit and API Functional Integration Toolkit include test cases to validate whether EDE Entity environments can successfully complete certain scenarios, these should not be the only test cases that EDE Entities rely on to confirm their EDE environments work appropriately in all scenarios. If an EDE Entity utilizes, and can successfully complete, the supplemental EDE Partner Test Cases, the EDE Entity will increase the likelihood that it will be approved without delay due to eligibility application or API risks. In addition, it is strongly recommended that EDE Entities not begin the business requirements portion of their third-party audits (i.e., that use the Eligibility Results Toolkits, API Functional Integration Toolkit, Communications Toolkit, or the Business Audit Instructions and Report Template) until CMS releases the new baseline versions of each toolkit and template in early 2020.

#### **V. Selection of an Auditor**

A prospective EDE Entity (including an existing primary EDE Entity seeking to change phases)<sup>43</sup> or an existing EDE Entity conducting an ISCM audit must enter into a written agreement with each independent Auditor it selects. Pursuant to its oversight authority, CMS may request a copy of all documentation related to an EDE Entity's engagement of its Auditor(s) and the Auditor(s)' work in relation to the engagement. Each EDE Entity must identify its selected Auditor(s) in the EDE Business Agreement and the ISA between CMS and the EDE Entity. The EDE Entity must also submit a copy of the signed agreement or contract between the Auditor(s) and the EDE Entity to CMS. Please see Section X.A, Pre-Audit Notification to CMS, for more information.

##### ***A. Allowance for Multiple Auditors***

An EDE Entity is permitted to select either one Auditor to complete both the business requirements audit and the privacy and security audit or the EDE Entity may select two Auditors, one to complete the business requirements audit and the other to complete the privacy and security audit. If the EDE Entity selects only one Auditor, that Auditor may choose to conduct either the business requirements audit or the privacy and security audit only, and subcontract with another Auditor to conduct the other audit.

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<sup>43</sup> See, *supra*, note 4.

When an EDE Entity retains two Auditors to complete the audits, it should notify CMS of this arrangement and provide the contact information for both Auditors, including for the subcontractor(s) of an Auditor, if applicable. In such cases, both the Auditor and subcontractor(s) of the Auditor will be considered downstream or delegated entities of the EDE Entity.<sup>44</sup> Auditors are permitted to subcontract these activities; however, an EDE Entity must disclose any subcontracting arrangements by its Auditor(s) in the EDE Business Agreement and/or ISA with CMS and disclose any potential conflicts of interest consistent with the EDE Business Agreement.

## ***B. Business Requirements Auditor Experience***

CMS requires that a prospective EDE Entity select an Auditor(s) with the experience outlined below and attest, within the EDE Business Agreement and the ISA, that the Auditor(s) have demonstrated or possess such experience.

### *i. Required Business Requirements Auditor Experience*

CMS requires that the Auditor selected by a prospective EDE Entity to conduct the business requirements audit possess audit experience, which an Auditor may demonstrate through experience conducting operational audits or similar services for federal, state, or private programs. A prospective EDE Entity may consider an Auditor to be qualified to conduct the business requirements audit if key Auditor personnel possess one or more of the following relevant auditing certifications: Certified Internal Auditor (CIA), Certification in Risk Management Assurance (CRMA), Certified Information Systems Auditor (CISA), or Certified Government Auditing Professional (CGAP).

### *ii. Recommended Business Requirements Auditor Experience*

CMS recommends that an Auditor conducting the business requirements audit has minimum technical experience with Extensible Markup Language (XML) and JavaScript Object Notation (JSON). Most of the new EDE APIs will be in JSON format; however, some will be in XML format. A general familiarity and understanding of XML and JSON request and response structure may be useful to an Auditor conducting the business requirements audit. The necessity of this experience may depend on the Auditor's approach to reviewing the prospective EDE Entity's environment and if the prospective EDE Entity provides information relevant to the audit in a user-friendly interface or in raw XML or JSON file format. CMS anticipates providing limited training and technical assistance to prospective EDE Entities and Auditors on understanding and reading the EDE XML and JSON files.

## ***C. Privacy and Security Auditor Experience***

### *i. Required Privacy and Security Auditor Experience*

CMS requires that the key personnel of an Auditor selected by a prospective EDE Entity or an existing EDE Entity conducting an ISCM audit to conduct the privacy and security audit possess a combination of privacy and security experience and relevant auditing certifications. Examples of acceptable privacy and security experience include: Federal Information Security Management Act (FISMA) experience; Federal Risk and Authorization Management Program

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<sup>44</sup> See 45 C.F.R. § 155.221(e).

(FedRAMP)-certified third-party assessment organization; Statement on Standards for Attestation Engagements (SSAE) 16 experience; reviewing compliance with National Institute of Standards and Technology (NIST) SP 800-53 Revision 4, *Security and Privacy Controls for Federal Information Systems and Organizations*; and reviewing compliance with the Health Insurance Portability and Accountability Act (HIPAA) Security Rule standards. Examples of relevant auditing certifications are: Certified Information Privacy Professional (CIPP), Certified Information Privacy Manager (CIPM), Certified Information Systems Security Professional (CISSP), Fellow of Information Privacy (FIP), HealthCare Information Security and Privacy Practitioner (HCISPP), Certified Internal Auditor (CIA), Certified in Risk Management Professional (CRMP), Certified Information Systems Auditor (CISA), or Certified Government Auditing Professional (CGAP).

In determining whether an Auditor has an acceptable combination of privacy and security experience and relevant auditing certifications, an EDE Entity may substitute extensive FISMA experience for multiple privacy and security certifications.

The Auditor must be familiar with NIST standards, HIPAA, and other applicable federal privacy and cybersecurity regulations and guidance. In addition, the Auditor must be capable of performing penetration testing and vulnerability scans on all interfaces that collect personally identifiable information (PII) or connect to CMS.

*ii. Recommended Privacy and Security Auditor Experience*

CMS strongly recommends that an Auditor selected to conduct the privacy and security audit have prior FISMA experience and/or is listed on the FedRAMP-certified third-party assessment organization website.<sup>45</sup> Prior FISMA experience is recommended in order for an Auditor to appropriately assess an EDE Entity's compliance with the required privacy and security controls and produce a high-quality comprehensive Security and Privacy Controls Assessment Test Plan (SAP) and Security and Privacy Assessment Report (SAR).

**D. Conflict of Interest and Auditor Independence and Objectivity**

*i. Conflict of Interest*

An EDE Entity that is contracting with an Auditor to submit an audit to CMS must select an Auditor who is free from any real or perceived conflicts of interest, including being free from personal, external, and organizational impairments to independence, or the appearance of such impairments to independence. An EDE Entity and its Auditor must disclose to HHS any financial relationship between the Auditor and individuals who own or are employed by the EDE Entity or who own or are employed by the EDE Entity for which the Auditor is conducting an ORR pursuant to 45 C.F.R. §§ 155.221(b)(4) and (e).

*ii. Auditor Independence and Objectivity*

An EDE Entity's Auditor must remain independent and objective throughout the audit process for both audits. An Auditor is independent if there is no perceived or actual conflict of interest involving the developmental, operational, and/or management chain associated with the EDE environment and the determination of security and privacy control effectiveness or business

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<sup>45</sup> Available at: <https://marketplace.fedramp.gov/#/assessors?sort=assessorName>.

requirement compliance. The Auditor’s role is to provide an independent assessment of the compliance of the EDE Entity’s EDE environment and to maintain the integrity of the audit process. Upon submission of the audit, Auditors will be required to attest to their independence and objectivity in completing the audit, and that neither the EDE Entity nor the Auditor took any actions that might impair the objectivity of the findings in the audit.

## VI. Business Audit Requirements and Scope

An Auditor will complete a business requirements audit to ensure the prospective EDE Entity (including an existing primary EDE Entity seeking to change phases)<sup>46</sup> has complied with applicable requirements. A prospective EDE Entity must submit the resulting business requirements audit package to CMS. The Auditor may define its own methodology to conduct the business requirements audit within the parameters defined in Exhibit 2, which summarizes the review areas and review standards for the business requirements audit.

**Exhibit 2. Business Requirements**

Review Category	Requirement and Audit Standard
Consumer Identity Proofing Implementation	<ul style="list-style-type: none"> <li>▪ <i>Requirement:</i> The EDE Entity must conduct identity proofing (ID proofing) for Consumers entering the EDE Pathway for enrollments through both Consumer and in-person Agent/Broker pathways.<sup>47</sup> The EDE Entity must conduct ID proofing prior to submitting a Consumer’s application to the Exchange. If an EDE Entity is unable to complete ID proofing of the Consumer, the EDE Entity may either direct the Consumer to the classic DE (i.e., double-redirect) pathway or direct the Consumer to the Exchange (HealthCare.gov or the Exchange Call Center at 1-800-318-2596 [TTY: 1-855-889-4325]).</li> <li>– <u>Remote Identity Proofing/Fraud Solutions Archive Reporting Services (RIDP/FARS) or Third-Party Identity Proofing Service:</u> CMS will make the Exchange RIDP and FARS services available for the EDE Entity to use when remote ID proofing consumers for the Consumer pathway (i.e., when a consumer is interacting directly with the EDE environment without the assistance of an individual agent or broker). If an EDE Entity uses the Exchange RIDP service, it must use the RIDP service only after confirming the Consumer is seeking coverage in a state supported by the Exchange/federal platform, and only after confirming the consumer is eligible for the EDE Entity’s chosen phase. However, CMS does not require that EDE Entities use the Exchange RIDP and FARS services, specifically, to complete ID proofing. An EDE Entity may instead opt to use a third-party identity proofing service for ID proofing in the consumer pathway. If an EDE Entity uses a third-party identity proofing service, the service must be Federal Identity, Credential, and Access Management (FICAM) Trust Framework Solutions (TFS)-approved, and the EDE Entity must be able to produce documentary evidence that each Applicant has been successfully identity proofed. Documentation related to a third-party service could be requested in an audit or investigation by CMS (or its designee), pursuant to the EDE Business Agreement. Applicants do not need to be ID proofed on subsequent interactions with the EDE Entity if the Applicant creates an account (i.e., username and password) on the EDE Entity’s website, and the EDE Entity tracks that ID proofing has occurred when the Applicant’s account was created.</li> </ul>

<sup>46</sup> See, *supra*, note 4.

<sup>47</sup> Consumer Pathway means the workflow, UI, and accompanying APIs for an EDE environment that is intended for use by a Consumer to complete an eligibility application and enrollment. Agent/Broker Pathway means the workflow, UI, and accompanying APIs for an EDE environment that is intended for use by an Agent or Broker to assist a consumer with completing an eligibility application and enrollment.

Review Category	Requirement and Audit Standard
<p><b>Consumer Identity Proofing Implementation (continued)</b></p>	<ul style="list-style-type: none"> <li>– <u>Manual ID Proofing in the In-Person Agent/Broker Pathway</u>: EDE Entities may also offer a manual ID proofing process. Consumers being identity proofed in the in-person Agent/Broker pathway (i.e. when an Agent/Broker is working with a consumer and conducting ID proofing in-person, rather than remotely) must be ID proofed following the guidelines outlined in the document “Acceptable Documentation for Identity Proofing” available on CMS zONE (<a href="https://zone.cms.gov/document/api-information">https://zone.cms.gov/document/api-information</a>).</li> <li>– For the Consumer and in-person Agent/Broker pathways, the EDE Entity must provide the User ID of the requester in the header for each EDE API call. For the Consumer pathway, the User ID should be the User ID for the Consumer’s account on the EDE Entity’s site, or some other distinct identifier the EDE Entity assigns to the Consumer. For the in-person Agent/Broker pathway, the User ID must exactly match the Exchange User ID (i.e. the agent/broker-created portal.cms.gov User ID) for the Agent or Broker.</li> <li>– Additionally, if an EDE Entity is using the Fetch Eligibility API, the same User ID requirements apply. However, instead of sending the User ID via the header, the User ID will be provided in the request body via the following path: ExchangeUser/ExchangeUserIdentification/IdentificationID.</li> <li>▪ Review Standard: <ul style="list-style-type: none"> <li>– If an EDE Entity uses the Exchange RIDP service, the Auditor must verify that the EDE Entity has successfully passed testing with the Hub.<sup>48</sup></li> <li>– If an EDE Entity uses a third-party identity proofing service, the Auditor must evaluate and certify the following: <ul style="list-style-type: none"> <li>○ The identity proofing service is FICAM TFS-approved, and</li> <li>○ The EDE Entity has implemented the service correctly.</li> </ul> </li> <li>– If an EDE Entity offers a Manual ID proofing option for an in-person Agent/Broker pathway, the Auditor must verify that the EDE Entity requires Agents/Brokers to ID proof consumers as described in the “Acceptable Documentation for Identity Proofing” document.</li> <li>– EDE Entity’s inclusion of the appropriate Consumer User ID fields in the EDE and Fetch Eligibility API calls.</li> </ul> </li> </ul>
<p><b>Agent and Broker Identity Proofing Verification</b></p>	<ul style="list-style-type: none"> <li>▪ <i>Requirement</i>: If an EDE Entity is implementing an Agent/Broker Pathway for its EDE environment, the EDE Entity must implement Agent and Broker identity (ID) proofing verification procedures that consist of the following requirements: <ul style="list-style-type: none"> <li>– EDE Entity must provide User ID of the requester in the header for each EDE API call. For Agents and Brokers, the User ID must exactly match the Exchange User ID (i.e. the agent/broker-created portal.cms.gov User ID) for the Agent or Broker, or the request will fail Exchange User ID validation. <ul style="list-style-type: none"> <li>○ If an EDE Entity is using the Fetch Eligibility API, the same User ID requirements apply. However, instead of sending the User ID via the header, the User ID will be provided in the request body via the following path: ExchangeUser/ExchangeUserIdentification/IdentificationID.</li> </ul> </li> <li>– EDE Entity must ID proof all Agents and Brokers prior to allowing the Agents and Brokers to use its EDE environment. EDE Entity may conduct ID proofing in one of the following ways: <ul style="list-style-type: none"> <li>○ Use the Exchange-provided RIDP/FARS APIs to remotely ID proof Agents and Brokers;</li> <li>OR</li> <li>○ Manually ID proof Agents and Brokers following the guidelines outlined in the document “Acceptable Documentation for Identity Proofing” available on CMS zONE EDE Documents and Materials webpage (<a href="https://zone.cms.gov/document/api-information">https://zone.cms.gov/document/api-information</a>).</li> <li>○ EDE Entities are permitted to use manual ID proofing as an alternative for agent/brokers that can’t be ID proofed via the RIDP/FARS services.</li> </ul> </li> <li>– EDE Entity must validate an Agent’s or Broker’s National Producer Number (NPN) using the National Insurance Producer Registry (<a href="https://www.nipr.com">https://www.nipr.com</a>) prior to allowing the Agent or Broker to use its EDE environment.</li> <li>– EDE Entity must systematically provide an Agent and Broker ID proofing process—that meets all of the requirements defined here—that applies to all downstream Agents and Brokers of the primary EDE Entity.</li> </ul> </li> </ul>

<sup>48</sup> RIDP/FARS testing requirements for the Hub can be found at the following link on CMS zONE: <https://zone.cms.gov/document/api-information>.

Review Category	Requirement and Audit Standard
<p><b>Agent and Broker Identity Proofing Verification (continued)</b></p>	<ul style="list-style-type: none"> <li>– Additionally, all Agent and Broker users of an upstream EDE Entity's EDE website (hosted by a primary EDE Entity) must be ID proofed consistent with these requirements. The primary EDE Entity may provide one centralized ID proofing approach for any Agents and Brokers that will use the primary EDE Entity's EDE environment (including when utilized by upstream EDE Entities and their downstream Agents and Brokers). <ul style="list-style-type: none"> <li>○ Alternatively, the upstream EDE Entity may conduct its own ID proofing process of its downstream Agents and Brokers consistent with these requirements. The upstream EDE Entity must provide the information for Agents and Brokers that have passed and failed ID proofing to the primary EDE Entity using a secure data transfer. If an upstream EDE Entity wants to pursue this flexibility, its ID proofing process must be audited by an Auditor consistent with these standards and the arrangement will be considered a hybrid arrangement.</li> </ul> </li> <li>– Note: If a primary EDE Entity does not provide a centralized process for identity proofing an upstream EDE Entity's downstream Agent and Broker and if the primary EDE Entity intends to provide the EDE environment to upstream EDE Entities, the upstream EDE Entities will be required to provide documentation of an Auditor's evaluation of its ID proofing approach consistent with these standards. This process must be categorized as an EDE Entity-initiated Change Request (Section XI.C, Other EDE Entity-initiated Change Requests) if it occurs after the primary EDE Entity's initial audit submission and the arrangement with the upstream EDE Entity will be considered a hybrid arrangement.</li> <li>▪ <b>Review Standard:</b> The Auditor must verify and certify the following: <ul style="list-style-type: none"> <li>– EDE Entity's inclusion of the appropriate Agent/Broker User ID fields in the EDE and Fetch Eligibility API calls.</li> <li>– EDE Entity's process for ID proofing an Agent or Broker prior to allowing an Agent or Broker to use its EDE environment.</li> <li>– EDE Entity's process for validating an Agent's or Broker's NPN using the National Insurance Producer Registry prior to allowing an Agent or Broker to use its EDE environment.</li> <li>– EDE Entity's process for systematically providing an Agent and Broker ID proofing approach for all downstream Agents and Brokers of the EDE Entity.</li> </ul> </li> <li>▪ All Agents and Brokers that will use EDE must be ID proofed consistent with these standards. This includes downstream Agents and Brokers of primary EDE Entities and upstream EDE Entities. The Auditor must evaluate the primary EDE Entity's centralized implementation for ID proofing (if applicable) or the upstream EDE Entity's implementation for ID proofing (if applicable).</li> </ul>
<p><b>Phase-dependent Screener Questions (EDE Phase 1 and 2 EDE Entities Only)</b></p>	<ul style="list-style-type: none"> <li>▪ <b>Requirement:</b> An EDE Entity that implements either EDE Phase 1 or Phase 2 must implement screening questions to identify Consumers whose eligibility circumstances the EDE Entity is unable to support consistent with the eligibility scenarios supported by the EDE Entity's selected EDE phase. These phase-dependent screener questions must be located at the beginning of the EDE application, but may follow the QHP plan compare experience. For those Consumers who won't be able to apply through scenarios covered by the EDE phase that the EDE Entity implements, the EDE Entity must either route the Consumer to the classic DE double-redirect pathway or direct the Consumer to the Exchange by providing the following options: HealthCare.gov or the Exchange Call Center at 1-800-318-2596 [TTY: 1-855-889-4325].</li> <li>▪ <b>Review Standard:</b> The Auditor must verify the following: <ul style="list-style-type: none"> <li>– The EDE Entity has implemented screening questions—consistent with the requirements in the Exchange Application UI Principles document and Application UI Toolkit—to identify Consumers with eligibility scenarios not supported by the EDE Entity's EDE environment and selected EDE phase.</li> <li>– The EDE Entity's EDE environment facilitates moving Consumers to one of the alternative enrollment pathways described immediately above.</li> </ul> </li> </ul>



Review Category	Requirement and Audit Standard
<p>Accurate and Streamlined Eligibility Application User Interface (UI)</p>	<ul style="list-style-type: none"> <li>▪ <b>Requirement:</b> EDE Entities using the EDE Pathway must support all application scenarios outlined in EDE Entity's selected EDE phase. The EDE Entity must adhere to the guidelines set forth in the FFE Application UI Principles document when implementing the application. EDE Entities can access the FFE Application UI Principles document on CMS zONE (<a href="https://zone.cms.gov/document/eligibility-information">https://zone.cms.gov/document/eligibility-information</a>). Auditors will need to access the FFE Application UI Principles document to conduct the audit. <ul style="list-style-type: none"> <li>– As explained in the FFE Application UI Principles document, the EDE Entity must implement the application in accordance with the Exchange requirements. For each applicable eligibility scenario, the EDE Entity must display all appropriate eligibility questions and answers, including all questions designated as optional. (Note: These questions are optional for the Consumer to answer, but are not optional for EDE Entities to implement.) The FFE Application UI Principles document and Application UI Toolkit define appropriate flexibility EDE Entities may implement with respect to question wording, question order or structure, format of answer choices (e.g., drop-down lists, radio buttons), and integrated help information (e.g., tool tips, URLs, help boxes). In most cases, answer choices, question logic (e.g., connections between related questions), and disclaimers (e.g., APTC attestation) must be identical to those of the Exchange.</li> <li>– EDE Entities will also need to plan their application's back-end data structure to ensure that attestations can be successfully submitted to Standalone Eligibility Service (SES) APIs at appropriate intervals within the application process and that the EDE Entity can process responses from SES and integrate them into the UI question flow logic, which is dynamic for an individual Consumer based on his or her responses. The EDE Entity will need to ensure that sufficient, non-contradictory information is collected and stored such that accurate eligibility results will be reached without any validation errors.</li> </ul> </li> <li>▪ <b>Review Standard:</b> The Auditor must review and certify the following: <ul style="list-style-type: none"> <li>– The FFE Application UI has been implemented in EDE Entity's environment in accordance with the Exchange Application UI Principles document.</li> <li>– The FFE Application UI displays all appropriate eligibility questions and answers from the Application UI Toolkit, including any questions designated as optional.</li> <li>– The Auditor will review the application for each supported eligibility scenario under the phase the EDE Entity has implemented to confirm that the application has been implemented in accordance with the FFE Application UI Principles document and Application UI Toolkit. The Auditor will document this compliance in the Application UI Toolkit. <ul style="list-style-type: none"> <li>○ Note: The phrase "supported eligibility scenario" does not refer to the Eligibility Results Toolkit scenarios. Auditors must verify that EDE Entities can support all scenarios supported by the EDE Entity's selected phase and this scope exceeds the scope of the test cases in the Eligibility Results Toolkits.</li> </ul> </li> </ul> </li> <li>▪ If EDE Entity has implemented Phase 1 or Phase 2, the Auditor will confirm that the UI includes a disclaimer stating that the environment does not support all application scenarios, and identifying which scenarios are and are not supported. The disclaimer should direct the Consumer to alternative pathways, such as the classic DE double-redirect pathway or direct the Consumer to the Exchange (HealthCare.gov or the Exchange Call Center at 1-800-318-2596 (TTY: 1-855-889-4325)). This requirement is included in the Communications Toolkit.</li> </ul>
<p>Post-eligibility Application Communications</p>	<ul style="list-style-type: none"> <li>▪ <b>Requirement:</b> The application must display high-level eligibility results, next steps for enrollment, and information about each Applicant's insurance affordability program eligibility (e.g., APTC, CSR, Medicaid, and/or CHIP eligibility), Data Matching Issues (DMIs), special enrollment periods (SEPs), SEP Verification Issues (SVIs), and enrollment steps in a clear, comprehensive and Consumer-friendly way. <ul style="list-style-type: none"> <li>– EDE Entity must provide Consumers with the CMS-provided Eligibility Determination Notices (EDNs) generated by the Exchange any time it submits or updates an application pursuant to requirements provided by CMS in the Communications Toolkit.</li> <li>– EDE Entity must provide the EDN in a downloadable format at the time the Consumer's application is submitted or updated and must have a process for providing access to the Consumer's most recent EDN via the API as well as providing access to the Consumer's historical notices—accessed via the Notice Retrieval API by the EDE Entity's EDE environment—within the UI. The EDE Entity must retain the Consumer's notices (it has received access to via the Notice Retrieval API) for at least ten (10) years. The UI requirements related to accessibility of a Consumer's EDN are set forth in the Communications Toolkit.</li> </ul> </li> </ul>

Review Category	Requirement and Audit Standard
<b>Post-eligibility Application Communications (continued)</b>	<ul style="list-style-type: none"> <li>– EDE Entity must provide and communicate status updates and access to information for Consumers to manage their applications and coverage. These communications include, but are not limited to, status of DMIs and SVIs, enrollment periods (e.g., SEP eligibility and the OEP), providing and communicating about new notices generated by the Exchange, application and enrollment status, and supporting document upload for DMIs and SVIs. This requirement is detailed in the Communications Toolkit.</li> <li>– EDE Entity must provide application and enrollment management functions for the Consumer in a clear, accessible location in the UI (e.g., an account management hub for managing all application- and enrollment-related actions).</li> <li>– For any Consumers enrolled, including via an Agent/Broker pathway, the EDE Entity must provide critical communications to Consumers notifying them of the availability of Exchange-generated EDNs, critical communications that the Consumer will no longer receive from the Exchange (to be identified by CMS), and any other critical communications that an EDE Entity is providing to the Consumer in relation to the Consumer's application or enrollment status.</li> <li>▪ <b>Review Standard:</b> The Auditor must verify and certify the following: <ul style="list-style-type: none"> <li>– The EDE Entity's EDE environment is compliant with the requirements contained in the Communications Toolkit.</li> <li>– The EDE Entity's EDE environment notifies Consumers of their eligibility results prior to QHP enrollment, including when submitting a CiC in the environment. For example, if a Consumer's APTC or CSR eligibility changes, EDE Entity must notify the Consumer of the change and allow the Consumer to modify his or her QHP selection (if SEP-eligible) or APTC allocation accordingly.</li> <li>– EDE Entity must have a process for providing Consumers with a downloadable EDN in its EDE environment and for providing access to a current EDN via the API. EDE Entity must share required eligibility information that is specified by CMS in the Communications Toolkit.</li> <li>– The Auditor must verify that EDE Entity's EDE environment is providing status updates and ongoing communications to Consumers according to CMS requirements in the Communications Toolkit as it relates to the status of their application, eligibility, enrollment, notices, and action items the Consumer needs to take.</li> <li>– The EDE Entity must provide application and enrollment management functions for the Consumer in a clear, accessible location in the UI.</li> <li>– The EDE Entity must have a means for providing critical communications to the Consumer consistent with the standards above.</li> </ul> </li> </ul>
<b>Accurate Information about the Exchange and Consumer Communications</b>	<ul style="list-style-type: none"> <li>▪ <b>Requirement:</b> EDE Entity must provide Consumers with CMS-provided language informing and educating the Consumers about the Exchanges and HealthCare.gov and Exchange-branded communications Consumers may receive with important action items. CMS defines these requirements in the Communications Toolkit.</li> <li>▪ <b>Review Standard:</b> The Auditor must verify and certify that the EDE Entity's EDE environment includes all required language, content, and disclaimers provided by CMS in accordance with the standards stated in guidance and the Communications Toolkit.</li> </ul>

Review Category	Requirement and Audit Standard
<p><b>Documentation of Interactions with Consumer Applications or the Exchange</b></p>	<ul style="list-style-type: none"> <li>▪ <i>Requirement:</i> EDE Entity must implement and maintain tracking functionality on its EDE environment to track Agent, Broker, and Consumer interactions, as applicable, with Consumer applications using a unique identifier for each individual, as well as an individual's interactions with the Exchanges (e.g., application; enrollment; handling of action items, such as uploading documents to resolve a DMI). This requirement also applies to any actions taken by a downstream Agent or Broker,<sup>49</sup> as well as the upstream EDE Entity users, of a primary EDE Entity's EDE environment.</li> <li>▪ <i>Review Standard:</i> The Auditor must verify EDE Entity's process for determining and tracking when an upstream EDE Entity, downstream Agent or Broker, and Consumer has interacted with a Consumer application or taken actions utilizing the EDE environment or EDE APIs. The Auditor must verify and certify the following: <ul style="list-style-type: none"> <li>– The EDE Entity's environment tracks, at a minimum, the interactions of upstream EDE Entities, downstream Agents or Brokers, and Consumers with a Consumer's account, records, application, or enrollment information utilizing the EDE environment or EDE APIs.</li> <li>– The EDE Entity's environment tracks when an upstream Entity, downstream Agent or Broker, or Consumer views a Consumer's record, enrollment information, or application information utilizing the EDE environment or EDE APIs.</li> <li>– The EDE Entity's environment uses unique identifiers to track and document activities by Consumers, downstream Agents and Brokers, and upstream EDE Entities using the EDE environment.</li> <li>– The EDE Entity's environment tracks interactions with the EDE suite of APIs by an upstream EDE Entity, a downstream Agent or Broker, or Consumer.</li> <li>– The EDE Entity's environment stores this information for 10 years.</li> </ul> </li> </ul>
<p><b>Eligibility Results Testing and SES Testing</b></p>	<ul style="list-style-type: none"> <li>▪ <i>Requirement:</i> EDE Entity must submit accurate applications through the EDE Pathway that result in accurate and consistent eligibility determinations for the Consumer eligibility scenarios covered by EDE Entity's chosen EDE phase. <ul style="list-style-type: none"> <li>– The business requirements audit package must include testing results in the designated Exchange EDE testing environment. CMS has provided a set of Eligibility Results Toolkits with the eligibility testing scenarios on CMS zONE <a href="https://zone.cms.gov/document/business-audit">https://zone.cms.gov/document/business-audit</a>.</li> </ul> </li> <li>▪ <i>Review Standard:</i> The Auditor must verify and certify the following: <ul style="list-style-type: none"> <li>– The Auditor was able to successfully complete a series of test eligibility scenarios using EDE Entity's EDE environment implementation using the Eligibility Results Toolkits. For example, these scenarios may include Medicaid and CHIP eligibility determinations, and different combinations of eligibility determinations for APTC and CSRs. Note: These scenarios do not test, and are not expected to test, every possible question in the Application UI flow for an EDE Entity's selected phase. In addition to reviewing the eligibility results test cases, the Auditor must review the Application UI for compliance as defined above.</li> <li>– The Auditor must test each scenario and verify that the eligibility results and the eligibility process were identical to the expected results and process. CMS will require the Auditor to provide confirmation that each relevant eligibility testing scenario was successful, that the expected results were received (as defined in the Eligibility Results Toolkits), and to submit screenshots, EDNs, the JSON from the Get App API response for the application version used to complete the scenario, and Exchange Application IDs, when applicable, for each test scenario.</li> </ul> </li> </ul>

<sup>49</sup> Note: References to downstream Agents and Brokers include downstream Agents and Brokers of either the primary EDE Entity or an upstream EDE Entity.

Review Category	Requirement and Audit Standard
<b>API Functional Integration Requirements</b>	<ul style="list-style-type: none"> <li>▪ <i>Requirement:</i> EDE Entity must implement the EDE API suite in accordance with the API specifications and EDE API Companion Guide provided by CMS. The EDE API specifications and EDE API Companion Guide are available on CMS zONE <a href="https://zone.cms.gov/document/api-information">https://zone.cms.gov/document/api-information</a>.</li> <li>▪ <i>Review Standard:</i> The Auditor must complete the set of test scenarios as outlined in the API Functional Integration Toolkit to confirm that the EDE Entity's API and corresponding UI integration performs the appropriate functions when completing the various EDE tasks. For example, the Auditor may have to complete a scenario to verify that a Consumer or Agent/Broker is able to view any SVIs or DMIs that may exist for a consumer, and confirm that the Consumer or Agent/Broker has the ability to upload documents to resolve any SVIs or DMIs. Some of the test cases require that the Auditor and EDE Entity request CMS to process adjudication actions; the Auditor cannot mark these particular test cases as compliant until evaluating whether the expected outcome occurred after CMS takes the requested action. The Auditor will also need to be aware of the following requirements related to the test scenarios: <ul style="list-style-type: none"> <li>– Test scenarios in the API Functionality Integration Toolkit must be completed in both the Consumer Pathway and the Agent/Broker Pathway, if an EDE Entity offers both pathways.</li> <li>– The API Functional Integration Toolkit includes a "Required Evidence" column, Column H, on the "Test Cases" tab. Auditors will need to submit the applicable "Required Evidence" as part of the audit submission.</li> </ul> </li> </ul>
<b>Application UI Validation</b>	<ul style="list-style-type: none"> <li>▪ <i>Requirement:</i> EDE Entity must implement CMS-defined validation requirements within the application. The validation requirements prevent EDE Entity from submitting incorrect data to the Exchange.</li> <li>▪ <i>Review Standard:</i> The Auditor must confirm that EDE Entity has implemented the appropriate application field-level validation requirements consistent with CMS requirements. These field-level validation requirements are documented in the FFE Application UI Principles document.</li> </ul>
<b>Section 508-compliant UI</b>	<ul style="list-style-type: none"> <li>▪ <i>Requirement:</i> Pursuant to 45 C.F.R. § 155.220(c)(3)(ii)(D) (citing 45 C.F.R. §§ 155.230 and 155.260(b)) and 45 C.F.R. § 156.265(b)(3)(iii) (citing 45 C.F.R. §§ 155.230 and 155.260(b)), web-brokers and QHP issuers participating in DE, including all EDE Entities, must implement an eligibility application UI that is Section 508-compliant. A Section 508-compliant application must meet the requirements set forth under Section 508 of the Rehabilitation Act of 1973, as amended (29 U.S.C. § 794(d)).</li> <li>▪ <i>Review Standard:</i> The Auditor must confirm that EDE Entity's application UI meets the requirements set forth under Section 508 of the Rehabilitation Act of 1973, as amended (29 U.S.C. § 794(d)). The Auditor must verify and certify the following: <ul style="list-style-type: none"> <li>– Within the Business Requirements Audit Report Template, the Auditor must confirm that the EDE Entity's application UI is Section 508-compliant. No specific report or supplemental documentation is required.</li> <li>– The Auditor may review results produced by a 508 compliance testing tool. If an EDE Entity uses a 508 compliance testing tool to verify that its application UI is 508-compliant, its Auditor must, at a minimum, review the results produced by the testing tool and document any non-compliance, as well as any mitigation or remediation to address the non-compliance. It is not sufficient for an Auditor to state that an EDE Entity complies with the 508-Compliant UI requirement by confirming that the EDE Entity utilized a 508 compliance testing tool.</li> </ul> </li> </ul>

Review Category	Requirement and Audit Standard
<p><b>Non-English-language Version of the Application UI and Communication Materials</b></p>	<ul style="list-style-type: none"> <li>▪ <i>Requirement:</i> In accordance with 45 C.F.R. § 155.205(c)(2)(iv)(B) and (C), QHP issuers and web-brokers, including those that are EDE Entities, must translate applicable website content (e.g., the application UI) on Consumer-facing websites into any non-English language that is spoken by a limited English proficient (LEP) population that reaches 10 percent or more of the population of the relevant state, as determined in current guidance published by the Secretary of HHS.<sup>50</sup> EDE Entities must also translate communications informing Consumers of the availability of Exchange-generated EDNs; critical communications that the Consumer will no longer receive from the Exchange (to be identified by CMS); and any other critical communications that an EDE Entity is providing to the Consumer in relation to the Consumer’s use of its EDE environment into any non-English language that is spoken by an LEP population that reaches 10 percent or more of the population of the relevant state, as determined in guidance published by the Secretary of HHS.<sup>51</sup></li> <li>▪ <i>Review Standard:</i> The Auditor must verify and certify the following: <ul style="list-style-type: none"> <li>– The Auditor must confirm that the non-English-language version of the application UI and associated critical communications are compliant with the Exchange requirements, including the Application UI Toolkit and Communications Toolkit.</li> <li>– The Auditor must verify that the application UI has the same meaning as its English-language version.</li> <li>– The Auditor must also verify that EDE Entity has met all EDE communications translation requirements released by CMS in the Communications Toolkit.</li> <li>– The Auditor must document compliance with this requirement within the Business Requirements Audit Report Template, the Application UI Toolkit, and the Communications Toolkit. In the toolkits, the Auditor can add additional columns for the Auditor compliance findings fields (yellow-shaded columns) or complete the Spanish audit in a second copy of each of the two toolkits.</li> </ul> </li> </ul>
<p><b>EDE Change Management Process</b></p>	<ul style="list-style-type: none"> <li>▪ <i>Requirement:</i> EDE Entity must develop and consistently implement processes for managing changes to the EDE environment relevant to the business requirements audit requirements. This requirement does not replace the evaluation necessary for relevant privacy and security controls. At a minimum, the EDE Entity’s change management plan must include the following elements: <ul style="list-style-type: none"> <li>– A process that incorporates all elements of the Change Notification SOP as referenced in Section XI, Processes for Changes to an Audited or Approved EDE Environment;</li> <li>– All application and business audit-related changes are thoroughly defined and evaluated prior to implementation, including the potential effect on other aspects of the EDE end-user experience;</li> <li>– A process for defining regression testing scope and developing or identifying applicable testing scenarios;</li> <li>– A process for conducting regression testing;</li> <li>– A process for identifying and correcting errors discovered through regression testing and re-testing the correction;</li> <li>– A process for maintaining separate testing environments and defining the purposes and releases for each environment; and</li> <li>– The change management process must be maintained in writing and relevant individuals must be informed on the change management process and on any updates to the process.</li> </ul> </li> <li>▪ <i>Review Standard:</i> The Auditor must evaluate the EDE Entity’s change management plan for compliance with the elements and criteria defined above.</li> </ul>

<sup>50</sup> Guidance and Population Data for Exchanges, Qualified Health Plan Issuers, and Web-Brokers to Ensure Meaningful Access by Limited-English Proficient Speakers Under 45 CFR §155.205(c) and §156.250 (March 30, 2016) <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Language-access-guidance.pdf> and “Appendix A- Top 15 Non-English Languages by State” [https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Appendix-A-Top-15-non-english-by-state-MM-508\\_update12-20-16.pdf](https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Appendix-A-Top-15-non-english-by-state-MM-508_update12-20-16.pdf).

<sup>51</sup> *Frequently Asked Questions (FAQs) Regarding Spanish Translation and Audit Requirements for Enhanced Direct Enrollment (EDE) Entities Serving Consumers in States with Federally-facilitated Exchanges (FFE)s* (June 20, 2018) provides further information regarding translation and audit requirements: <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/FAQ-EDE-Spanish-Translation-and-Audit-Requirements.PDF>.

**A. Audit Documentation**

*i. Required Business Requirements Audit Documentation*

Exhibit 3 contains the required information that prospective EDE Entities (including an existing primary EDE Entity seeking to change phases)<sup>52</sup> must submit to CMS as part of the Business Requirements Audit to be approved to participate in EDE. CMS encourages prospective EDE Entities to use this table as a checklist to ensure they have met all requirements. Note: CMS may require prospective EDE Entities and/or their Auditors to submit additional documents and information at CMS's discretion.

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<sup>52</sup> See, *supra*, note 4.

**Exhibit 3: Required Information for Business Audit**

Document	Description	Submission Requirements	Entity Responsible (Upstream/Primary/ Both Primary and Upstream/Auditor)	Deadline
<p><b>Notice of Intent to Participate and Auditor Confirmation</b></p>	<ul style="list-style-type: none"> <li>▪ Once the prospective EDE Entity has a confirmed Auditor(s) who will be completing its audit(s), it must notify CMS that it intends to apply to use the EDE pathway for Year 3 of EDE prior to initiating the audit. The email must include the following:               <ul style="list-style-type: none"> <li>– Prospective EDE Entity Name</li> <li>– Auditor Name(s) and Contact Information (Business Requirements and Privacy and Security, if different)</li> <li>– A copy of the executed contract with the Auditor(s) (pricing and proprietary information may be redacted)</li> <li>– EDE Phase (1, 2, or 3)</li> <li>– Prospective EDE Entity Primary Point of Contact (POC) name, email, and phone number</li> <li>– Prospective EDE Entity Technical POC name, email, and phone number</li> <li>– Prospective EDE Entity Emergency POC name, email, and phone number</li> <li>– CMS-issued Hub Partner ID</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>▪ The QHP issuer or web-broker should email <a href="mailto:directenrollment@cms.hhs.gov">directenrollment@cms.hhs.gov</a></li> <li>▪ Subject line should state: "Enhanced DE: Intent."</li> </ul>	<p>Primary</p> <p>Note: CMS is not collecting notices of intent from upstream EDE Entities.</p>	<p>April 1, 2020</p>

Document	Description	Submission Requirements	Entity Responsible (Upstream/Primary/Both Primary and Upstream/Auditor)	Deadline
<p><b>Primary EDE Entity Documentation Package—Privacy Questionnaire (or attestation, if applicable, see Submission Requirements)</b></p>	<ul style="list-style-type: none"> <li>▪ CMS will provide the questionnaire to each EDE Entity as part of the audit submission package.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Submit via the secure portal</li> <li>▪ If an EDE Entity submitted a questionnaire during EDE Agreement Renewal in 2019, the Entity may submit an attestation if the responses to the privacy questionnaire will remain unchanged from the language already submitted to CMS.</li> </ul>	<p>Primary</p>	<p>Submit with audit submission</p>
<p><b>Primary and Upstream EDE Entity Documentation Packages—Entity’s website privacy policy statement(s) and Terms of Service (or attestation, if applicable; see Submission Requirements)</b></p>	<ul style="list-style-type: none"> <li>▪ Submit the URL and text of each privacy policy statement displayed on your website and your website’s Terms of Service in a Microsoft Word document or a PDF.</li> <li>▪ The privacy policy and terms of service must be submitted for any EDE Entity’s website that is collecting consumer data as part of the EDE end-user experience.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Submit via the secure portal</li> <li>▪ If an EDE Entity submitted a privacy policy and Terms of Service during EDE Agreement Renewal in 2019, the Entity may submit an attestation if the privacy policy and Terms of Service will remain unchanged from the language already submitted to CMS.</li> </ul>	<p>Both primary and upstream</p>	<p>Primary EDE Entities: Submit with audit submission.</p> <p>Upstream EDE Entities: Submit after the primary EDE Entity has submitted its audit. There is no deadline to submit the upstream EDE Entity documentation package, but to be reasonably certain an upstream EDE Entity will be approved by November 1, 2020, CMS strongly recommends that EDE Entities submit the required documentation no later than October 1, 2020 or as soon as feasible to allow time to review prior to activating their Partner IDs.</p>



Document	Description	Submission Requirements	Entity Responsible (Upstream/Primary/Both Primary and Upstream/Auditor)	Deadline
<b>Primary and Upstream EDE Entity Documentation Packages—EDE Business Agreement</b>	<ul style="list-style-type: none"> <li>▪ EDE Entities must execute the EDE Business Agreement to use the EDE pathway. The agreement must identify the Entity's selected Auditor(s) (if applicable).</li> <li>▪ CMS will countersign the EDE Business Agreement after CMS has reviewed and approved the EDE Entity's business requirements audit and the privacy and security audit.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Submit via the secure portal</li> </ul>	Both primary and upstream	<p>Primary EDE Entities: Submit with audit submission.</p> <p>Upstream EDE Entities: Submit after the primary EDE Entity has submitted its audit. There is no deadline to submit the upstream EDE Entity documentation package, but to be reasonably certain an upstream EDE Entity will be approved by November 1, 2020, CMS strongly recommends that Entities submit the required documentation no later than October 1, 2020 or as soon as feasible to allow time to review prior to activating their Partner IDs.</p>
<b>Primary and Upstream EDE Entity Documentation Packages—Operational and Oversight Information</b>	<ul style="list-style-type: none"> <li>▪ EDE Entities must submit the operational and oversight information to CMS to use the EDE pathway. This form must be filled out completely.</li> <li>▪ The form is an Excel file that the EDE Entity will complete and submit to CMS.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Submit via the secure portal</li> <li>▪ Primary EDE Entities will receive an encrypted, pre-populated version of the form from CMS</li> <li>▪ Upstream EDE Entities will complete a blank version of the form that is stored on CMS zONE</li> </ul>	Both primary and upstream	<p>Primary EDE Entities: Submit with audit submission.</p> <p>Upstream EDE Entities: Submit after the primary EDE Entity has submitted its audit. There is no deadline to submit the upstream EDE Entity documentation package, but to be reasonably certain an upstream EDE Entity will be approved by November 1, 2020, CMS strongly recommends that Entities submit the required documentation no later than October 1, 2020 or as soon as feasible to allow time to review prior to activating their Partner IDs.</p>
<b>Business Audit Report and Toolkits</b>	<ul style="list-style-type: none"> <li>▪ EDE Entities must submit the Business Requirements Audit Report Template and all applicable toolkits completed by its Auditor(s).</li> <li>▪ See Section VI.A.ii, Business Requirements Audit Resources, for more information.</li> </ul>	<ul style="list-style-type: none"> <li>▪ The EDE Entity and its Auditor(s) must submit the different parts of the Auditor resources package via the secure portal</li> </ul>	Primary and Auditor(s)	April 1, 2020–June 30, 2020

Document	Description	Submission Requirements	Entity Responsible (Upstream/Primary/ Both Primary and Upstream/Auditor)	Deadline
<b>Training</b>	<ul style="list-style-type: none"> <li>▪ EDE Entities (and their Auditors must complete the trainings as outlined in Section VIII, Required Auditor and EDE Entity Training.</li> <li>▪ The trainings are located on REGTAP (located at the following link: <a href="https://www.regtap.info/">https://www.regtap.info/</a>).</li> </ul>	<ul style="list-style-type: none"> <li>▪ The person taking the training must complete the course conclusion pages at the end of each module.</li> <li>▪ The EDE Entity and Auditor are NOT required to submit anything additional to CMS but must print a copy of the training confirmation webpage to provide to CMS, if requested.</li> </ul>	Primary, upstream, and Auditor(s)	Trainings must be completed by EDE Entities and Auditors prior to Audit Submission
<b>HUB Onboarding Form</b>	<ul style="list-style-type: none"> <li>▪ All EDE Entities must submit a new or updated Hub Onboarding Form to request EDE access. If an EDE Entity does not already have a Partner ID, the Hub will create a Partner ID for the EDE Entity upon receiving the Hub Onboarding Form.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Follow instructions on the Hub Onboarding Form (located at the following link: <a href="https://zone.cms.gov/document/hub-onboarding-form">https://zone.cms.gov/document/hub-onboarding-form</a>)</li> <li>▪ Send to <a href="mailto:dsh.support@qssinc.com">dsh.support@qssinc.com</a>.</li> </ul>	Both primary and upstream	Prior to accessing the EDE APIs
<b>Application Technical Assistance and Mini Audit Testing Credentials</b>	<ul style="list-style-type: none"> <li>▪ An EDE Entity must provide application technical assistance and mini audit testing credentials to CMS consistent with the process defined in Sections VI.B, Application Technical Assistance, and X.D, Audit Submission Review, below</li> </ul>	<ul style="list-style-type: none"> <li>▪ Follow instructions on the EDE UI Eligibility Technical Assistance Credentials Form Template on CMS zONE: <a href="https://zone.cms.gov/document/eligibility-information">https://zone.cms.gov/document/eligibility-information</a></li> </ul>	Primary	Submitted no later than the EDE Entity's audit submission date

ii. Business Requirements Audit Resources

CMS has provided the following resources and templates for Auditors to review and/or complete as part of each business requirements audit. The resources will be available on CMS zONE.<sup>53</sup>

CMS will provide an updated Auditor resources package that will contain the following:

- *Business Requirements Audit Report Template:* The template will provide an outline and instructions for the contents of the business requirements audit report. Auditors will use this template to document a prospective EDE Entity's compliance with all business requirements, including those that the Auditor has reviewed using CMS-provided toolkits. Auditors must carefully review the instructions in the EDE Business Audit Instructions and Report Template.
- *Toolkits:* The Auditor resources package will contain multiple toolkits, each of which will correspond with one or more of the business requirements set forth in Exhibit 2. Each toolkit will provide testing scenarios that the Auditor will use to verify the prospective EDE Entity's compliance with the corresponding requirement(s). Each toolkit will contain a template that lists each scenario or requirement and provides a space for the Auditor to indicate the prospective EDE Entity's compliance. The prospective EDE Entity must submit the completed templates to CMS as part of the business requirements audit package. CMS will provide toolkits for the Eligibility Results Testing, API Functional Integration Testing, Application UI, and Consumer Communications requirements.
  - **Note:** CMS will identify baseline versions of each toolkit in early 2020. EDE Entities can use the baseline toolkit versions or a subsequently released version of the toolkit as the basis for the audit submission package for Year 3 of EDE. EDE Entities that begin their audit using the initial baseline toolkit versions are not required to switch to use the updated toolkits. However, CMS may designate specific changes made to subsequent versions of the toolkits as CMS-initiated Change Requests. In order to receive final approval to use EDE, CMS will require EDE Entities to implement any CMS-initiated Change Requests with due dates that have elapsed before the EDE Entity's approval date consistent with the processes defined in Section XI.B, CMS-initiated Change Requests, prior to receiving CMS approval to use the EDE environment. CMS-initiated Change Requests may be issued throughout the year. Prospective EDE Entities should not begin their audits until CMS identifies the baseline toolkits and the Entity has completed its kickoff call and related pre-audit notification requirements (see Section X.A, Pre-Audit Notification to CMS). CMS recommends prospective EDE Entities not delay the start or completion of their audits in the interest of attempting to incorporate as many CMS-initiated Change Requests as possible in their initial audit submissions.

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<sup>53</sup> The Business Audit documentation is available at the following link: <https://zone.cms.gov/document/business-audit>. Auditors can access CMS zONE through the EDE Auditor Community. EDE Entities must download the instructions for accessing the EDE Auditor Community, and provide the instructions to their Auditor(s). The instructions are labeled "accessing\_the\_edc\_auditor\_community.pdf." Auditors will need to be approved by CMS prior to gaining access to the EDE Auditor Community on CMS zONE. Auditor(s) should follow the instructions closely. Failure to do so may delay the EDE Auditor Community zONE approval process.

- **Note:** The Auditor must not modify or delete any language provided in any toolkit or template.
- **Note Regarding Phase-specific Requirements:** The Application UI and Eligibility Results Toolkits contain phase-specific requirements throughout the toolkits. Auditors and prospective EDE Entities must carefully review the **User Guide** tabs of these toolkits for information on how to identify the phase-specific requirements within the toolkits. For example, depending on the EDE Entity’s selected end-state phase, the Auditor may need to complete multiple Eligibility Results Toolkits.

As of February 2020 the Auditor resources package is a zip file that contains, at a high level, the following files for Auditors and prospective EDE Entities to reference:

1. EDE Business Audit Instructions and Report Template – PY2020
2. Application User Interface (UI) Toolkit – PY2020
3. EDE End-to-End Test Data (used as part of the API Functional Integration Toolkit)
4. EDE Eligibility Results Toolkits (three phase-specific versions)
  - EDE Eligibility Results Toolkit - Phase 1 – PY2020
  - EDE Eligibility Results Toolkit - Phase 2 – PY2020
  - EDE Eligibility Results Toolkit - Phase 3 – PY2020
5. Communications Toolkit – PY2020
6. API Functional Integration Toolkit – PY2020
7. Communications Supplemental Content (English)
8. Communications Supplemental Content (Spanish)
9. Application Supplemental Content

## **B. Application Technical Assistance**

### *i. Optional UI Flexibility Consults*

Prior to conducting and submitting an audit, a prospective EDE Entity can request feedback from CMS on its planned application UI build. CMS refers to this as a UI Flexibility Consult. UI Flexibility Consults consist of questions, screenshots, and/or narrative descriptions of a proposed application UI build. EDE Entities should submit UI Flexibility Consults through the secure portal.<sup>54</sup> The purpose of this process is to answer clarifying questions about application requirements and help mitigate the risk that CMS identifies compliance issues during the CMS-conducted mini audit (discussed in Section X.D, Audit Submission Review). Requests should contain specific questions related to UI development such as policy guidance, application requirements and flexibilities, technical design, and high-level application requirements and flow. Prospective EDE Entities should use the form provided by CMS on CMS zONE to request a UI Flexibility Consult.<sup>55</sup>

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<sup>54</sup> Please refer to Section IX, Secure Portal for Document Submission.

<sup>55</sup> “Requesting a UI Flexibility Consult” located at <https://zone.cms.gov/document/eligibility-information>.

A prospective EDE Entity may submit UI Flexibility Consult requests up until the completion of the business requirements audit; upon submission of the audit, the prospective EDE Entity’s application must be finalized. Upon submission of the audit, any Entity-initiated changes—that CMS has not identified and reviewed as part of the audit submission review activities—must follow the process described in Section XI.C, Other EDE Entity-initiated Change Requests.

CMS may release updated application guidance based on feedback received. While CMS may provide UI Flexibility Consult feedback to prospective EDE Entities on the application and UI, the Entity’s Auditor should still include a compliance determination with respect to all requirements consistent with these Guidelines and other guidance.

*ii. Mandatory UI Eligibility Technical Assistance (TA) Review Processes*

The UI Eligibility TA Review process described in this section is a separate process from the optional UI Flexibility Consults (described above) and the audit review and mini audit process discussed in Section X.D, Audit Submission Review. During the UI Eligibility Technical Assistance Review, CMS will access the EDE Entity’s test (pre-production) environment to conduct testing. Similar to the optional UI Flexibility Consults, the purpose of the required UI Eligibility TA Review process is to help mitigate the risk that CMS identifies compliance issues during the CMS-conducted mini audit (discussed in Section X.D, Audit Submission Review).

All prospective EDE Entities must provide testing environment credentials using the EDE UI Eligibility Technical Assistance Credentials Form posted on CMS zONE.<sup>56</sup> Prospective EDE Entities must submit two separate sets of credentials to access their Consumer Pathway, and two separate sets of credentials to access their Agent/Broker Pathway. For example, EDE Entities pursuing both types of pathways will submit four sets of credentials, but Entities pursuing either the consumer pathway or Agent/Broker pathway will submit two sets of credentials. The prospective EDE Entity must ensure that the testing credentials are valid and that all APIs and components of its EDE implementation in its testing environment, including the RIDP services, are accessible for the duration of the UI Eligibility Technical Assistance Review and mini audit. CMS will conduct the UI Eligibility TA Review when an EDE Entity’s UI is complete and ready for review. CMS recommends submitting a UI Flexibility Consult prior to the UI Eligibility TA Review.

Similar to the audit compliance review processes defined in Section X.D, Audit Submission Review, the application TA process will entail multiple rounds of feedback while a prospective EDE Entity attempts to resolve the risks identified by CMS during the UI Eligibility TA Review. This TA process is required, and a prospective EDE Entity may be unable to progress in the audit queue until they have resolved critical risks identified during the TA process.

## **VII. Privacy and Security Audit Requirements and Scope**

An Auditor must complete the Security and Privacy Controls Assessment Test Plan (SAP), which must be submitted to CMS for review prior to initiating the Security and Privacy Controls Assessment (SCA) portion of the audit. The Auditor will complete a privacy and security audit to ensure that the prospective EDE Entity complies with applicable requirements as defined in

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<sup>56</sup> “EDE UI Eligibility Technical Assistance Credentials Form Template” located at <https://zone.cms.gov/document/eligibility-information>.

CMS regulations and these Guidelines. A prospective EDE Entity must submit the resulting privacy and security audit package to CMS. Exhibit 4 describes the review areas and review standards for the privacy and security requirements.

**Exhibit 4. Privacy and Security Requirements**

Review Category	Audit Standards
Privacy and Security Control Implementation	<ul style="list-style-type: none"> <li>▪ <i>Requirement:</i> An EDE Entity must implement security and privacy controls, a fully completed SSP, as well as other privacy and security standards, for protecting the confidentiality, integrity, and availability of the information collected, used, disclosed, and/or retained by the EDE Entity as defined in the ISA, EDE Business Agreement, and applicable laws and regulations prior to conducting the privacy and security audit.</li> <li>▪ <i>Review Standard:</i> The Auditor must conduct a SCA and produce a SAR to certify that the EDE Entity has implemented processes sufficient to meet the privacy and security requirements set forth in the ISA and EDE Business Agreement and in applicable laws and regulations.</li> <li>▪ If the Auditor determines that the EDE Entity does not meet one or more privacy and security requirements, the EDE Entity must create a plan of action and milestones (POA&amp;M) to resolve the deficiency. The POA&amp;M should include a corrective action plan that explains how the EDE Entity will come into compliance with each requirement and will state the estimated completion date for each identified milestone. Monthly reviews and updates are required to be submitted to CMS until all significant findings are resolved based on findings from SCAs, security impact analyses, and continuous monitoring activities outlined in the ISCM Strategy Guide. Auditors must verify that the EDE Entity's website complies with the privacy and security standards, and that the website is consistent with third-party data collection tools and standards defined by CMS in guidance; CMS regulations; and subsequent technical, and training documents. Additional information can be found in the EDE Privacy/Security Standards training module.</li> </ul>

The primary EDE Entity's privacy and security audit boundaries must include any system(s) supporting the Entity's QHP shopping experience if a distinct system or systems hosting QHP shopping exist and the system(s) will exchange and/or store data.<sup>57</sup> If the primary EDE Entity is sharing data with an upstream EDE Entity, the primary EDE Entity must document this arrangement in its ISA Appendix B as a data exchange between the primary EDE Entity and the upstream EDE Entity. If the primary EDE Entity will not share EDE-specific eligibility data received via API from the Exchange (e.g., SVI or DMI information) with the system(s) hosting the Entity's QHP shopping experience (whether the QHP shopping experience is hosted by a primary EDE Entity or an upstream EDE Entity), then the primary EDE Entity must work with its Auditor to fully document the approach the Entity is taking to meet applicable EDE requirements without sharing this data between systems.<sup>58</sup>

**A. Audit Documentation**

*i. Required Privacy and Security Audit Documentation*

The table below contains the required information that prospective primary and hybrid, non-issuer upstream EDE Entities must submit to CMS as part of their Privacy and Security Audits to be approved to participate in EDE.

<sup>57</sup> See, *supra*, notes 21-23.

<sup>58</sup> For example, audit requirements that may be affected by this implementation may include the following: post-enrollment communications requirements and the DMI and SVI action items requirements in the Communications Toolkit.



**Exhibit 5: Privacy and Security Audit Information Requirements**

Document	Description	Submission Requirements	Deadline
<p><b>Interconnection Security Agreement (ISA)</b></p>	<ul style="list-style-type: none"> <li>▪ A prospective primary EDE Entity must submit the ISA to use the EDE pathway.</li> <li>▪ CMS will countersign the ISA after CMS has reviewed and approved the EDE Entity's business requirements audit and privacy and security audit.</li> </ul>	<ul style="list-style-type: none"> <li>▪ A prospective primary EDE Entity must submit the ISA via the secure portal.</li> <li>▪ The ISA contains Appendices that must be completed in full for an EDE Entity to be considered for approval.</li> <li>▪ Appendix B of the ISA must detail: (1) all arrangements with upstream EDE Entities and any related data connections or exchanges, (2) any arrangements involving web-brokers, and (3) any arrangements with downstream agents and brokers that involve limited data collections, as described in Section IV.D., Downstream Third-party Agent and Broker Arrangements.</li> <li>▪ Appendix B of the ISA must be updated and resubmitted as a primary EDE Entity adds or changes any of the arrangements noted above consistent with the requirements in the ISA.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Submit with the audit submission</li> </ul>
<p><b>Security Privacy Controls Assessment Test Plan (SAP)</b></p>	<ul style="list-style-type: none"> <li>▪ This report is to be completed by the Auditor and submitted to CMS prior to initiating the audit.</li> <li>▪ The SAP describes the Auditor's scope and methodology of the assessment. The SAP includes an attestation of the Auditor's independence.</li> </ul>	<ul style="list-style-type: none"> <li>▪ A prospective EDE Entity and its Auditor must submit the SAP completed by its Auditor via the secure portal.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Before commencing the privacy and security audit; during the planning phase</li> </ul>
<p><b>Security Privacy Assessment Report (SAR)</b></p>	<ul style="list-style-type: none"> <li>▪ This report details the Auditor's assessment findings of the prospective EDE Entity's security and privacy controls implementation.</li> </ul>	<ul style="list-style-type: none"> <li>▪ A prospective EDE Entity and its Auditor must submit the SAR completed by its Auditor via the secure portal.</li> </ul>	<ul style="list-style-type: none"> <li>▪ April 1, 2020–June 30, 2020</li> </ul>
<p><b>Plan of Action &amp; Milestones (POA&amp;M)</b></p>	<ul style="list-style-type: none"> <li>▪ A prospective EDE Entity must submit a POA&amp;M if its Auditor identifies any privacy and security compliance issues in the SAR.</li> <li>▪ The POA&amp;M details a corrective action plan and the estimated completion date for identified milestones.</li> </ul>	<ul style="list-style-type: none"> <li>▪ A prospective EDE Entity and its Auditor must submit the POA&amp;M in conjunction with the SAR via the secure portal.</li> <li>▪ POA&amp;Ms with outstanding findings must be submitted monthly to CMS until all the findings from security controls assessments, security impact analyses, and continuous monitoring activities described in the EDE SSP controls CA-5 and CA-7 are resolved. Prospective EDE Entities can schedule their own time for monthly submissions of the POA&amp;M, but must submit an update monthly to CMS until all significant or major findings are resolved. Thereafter, quarterly POA&amp;M submissions are required as part of the ISCM activities.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Initial: April 1, 2020–June 30, 2020</li> <li>▪ Monthly submissions, as necessary, if outstanding findings.</li> <li>▪ Thereafter, consistent with the ISCM Strategy Guide, EDE Entities must submit quarterly POA&amp;Ms by the last business day of March, June, August, and December 2020.</li> </ul>

Document	Description	Submission Requirements	Deadline
Privacy Impact Assessment (PIA)	<ul style="list-style-type: none"> <li>The PIA will detail the prospective EDE Entity's evaluation of its controls for protecting PII.</li> </ul>	<ul style="list-style-type: none"> <li>A prospective EDE Entity is not required to submit the PIA to CMS. However, per the ISA, CMS may request and review an EDE Entity's PIA at any time, including for audit purposes.</li> </ul>	<ul style="list-style-type: none"> <li>Before commencing the privacy and security audit as part of the EDE SSP</li> </ul>
System Security and Privacy Plan (SSP)	<ul style="list-style-type: none"> <li>The SSP will include detailed information about the prospective EDE Entity's implementation of required security and privacy controls.</li> </ul>	<ul style="list-style-type: none"> <li>A prospective EDE Entity is not required to submit the SSP to CMS. However, per the ISA, CMS may request and review an EDE Entity's SSP at any time, including for audit purposes.</li> <li>The implementation of security and privacy controls must be completely documented in the SSP before the audit is initiated.</li> </ul>	<ul style="list-style-type: none"> <li>Before commencing the privacy and security audit</li> </ul>
Incident Response Plan and Incident/Breach Notification Plan	<ul style="list-style-type: none"> <li>A prospective EDE Entity is required to implement breach and incident handling procedures that are consistent with CMS' Incident and Breach Notification Procedures.</li> <li>A prospective EDE Entity must incorporate these procedures into its own written policies and procedures.<sup>59</sup></li> </ul>	<ul style="list-style-type: none"> <li>A prospective EDE Entity is not required to submit the Incident Response Plan and Incident/Breach Notification Plan to CMS. However, per the ISA, CMS may request and review an EDE Entity's Incident Response Plan and Incident/Breach Notification Plan at any time, including for audit purposes.</li> </ul>	<ul style="list-style-type: none"> <li>Before commencing the privacy and security audit as part of the EDE SSP</li> </ul>
Vulnerability Scan	<ul style="list-style-type: none"> <li>A prospective EDE Entity is required to conduct monthly Vulnerability Scans.</li> </ul>	<ul style="list-style-type: none"> <li>A prospective EDE Entity and its Auditor must submit the last three months of their Vulnerability Scan Reports, in conjunction with POA&amp;M and SAR via the secure portal.</li> <li>All findings from vulnerability scans are expected to be consolidated in the monthly POA&amp;M.</li> <li>Similar findings can be consolidated.</li> </ul>	<ul style="list-style-type: none"> <li>Initial: April 1, 2020–June 30, 2020</li> <li>Thereafter, consistent with the ISCM Strategy Guide, EDE Entities must submit Vulnerability Scans annually.</li> </ul>

ii. *Privacy and Security Audit Resources*

CMS will provide the following resources and templates for Auditors to review and/or complete as part of each privacy and security audit. The resources will be available on CMS zONE.<sup>60</sup>

CMS will provide an Auditor resources package that will contain the following<sup>61</sup>:

- Framework for the Independent Assessment of Security and Privacy Controls (Framework):** The Framework will provide an overview of the independent security and privacy assessment requirements. The Auditor should review the Framework prior to conducting the privacy and security audit.

<sup>59</sup> <https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/InformationSecurity/Downloads/RMH-Chapter-08-Incident-Response.pdf>.

<sup>60</sup> The Privacy and Security Audit documentation is available at the following link: <https://zone.cms.gov/document/privacy-and-security-audit>.

<sup>61</sup> The resource templates are available at the following link: <https://zone.cms.gov/document/privacy-and-security-audit>.



- **System Security and Privacy Plan (SSP) Workbook and Final SSP:** The prospective EDE Entity will use the SSP Workbook to create a final SSP, which will include detailed information about the prospective EDE Entity's implementation of security and privacy controls. The Auditor will review the SSP Workbook and final SSP to make its assessment of the prospective EDE Entity's compliance with the required privacy and security controls.
- **Security and Privacy Controls Assessment Test Plan (SAP) Template:** The SAP will contain a high-level description of the critical items that the Auditor must test. The Auditor and the prospective EDE Entity must supply this document and submit it to CMS for review prior to conducting the privacy and security audit.
- **Security & Privacy Assessment Report (SAR) Template:** The Auditor is required to use this template to document the audit findings on whether or not the prospective EDE Entity has implemented the required privacy and security controls correctly.
- **Plan of Action and Milestones (POA&M) Template:** The prospective EDE Entity will be required to use this template to create a POA&M. The POA&M entries are created within thirty (30) days of the final results for every internal/external audit/review or test (e.g., security controls assessment, penetration test) to document the EDE Entity's planned remedial actions to correct weaknesses or deficiencies noted during the assessment of the security and privacy controls and to reduce or eliminate known vulnerabilities. The POA&Ms should be submitted to CMS by prospective EDE Entities monthly until all significant vulnerabilities are remediated. For Year 3 of EDE, CMS requires approved primary EDE Entities and hybrid, non-issuer upstream EDE Entities to submit quarterly POA&Ms by the last business day of March, June, August, and December 2020.
- **Information Security and Privacy Continuous Monitoring (ISCM) Strategy Guide:** The ISCM Strategy Guide provides the minimum requirements for an EDE Entity to implement an ISCM program for its systems and to maintain ongoing CMS authorization and approval to participate in EDE. ISCM provides a mechanism for an EDE Entity to identify and respond to new vulnerabilities, evolving threats, and constantly changing enterprise architecture and operational environment, such as changes in the hardware or software, as well as data creation, collection, disclosure, access, maintenance, storage, and use. Ongoing assessment and authorization provides CMS a method of detecting changes to the security and privacy posture of an EDE Entity's IT system that are essential to making well-informed, risk-based decisions. Approved primary EDE Entities and hybrid, non-issuer upstream EDE Entities are required to submit ISCM packages, including the third quarter POA&M, by August 31, 2020.

## VIII. Required Auditor and EDE Entity Training

The Auditor(s) selected by the prospective EDE Entity (including an existing primary EDE Entity seeking to change phases)<sup>62</sup> and representative(s) from the EDE Entities (both prospective and existing) are required to take CMS-mandated training, as summarized in Exhibit 6.

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<sup>62</sup> See, *supra*, note 4.

**Exhibit 6: Auditor and EDE Entity Training Requirements**

Business Requirements Auditor Training Requirements	Privacy and Security Auditor Training Requirements	Prospective EDE Entity Training Requirements	Existing EDE Entity Training Requirements
<ul style="list-style-type: none"> <li>• An Auditor who will be completing the business requirements audit must complete the following training modules before initiating that audit:               <ul style="list-style-type: none"> <li>- EDE Regulatory/Compliance Standards,</li> <li>- EDE Application UI Overview,</li> <li>- EDE ORR and CMS Reporting Requirements, and</li> <li>- EDE UI Services.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• An Auditor who will be completing the privacy and security audit must complete the following training modules before initiating the audit:               <ul style="list-style-type: none"> <li>- EDE Regulatory/Compliance Standards and</li> <li>- EDE Privacy/Security Standards.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• <b>Primary EDE Entities:</b> Representative(s) from the prospective primary EDE Entity must take all training modules. The same representative does not need to take all trainings, if only a few are relevant to their job area; however, each module must be completed by at least one representative from the EDE Entity.</li> <li>• <b>Upstream EDE Entities:</b> CMS requires representatives from upstream entities to take the following three training modules. The same representative does not need to take all trainings, if only a few are relevant to their job area; however, each module must be completed by at least one representative from the EDE Entity:               <ul style="list-style-type: none"> <li>- EDE Regulatory/Compliance Standards,</li> <li>- EDE ORR and CMS Reporting Requirements, and</li> <li>- EDE Privacy/Security Standards.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• <b>Existing EDE Entities:</b> Representative(s) from the existing primary and upstream EDE Entities must retake the following three updated training modules:               <ul style="list-style-type: none"> <li>- EDE Regulatory/Compliance Standards</li> <li>- EDE ORR and CMS Reporting Requirements, and</li> <li>- EDE Privacy/Security Standards.</li> </ul> </li> </ul>

All Auditor representatives responsible for conducting the business requirements audit and/or the privacy and security audit must take the required trainings relevant to the audit(s) they are conducting. The same individual from each respective EDE Entity and Auditor does not need to complete all trainings; in this situation, CMS expects that an individual would take the training most suited to the individual’s role in conducting the audit or implementing the EDE environment. However, each module must be completed by at least one representative from the Auditor and EDE Entity.

The trainings are self-paced computer-based trainings (CBTs) and provide information about compliance, EDE technical requirements, privacy and security, and reporting requirements. CMS will release further information regarding the trainings via REGTAP and anticipates the trainings

for Year 3 of EDE will become available beginning in early 2020. All training modules will be posted on REGTAP as they become available.<sup>63</sup>

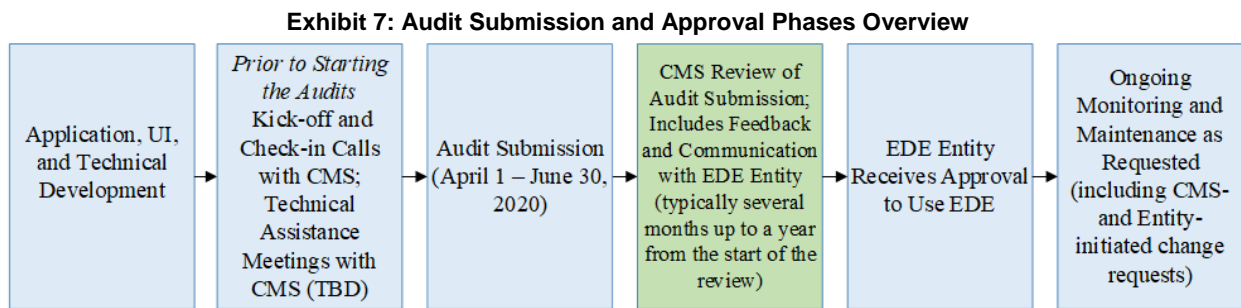
Trainings from the PY 2020 OEP approval process (Year 2 of EDE) are still available on REGTAP; however, CMS will release updates to these modules in early 2020 for Auditors and EDE Entities to take the revised modules (i.e., trainings for Year 3 of EDE). EDE Entities and their Auditors may take the existing trainings from Year 2 of EDE that currently exist on REGTAP prior to starting the audit instead of waiting for the updated trainings. EDE Entities and their Auditors who use this option must still take the updated trainings prior to submitting the audit. EDE Entities and their Auditors will be accountable for any updates in the updated trainings if they take this approach (i.e., they take the trainings from Year 2 of EDE prior to taking the trainings for Year 3 of EDE). EDE Entities and Auditors must take all of the updated modules listed above that CMS releases for Year 3 of EDE.

### IX. Secure Portal for Document Submission

CMS requires EDE Entities to submit documents to CMS via a secure portal. After the Entity informs CMS that it has entered into an agreement with its Auditor(s), CMS will provide the Entity with instructions to establish an account on the secure portal that the Entity will use to access and upload documents to the portal. CMS will also provide written instructions for using the secure portal via email at that time. CMS will not require EDE Entities to encrypt documents containing proprietary information before uploading them to the portal.

### X. Approval Process and Audit Submission Window

As shown in Exhibit 7, the EDE approval process consists of several phases. Additional information is provided below.



#### A. Pre-Audit Notification to CMS

Once an Entity has contracted with an Auditor(s) to complete the two parts of the ORR, the Entity’s privacy and security Auditor must complete the SAP. This must be submitted to CMS for review prior to conducting the privacy and security audit. The Entity must also submit a copy of the signed agreement or contract between the Auditor(s) and Entity as part of the notice of intent. The contract must describe the Auditor’s entire scope of work and include provisions consistent with 45 C.F.R. § 155.221(f). The Entity may redact information (e.g., pricing and proprietary information) that is not necessary for CMS review. The Entity must notify DE Support ([directenrollment@cms.hhs.gov](mailto:directenrollment@cms.hhs.gov)) before its Auditor begins its audits (at least one to two weeks prior). CMS will schedule a kickoff call with the Entity and the Auditor(s) before the

<sup>63</sup> REGTAP can be accessed at the following link: <https://www.regtap.info/>.

audits are initiated to answer questions, ensure expectations are clear, and ensure the Auditor(s) and Entity are using the correct audit documents. Additional check-in calls may be scheduled.

### ***B. Audit Submission Deadlines***

Prospective primary EDE Entities interested in implementing EDE in calendar year 2020 (including an existing primary EDE Entity seeking to change phases)<sup>64</sup> must submit business requirements and privacy and security audits during the audit submission window from April 1, 2020–June 30, 2020. CMS will not accept audits received outside of this submission window for initial approval as a primary EDE Entity or for phase changes.<sup>65</sup> There is no guarantee that every prospective primary EDE Entity that submits an audit in the submission window will receive approval to go live with EDE before the start of the PY 2021 OEP or even during calendar year 2020. If a prospective EDE Entity submits an audit, and then resubmits its audit before receiving feedback from CMS, 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 submitted.

If a prospective primary EDE Entity intends to submit its audit during the April 1, 2020–June 30, 2020 submission window, it should submit its notice of intent to [directenrollment@cms.hhs.gov](mailto:directenrollment@cms.hhs.gov) by April 1, 2020. If an Entity submits an incomplete audit, once the Entity resubmits its audit, CMS will prioritize that resubmitted audit at the end of the review queue. CMS does not guarantee any approval timelines.

For calendar year 2020, CMS will conduct completeness reviews<sup>66</sup> on all prospective primary EDE Entity audits submitted during the audit submission window. CMS does not guarantee that an Entity will have an opportunity to correct an incomplete audit submission within the audit submission window. If CMS deems an audit incomplete or if the EDE Entity submits the remedial documentation after the audit submission window has closed (June 30, 2020 at 3:00 AM ET), the next opportunity the prospective primary EDE Entity would have to attempt to submit an audit would be during the next audit submission window.<sup>67</sup>

As previously stated, the EDE approval process typically takes several months, and may take a year or more depending on the selected end-state phase, the quality of the build of the EDE environment, the quality of the audit and documentation submitted to CMS, and the quality and timeliness of resubmissions. Based on CMS's experience with prior audits, prospective primary EDE Entities that submit complete audits later in the audit window (i.e., mid-to-late May through June), depending on the quality of the submission and phase, have a low probability of going live before the subsequent OEP.

CMS expects to issue updated trainings (required for both Auditors and representatives of EDE Entities), agreements, and baseline toolkits for the April 1, 2020–June 30, 2020 audit submission window in early 2020. CMS expects to primarily use the same content as the materials released

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<sup>64</sup> See, *supra*, note 4.

<sup>65</sup> CMS will accept prospective hybrid, non-issuer upstream EDE Entity privacy and security and business requirements audits on a rolling basis.

<sup>66</sup> Please refer to Section X.C, Completeness Requirements.

<sup>67</sup> Similar to the audit windows for 2019 and 2020, CMS expects to open an audit submission window in early calendar year 2021.

in 2019 for PY 2020, with updates to reflect any new applicable guidelines or standards. Accordingly, prospective primary 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>68</sup> CMS will continue to update these toolkits throughout the audit submission window and after it closes. EDE Entities must use at least the baseline version of the toolkits for the audit submission (as designated by CMS prior to the audit window), but can choose to use a later, updated version of a toolkit, if available. Important note: EDE Entities are only required to build to the baseline version of each toolkit for the audit submission. All subsequent toolkit updates that the EDE Entity must implement will be released as CMS-initiated Change Requests.<sup>69</sup>

### C. *Completeness Requirements*

#### i. *Submitting a Complete Business Requirements Audit*

CMS will review each business requirements audit submission for completeness. CMS will not accept incomplete audits. A complete business requirements audit submission meets the criteria described in Exhibit 8, at a minimum.

**Exhibit 8: Business Requirements Audit Submission Requirements for a Complete Audit**

Toolkit & Template	Minimum Requirements for a Complete Audit
All Toolkits	<ul style="list-style-type: none"> <li>▪ Provide complete Auditor documentation (i.e., required columns indicated for Auditor results contain details regarding the Auditor's evaluation of the requirement, including compliance status, risks, and mitigation strategies (if applicable)). The Auditor's evaluation must contain no ambiguous language about potential unmitigated risks (e.g., stating that the Auditor has identified risks, or the prospective EDE Entity has mitigated the risks without a description of the risks or mitigation strategies).</li> <li>▪ Complete screenshots that demonstrate all reviewed content without missing, obscured, or cut-off elements that are required to evaluate compliance with the requirements represented by the screenshot.</li> <li>▪ All required rows, across all required tabs, of each toolkit are completed. Auditors should refer to the Auditor User Guide tab of each Toolkit to identify required tabs, columns, and rows.</li> <li>▪ Risks identified during the course of the audit must be documented and explained, even if the EDE Entity has subsequently mitigated the risks (i.e., a history of initial risk identification and attempted mitigation through any and all subsequent reviews and mitigation attempts should be documented to enable CMS to understand the original and subsequent risks identified and how all risks were mitigated).</li> <li>▪ Note: For any issues or risks identified during the completeness review that are attributable to CMS-confirmed Exchange defects, CMS will not hold prospective EDE Entities responsible for such defects; however, the prospective EDE Entity must confirm the defect exists with CMS help desk teams<sup>70</sup> and document that the issue exists in the applicable Toolkit or Business Audit Report.</li> </ul>

<sup>68</sup> The Business Audit documentation is located at the following link: <https://zone.cms.gov/document/business-audit>. The Privacy and Security Audit documentation is located at the following link: <https://zone.cms.gov/document/privacy-and-security-audit>. Generally, EDE documents and materials will be posted at the following link on CMS zONE: <https://zone.cms.gov/document/enhanced-direct-enrollment>. Note that prospective EDE Entities must set up a CMS Enterprise Portal account and request CMS zONE access to view the CMS zONE website. 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>69</sup> Please refer to Section XI.B, CMS-initiated Change Requests, for more information.

<sup>70</sup> Please refer to Section XII.A, Help Desk, for more information on submitting tickets to the appropriate CMS help desk.

Toolkit & Template	Minimum Requirements for a Complete Audit
Communications Toolkit	<ul style="list-style-type: none"> <li>▪ Screenshots that demonstrate compliance (in English and Spanish, if applicable) when the applicable requirements require screenshots to be provided as evidence under the <b>Requirements</b> tab in the toolkit.</li> <li>▪ Complete screenshots for each requirement that has a designated screenshot requirement.</li> </ul>
Application User Interface (UI) Toolkit	<ul style="list-style-type: none"> <li>▪ Clear assessment of the Spanish-language application, if applicable, consistent with the <i>Frequently Asked Questions (FAQs) Regarding Spanish Translation and Audit Requirements for Enhanced Direct Enrollment (EDE) Entities Serving Consumers in States with FFEs</i>.<sup>71</sup></li> <li>▪ The Application UI Toolkit must be reviewed in full and documented appropriately (see the “All Toolkits” minimum requirements above) for the applicable phase, which includes all UI elements included in that phase (e.g., an audit of a phase 3 application would include application questions that are also applicable to phases 1 and 2, as well as application questions specific to phase 3 only). Note: The test cases in the Eligibility Results Toolkits do not cover all questions or requirements in the Application UI Toolkit. As a result, Auditors must develop a methodology to ensure each element of the Toolkit is evaluated.</li> </ul>
Eligibility Results Toolkit(s)	<ul style="list-style-type: none"> <li>▪ Screenshots of the entire application flow are provided for each test case from either the coverage year and coverage state questions (items #1 and #2 in the Application UI Toolkit) or the privacy notice disclaimer (item #3 in the Application UI Toolkit), whichever comes first in the Entity’s environment, through the entire application including the eligibility results page.</li> <li>▪ A screenshot depicting the eligibility results page with correct eligibility results and EDN are provided for each test case. The eligibility results must not differ between the eligibility results page and the EDN, and every element of the eligibility results should be correctly represented.</li> <li>▪ A copy of the JSON from a Get App API Response for the application version depicted in the screenshots for each test case.</li> <li>▪ CMS will review the eligibility results page and the EDN for the correct results for each applicant based on the Toolkits and consistent results between the eligibility results page and the EDN for the following elements: <ul style="list-style-type: none"> <li>– Exchange OEP or SEP eligibility (QHP);</li> <li>– Advance payments of the premium tax credit (exact amount, if applicable);</li> <li>– CSRs;</li> <li>– Medicaid eligibility;</li> <li>– CHIP eligibility;</li> <li>– SVIs; and</li> <li>– Non-MAGI Medicaid Referral.</li> </ul> </li> <li>▪ Each phase has its own Eligibility Results Toolkit. Phase 1 EDE Entities must complete all phase 1 test cases. Phase 2 EDE Entities must complete all phase 2 test cases and some of the phase 1 test cases. Phase 3 EDE Entities must complete all phase 3 test cases and some of the phase 1 and phase 2 test cases. Please refer to the User Guide tab in the Eligibility Results Toolkits for more specific test case instructions. Please note, depending upon an Entity’s planned service areas, it may need to request modifications to test cases, as described in the User Guide tab in the Eligibility Results Toolkits.</li> </ul>
API Functional Integration Toolkit	<ul style="list-style-type: none"> <li>▪ Correct results and successful completion of each test case is documented. <ul style="list-style-type: none"> <li>– If an EDE Entity will provide both a Consumer and an Agent/Broker pathway, the submission must include documentation reflecting the expected results for each pathway.</li> </ul> </li> <li>▪ Successful completion of the DMI and SVI test cases consistent with the Toolkit’s instructions.</li> <li>▪ Successful submission of all required evidence outlined in the “Required Evidence” column, Column H, on the “Test Cases” tab within the API Functional Integration Toolkit.</li> </ul>

<sup>71</sup> *Frequently Asked Questions (FAQs) Regarding Spanish Translation and Audit Requirements for Enhanced Direct Enrollment (EDE) Entities Serving Consumers in States with FFEs* (June 20, 2018) provides further information regarding translation and audit requirements: <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/FAQ-EDE-Spanish-Translation-and-Audit-Requirements.PDF>.

Toolkit & Template	Minimum Requirements for a Complete Audit
EDE Business Audit Report Template	<ul style="list-style-type: none"> <li>▪ Complete descriptions of each requirement; Auditors must not exclude required review criteria from their review and description of each requirement (e.g., the Requirement and Review Standard criteria for each business requirement).</li> </ul>
Supplemental Documentation	<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 Report or toolkits.</li> </ul>

An incomplete business requirements audit is an audit that does not meet the criteria described above. The Auditor must take the appropriate actions to complete the incomplete audit and the prospective EDE Entity must resubmit it, as applicable. Please review Section X.B, Audit Submission Deadlines, for more information.

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 be pulled from the review queue. Consistent with the deadlines in Section X.B, Audit Submission Deadlines, 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.

Audits should not include comments that describe the Auditor’s process for verifying the requirement unless there is a specific issue or concern with respect to the requirement that warrants raising the concern to CMS.

*ii. Submitting a Complete Privacy and Security Audit*

CMS will review each privacy and security audit submission for completeness. CMS will not accept incomplete audits. A complete security audit submission meets the criteria described in Exhibit 9, at a minimum.

**Exhibit 9: Privacy and Security Audit Submission Requirements for a Complete Audit**

Document	Minimum Requirements for a Complete Audit
Security and Privacy Controls Assessment Test Plan (SAP)	<ul style="list-style-type: none"> <li>▪ The SAP describes the Auditor’s scope and methodology of the assessment.</li> <li>▪ The SAP includes an attestation of the Auditor’s independence.</li> <li>▪ The SAP must be completed by the Auditor and submitted to CMS for review, prior to conducting the security and privacy controls assessment (SCA).</li> </ul>
Security Assessment Report (SAR)	<ul style="list-style-type: none"> <li>▪ The SAR is not a living document; findings should not be added/removed from the SAR unless CMS’ 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 that 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>



Document	Minimum Requirements for a Complete Audit
Plan of Action and Milestones (POA&M)	<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>▪ Ensure scheduled completion dates, milestones with dates, and appropriate risk levels are included.</li> </ul>

An audit that does not meet the criteria described above is an incomplete privacy and security audit. The Auditor must take the appropriate actions to complete the incomplete audit and the prospective EDE Entity must resubmit it, as applicable. Consistent with the deadlines in Section X.B, Audit Submission Deadlines, prospective EDE Entities with incomplete audits must resubmit complete audits and will not be reviewed further until the Entity submits an audit that CMS reviews and deems complete consistent with the completeness criteria in this section.

***D. Audit Submission Review***

After determining that a prospective EDE Entity’s audit is complete, CMS will conduct a thorough compliance review of the entire audit package. CMS will review this content with subject matter experts and generate compliance findings for the Entity to resolve. On both the privacy and security audit and the business requirements audit, the Entity should expect to receive multiple rounds of feedback from CMS. This process may take several months or more (e.g., potentially a year or more) to resolve all critical risks that the Entity must address prior to advancing in the audit queue. In order to progress through the audit queue, an Entity must thoroughly address the risks identified by CMS and provide sufficient documentation of the resolution of the risk(s). When CMS confirms that a prospective EDE Entity has resolved the critical risks identified during the compliance review of the business requirements audit package and any feedback from the CMS TA team, the EDE Entity will progress to the mini audit phase of the review process. During this next phase, CMS will conduct a mini audit of the Entity’s application prior to providing final approval of the Entity’s EDE environment. The mini audit is not intended to replicate an Auditor’s review of a prospective EDE Entity’s EDE environment; the mini audit focuses on reviewing a subset of eligibility scenarios for compliance. The prospective EDE Entity must not make changes to its EDE environment after submitting its audit package, unless instructed by CMS or following the Entity-initiated CR protocol.

CMS will review any compliance issues identified during the mini audit and provide written feedback to the prospective EDE Entity of changes that the prospective EDE Entity will be required to make prior to final approval. The prospective EDE Entity must submit proof that it implemented the required changes to CMS. CMS will subsequently provide further feedback or approval.

Throughout the compliance review and mini audit process, CMS will regularly provide the prospective EDE Entity with a checklist that describes the prospective EDE Entity’s progress through the EDE approval process. This checklist will allow a prospective EDE Entity to confirm the status of their audit submission and any required documentation that must be submitted to CMS. CMS will establish status calls with a prospective EDE Entity that has



submitted complete audits after CMS has provided compliance feedback to the prospective EDE Entity.

### ***E. Final Approval Process***

CMS strongly encourages each prospective EDE Entity to request technical assistance from CMS per the process defined in Section VI.B.i, Optional UI Flexibility Consults. CMS requires entities follow the process discussed in Section VI.B.ii, Mandatory UI Eligibility Technical Assistance (TA) Review Processes, and strongly encourages Entities to respond quickly and thoroughly to any feedback that CMS provides as part of that process. Once the Entities submit a complete audit (as defined above), CMS will review and approve prospective EDE Entities to use the EDE pathway on a first-come, first-served basis. Prospective EDE Entities must submit their initial documentation no later than June 30, 2020 for their audit to be reviewed and potentially approved for the PY 2021 OEP (please review Sections I, Summary, and X.B, Audit Submission Deadlines, for more information). CMS encourages prospective EDE Entities to submit as early as possible in the audit submission window (but no earlier than April 1, 2020); however, prospective EDE Entities should *not* submit incomplete audits, audits with material deficiencies, or audits that evaluated incomplete EDE environments or systems.<sup>72</sup> Once an audit is deemed complete, CMS will review the audit submission for compliance and will work with the Entity to carry out the next steps in the approval process and will provide additional feedback.

CMS will notify prospective EDE Entities on a rolling basis of approval to use the EDE pathway. Prospective EDE Entities may not be approved in the order in which their audits were submitted because the content and quality of the audit submissions vary substantially and that affects the amount of time it takes to review and approve a prospective EDE Entity's EDE environment. CMS will countersign a prospective EDE Entity's EDE Business Agreement and ISA after CMS reviews and approves the Entity's business requirements audit package and privacy and security audit package, and after it confirms that the Entity's EDE environment is functional. After CMS countersigns the EDE Business Agreement and the ISA, CMS will inform the Entity of the subsequent steps to connect its EDE environment to the EDE pathway.

### ***F. Post-EDE-Approval Oversight Processes***

After CMS issues final approval, it will conduct periodic, post-go-live mini audits. If CMS identifies compliance issues during these mini audits, CMS may immediately suspend the EDE Entity's EDE environment's connection to the EDE pathway until the Entity has addressed any identified compliance issues to CMS' satisfaction. If CMS identifies any compliance issues likely to affect a consumer's eligibility application or results during a post-go-live mini audit, CMS may require the EDE Entity to contact consumers to collect the appropriate eligibility information and resubmit applications that may have been affected by the compliance issues.

CMS may, at its discretion, conduct mini audits following any post-approval changes (see Section XI, Processes for Changes to an Audited or Approved EDE Environment) in an EDE Entity's EDE environment.

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<sup>72</sup> Please refer to Section X.C, Completeness Requirements, regarding the audit completeness criteria.

## **XI. Processes for Changes to an Audited or Approved EDE Environment**

### **A. EDE Entity-initiated EDE Phase Change Requests**

#### *i. Business Requirements Audit*

If an EDE Entity opts to change to a different EDE application phase (from its approved or audited EDE phase), the Auditor must conduct portions of a revised business requirements audit to account for the changes to the EDE Entity's EDE environment necessary to implement the newly selected phase and to confirm compliance with all applicable EDE requirements. CMS will review business requirements audit submissions for new phases as if they were initial audit submissions. Any phase change business requirements audit submissions must be received during an audit submission window. See Section X.B, Audit Submission Deadlines.

Exhibit 10 indicates the required materials an EDE Entity must have an Auditor complete for the business requirements audit for an EDE Entity to transition to a new application phase.

**Exhibit 10: Business Audit Phase Change Requirements**

Business Audit Documentation	Business Audit Phase Change Requirements
Business Audit Report	<ul style="list-style-type: none"> <li>▪ For all phase CRs, the EDE Entity's Auditor must document compliance with the business review categories (and the associated toolkits):               <ul style="list-style-type: none"> <li>– Consumer Identity Proofing Implementation</li> <li>– Phase-dependent Screener Questions (EDE Phase 1 and 2 EDE Entities Only) (if applicable)</li> <li>– Accurate and Streamlined Eligibility Application User Interface (UI)</li> <li>– Post-eligibility Application Communications</li> <li>– Accurate Information about the Exchange and Consumer Communications</li> <li>– Eligibility Results Testing and SES Testing</li> <li>– API Functional Integration Requirements</li> <li>– Application UI Validation</li> <li>– Section 508-compliant UI</li> <li>– Non-English-language Version of the Application UI and Communication Materials (if applicable)</li> <li>– Agent and Broker Identity Proofing Verification (if applicable)</li> <li>– EDE Change Management Process</li> </ul> </li> </ul>
Application UI Toolkit	<ul style="list-style-type: none"> <li>▪ For all phase CRs, the EDE Entity's Auditor must complete the entirety of the Application UI Toolkit for the EDE Entity's new phase. This includes the screening questions tabs (for Phase 1 or Phase 2 EDE Entities only), the UI Questions tab, the High-Level Requirements tab, and the Eligibility Results tab.</li> </ul>
Eligibility Results Toolkit	<ul style="list-style-type: none"> <li>▪ For all phase CRs, the EDE Entity's Auditor must complete all of the relevant test cases for the applicable EDE Entity's phase. For example, if an EDE Entity is changing to Phase 3, the Auditor must complete and submit evidence for all test cases, as noted in the "Auditor User Guide" tab, including the documentation for the applicable test cases in the Phase 1 and Phase 2 Eligibility Results Toolkits.</li> </ul>
Communications Toolkit	<ul style="list-style-type: none"> <li>▪ For phase changes to phase 3 or down from phase 3, the EDE Entity's Auditor must re-evaluate the compliance of any phase-specific requirements as defined in the Communications Toolkit.</li> </ul>
API Functional Integration Toolkit	<ul style="list-style-type: none"> <li>▪ For all phase CRs, the EDE Entity's Auditor must complete all test cases within the API Functional Integration Toolkit.</li> </ul>

ii. *Privacy and Security Audit*

EDE Entities will not need to submit additional privacy and security documentation specifically for an EDE application phase change.

**B. CMS-initiated Change Requests**

i. *CMS-initiated Change Request Process*

CMS will periodically release updates to EDE program requirements in the form of CMS-initiated CRs. Usually, these changes will take the form of an update to one of the business report toolkits. CMS may require EDE Entities to implement new or updated EDE requirements, including updates to business requirements audit toolkit versions that are released after the date of the CMS-designated baseline version of each toolkit. These required revisions will be considered CMS-initiated CRs.

EDE Entities have two options to implement required revisions:

- Submit supplemental documentation; or
- Have their Auditor review the required revision as part of the business requirements audit. For example, if the required revision is in a toolkit, the Auditor will use the version of the toolkit containing the revision(s) to complete the business requirements audit.

– **Note:** The EDE Change Request Tracker is stored on CMS zONE.<sup>73</sup>

All EDE Entities participating in EDE must implement CMS-initiated CRs. However, depending on when an EDE Entity submits its business requirements audit in relation to when CMS notifies EDE Entities about a required CR, the CR may be audited as part of the business requirements audit or the EDE Entity may demonstrate that it has implemented the CR as part of a separate process. Specifically:

- EDE Entities that have already submitted their business requirements audit before the CR is released must submit evidence of their implementation of the CR in clearly labeled supplemental documentation, rather than have their Auditor re-review the portion of the audit affected by the CR.
- EDE Entities that submit their audits after the CR is released, but before the implementation deadline have two options: (1) they may have their Auditor review the CR as part of the business requirements audit or (2) they may provide clearly labeled supplemental documentation of their implementation of the CR anytime up until the implementation deadline stated in the EDE Change Request Tracker (explained below).
- EDE Entities that submit their audits after the CR implementation deadline will be required to submit documentation of their implementation of the CR with their audit submission (either incorporated in the Auditor's review or in clearly labeled supplemental documentation).

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<sup>73</sup> The EDE Change Request Tracker is located on CMS zONE: <https://zone.cms.gov/document/business-audit>.

*ii. CMS Change Request Tracker*

CMS will specify the changes that EDE Entities are required to implement via the EDE Change Request Tracker, which is posted on CMS zONE.<sup>74</sup>

The EDE Change Request Tracker is a spreadsheet containing information about each CMS-initiated CR, including a description of each CR; the EDE document in which the CR appears; whether the EDE Entity must submit documentation to demonstrate compliance and, if so, the type of documentation the EDE Entity must submit (e.g., if EDE Entities must submit screenshots or some other type of evidence of implementation); the deadline for submission of documentation; the method of submission of required documentation; and conditional requirements, if applicable. The Change Request Tracker only describes the CR; the EDE Entity must review the CR within the identified EDE document.

*iii. Deadlines for Implementation of Required Changes and Potential Penalties*

CMS will attempt to provide as much notice to EDE Entities as feasible regarding CMS-initiated CRs. Per the EDE Business Agreement, CMS will provide a timeline for each CMS-initiated CR for EDE Entities to implement the change. While CMS anticipates that this will be a rare occasion, some CMS-initiated CRs may require significant revisions to the EDE environment that would require independent verification by a third-party Auditor. CMS will attempt to provide more advance notice to EDE Entities in the event CMS requires a CMS-initiated CR of this type.

If an EDE Entity does not timely submit documentation of its implementation of such CRs, CMS may suspend the non-compliant EDE Entity's access to the EDE pathway. If an EDE Entity does not meet the deadline to provide evidence of implementation of the CR and has not already been approved to participate in EDE, the EDE Entity will not be approved until after the appropriate documentation is submitted.

*iv. Implementation of Other Changes*

CMS will periodically release updates to EDE documentation that are not included in the Change Request Tracker. These updates include clarifications, technical corrections, and content updates. These types of updates do not amount to changes in business requirements and accordingly will not be communicated through the Change Request Tracker. Instead, these changes will be noted through release of new versions of EDE documentation and communicated through EDE partner calls, e-blasts, and other technical assistance channels.

While proof of implementation is not required for this category of changes, EDE Entities are strongly encouraged to pay close attention to and implement these updates where appropriate, as failure to do so may result in validation or other errors or have other adverse impacts on an EDE Entity's environment.

If an EDE Entity is making a change to its EDE environment consistent with this subsection (Section XI.B.iv, Implementation of Other Changes), the EDE Entity must review the Change

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<sup>74</sup> The EDE Change Request Tracker is located on CMS zONE: <https://zone.cms.gov/document/business-audit>.

Notification Procedures for Enhanced Direct Enrollment Entity Information Technology Systems document consistent with Section XI.C, Other EDE Entity-initiated Change Requests.

### ***C. Other EDE Entity-initiated Change Requests***

If an EDE Entity wishes to make changes to its audited or approved EDE environment that are not in response to an auditor’s documented findings, CMS feedback, or compliance findings, the EDE Entity must follow the process defined in the Change Notification Procedures for Enhanced Direct Enrollment Entity Information Technology Systems and the Change Notification Form for Enhanced Direct Enrollment Entities Information Technology Systems located on [CMS zONE](#). This process is specific to other EDE Entity-initiated changes—including those changes defined in Section XI.B.iv, Implementation of Other Changes—and does not include EDE Entity-initiated EDE phase CRs (Section XI.A, EDE Entity-initiated EDE Phase Change Requests above) or CMS-initiated CRs (Section XI.B, CMS-initiated Change Requests above). The EDE Entity must continue to comply with requirements of the configuration management control family as outlined in the Non-Exchange Entities (NEE) Security and Privacy Plan (SSP) workbook.<sup>75</sup> All changes must be tested, validated, and documented before implementing the changes in the operational system.

## **XII. Resources**

### ***A. Help Desk***

In addition to hosting weekly webinars inclusive of interactive question and answers, CMS currently manages multiple EDE Entity-facing help desks to address questions; help EDE Entities and prospective EDE Entities resolve technical problems, operational issues, and other issues, and respond to policy questions. An Entity must either remove PII in documents before sending them to the help desks or encrypt the e-mail transmitting the PII.

- An EDE Entity with technical issues or questions that concern its technical build or system issues identified in the test or production environment should email both [CMS.FFM.EDESupport@accenturefederal.com](mailto:CMS.FFM.EDESupport@accenturefederal.com) and [CMS\\_FEPS@cms.hhs.gov](mailto:CMS_FEPS@cms.hhs.gov) with the subject line “EDE: Tech Q for [Partner] on [Topic].” An EDE Entity may also use the same Help Desks to send technical questions asked by its Auditor(s).
- An EDE Entity with technical questions related to Hub access or connectivity with any of the EDE APIs or services, or with questions about testing or approval to use the RIDP/FARS services should email both [dsh.support@qssinc.com](mailto:dsh.support@qssinc.com) and [CMS\\_FEPS@cms.hhs.gov](mailto:CMS_FEPS@cms.hhs.gov) with the subject line “EDE: Tech Q for [Partner] on [Topic].” An EDE Entity may also use the same Help Desks to send related questions asked by its Auditor(s).

For a timely response, the EDE Entity representative submitting the question should ensure that emails to the Help Desks include the following information:

- Your contact information (e-mail and phone number).

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<sup>75</sup> The NEE SSP workbook is available on the EDE Documents and Materials webpage on CMS zONE: <https://zone.cms.gov/document/privacy-and-security-audit>.

- Name of your organization and either your organization’s five-character Health Insurance Oversight System (HIOS) ID (if an existing issuer) or CMS-issued Partner ID (if an existing web-broker).
- At the top of your email, please summarize whether your e-mail concerns an EDE technical question, testing issue, or production issue, where possible. Additionally, please note the environment where the issue was encountered, if applicable. This summary will enable the Help Desk to route the email to the right SME for a more efficient response.
- If reporting on a technical issue you encounter in production or while testing EDE, please include the request/response XMLs/JSONs (API requests and responses) for troubleshooting when applicable. If the XMLs/JSONs include PII, EDE Entities must remove PII prior to sending the XMLs/JSONs to the Help Desks or the EDE Entity must encrypt the email.

An EDE Entity with a policy and compliance question related to the business requirements audit or EDE Business Agreement should email DE Support at [directenrollment@cms.hhs.gov](mailto:directenrollment@cms.hhs.gov) with the subject line “EDE: [Audit/Compliance] Q for [Partner] on [Topic].”

An EDE Entity with a policy and compliance question related to the privacy and security audit, privacy and security controls, or its ISA should email DE Support at [directenrollment@cms.hhs.gov](mailto:directenrollment@cms.hhs.gov) with the subject line “EDE: [Privacy/Security] Q for [Partner] on [Topic].”

An EDE Entity with an eligibility application requirements and/or eligibility application UI flexibility question should email DE Support at [directenrollment@cms.hhs.gov](mailto:directenrollment@cms.hhs.gov) with the subject line “EDE: [Eligibility Application Requirements] Q for [Partner] on [Topic].”

CMS will summarize and share answers to frequently asked questions (FAQs) on EDE that are sent to DE Support on the CMS-Issuer Technical Work Group (ITWG) webinar, which is open to all issuers and web-brokers on Tuesday afternoons. Not all workgroup content is relevant to EDE Entities, but CMS strongly recommends that EDE Entities attend these calls to hear important announcements, updates, reminders, and clarifications. Please see the Section XII.C, Webinars, for webinar details.

Questions related to policy or compliance issues for either the business requirements audit or the privacy and security audit must be sent to DE Support at [directenrollment@cms.hhs.gov](mailto:directenrollment@cms.hhs.gov). CMS will not respond to policy questions on either of these topics if they are not sent to DE Support. If an EDE Entity has been assigned a Direct Enrollment Point of Contact (DEPOC) at CMS, it should copy its DEPOC on all emails it sends to the FEPS Help Desk, Hub Help Desk, and DE Support.

### ***B. Office Hours***

CMS will host office hours through June 30, 2020 (the end of the audit submission window). During these office hours, CMS will aim to provide targeted, detailed technical assistance to prospective and existing EDE Entities and their Auditors. These office hours have limited availability and will be assigned on a first-come, first-served basis based on the following categories:

- Category 1: EDE Entities and Auditors with difficult legal, policy, or technical inquiries.

- Category 2: EDE Entities and Auditors who request a walkthrough or explanation of audit or technical documentation with subject matter experts (e.g., technical experts, security and privacy experts, or eligibility experts).

CMS will not schedule office hour sessions to discuss standard help desk inquiries that can be resolved through DE Support. EDE Entities and Auditors can only request office hours pursuant to category 2 above. Category 1 requests will be offered and assigned in CMS's sole discretion.

EDE Entities should submit requests for office hours under category 2 above to DE Support ([directenrollment@cms.hhs.gov](mailto:directenrollment@cms.hhs.gov)).

### **C. Webinars**

CMS currently hosts the ITWG webinar weekly on Tuesdays from 3:00 PM to 4:30 PM ET. The ITWG call is open to all web-brokers and issuers operating on the FFE or SBE-FPs. CMS will continue to use the ITWG call to update the DE/EDE community on developments related to EDE and offer interactive question and answer time at the end of each session.

To obtain the call-in information for the weekly ITWG webinar, users must register via a one-time Webinar Registration URL for the ITWG meeting series. This URL can be found on CMS zONE.<sup>76</sup> Note: If you have already registered for this webinar series please use the login information sent to you by webex.com.

For all webinars, CMS will make the slides available during or shortly after the presentation. CMS will advertise and update logistical information (dates/times, dial-in numbers, and webinar URLs) on the CMS zONE Private Issuer Community and Web-Broker Community webpage.

### **D. CMS zONE Communities (Guidance & Technical Resources)**

CMS currently posts all technical information, guidelines, such as those referenced in this document, as well as webinar slide decks, audit resources, and other documentation on the CMS zONE EDE Documents and Materials webpage.<sup>77</sup> CMS has divided these pages and the documentation across the following subject areas (as of December 2019): Business Audit Resources, Privacy and Security Audit Resources, Eligibility Information, API Information, Issuer Technical Workgroup Slides, and Frequently Asked Questions.

This webpage is accessible by members of the following CMS zONE communities: Private Issuer Community (for issuers), the Web-Broker Community (for web-brokers), and the EDE Auditors Community.<sup>78</sup> CMS will post all EDE updates, information for third-party Auditors, webinar slide decks, and FAQs to these communities, and will highlight updates during the weekly ITWG webinars.

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<sup>76</sup> Webinar Registration can be found at the following link on CMS zONE: <https://zone.cms.gov/document/slides-cms-issuer-technical-workgroups-tuesdays>

<sup>77</sup> Generally, EDE documents and materials will be posted at the following link on CMS zONE: <https://zone.cms.gov/document/enhanced-direct-enrollment>.

<sup>78</sup> Once CMS receives a copy of the Auditor's contract with a primary EDE Entity, CMS will send a copy of the instructions to access CMS zONE to the primary EDE Entity for sharing with the Auditor.



CMS will provide updates with further requirements and resources as they become available. A prospective EDE Entity should regularly check the EDE Documents and Materials webpage. Unless otherwise specified, any guidance or requirements stated as forthcoming in this document are expected to be made available through the CMS zONE Communities for EDE.

### ***E. REGTAP***

CMS will make the trainings and a list of essential EDE resources available via REGTAP.<sup>79</sup>

### ***F. Additional Guidance***

- Frequently Asked Questions Regarding Participation Requirements for Enhanced Direct Enrollment (EDE) Entities Serving Consumers in States with Federally-facilitated Exchanges (FFE): <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/FAQ-EDE-CY2019.pdf>
- Federally-facilitated Exchanges (FFE) and Federally-facilitated Small Business Health Options Program (FF-SHOP) Enrollment Manual: [https://www.regtap.info/uploads/library/ENR\\_EnrollmentManualForFFEandFF-SHOP\\_v1\\_5CR\\_092519.pdf](https://www.regtap.info/uploads/library/ENR_EnrollmentManualForFFEandFF-SHOP_v1_5CR_092519.pdf)
- Web-broker Guidance on CMS Web-brokers in the Health Insurance Marketplace webpage: <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Web-brokers-in-the-Health-Insurance-Marketplace.html>
- For a current list of states that run their own State-based Exchange and do not use the federal platform, visit <https://www.healthcare.gov/marketplace-in-your-state/>. EDE Entities can use this list with state website links to refer consumers or agents/brokers in these states to their state's website
  - **Note:** Some states listed use the federal platform (HealthCare.gov) for individual coverage but run their own SHOP coverage operations. CMS will provide information to EDE Entities if changes are made in the future.
- Privacy Act of 1974: <http://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Privacy/PrivacyActof1974.html>
- The Current Acceptable Risk Safeguards (ARS) documentation: <https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/CIO-Directives-and-Policies/CIO-IT-Policy-Library-Items/STANDARD-ARS-Acceptable-Risk-Safeguards.html>
- CCIIO Regulations and Standards: <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/index.html>
- CMS Risk Management Handbook (RMH) Chapter 08: Incident Response: <https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/InformationSecurity/Downloads/RMH-Chapter-08-Incident-Response.pdf>

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<sup>79</sup> REGTAP can be accessed at the following link: <https://www.regtap.info/>.

## Appendix A. Privacy and Security Controls for Hybrid, Non-issuer Upstream EDE Entities

Exhibit 11 and Exhibit 12 in this Appendix only apply to hybrid, non-issuer upstream EDE Entities as described in Section IV.B.iv, Privacy and Security Audit Requirements for Hybrid, Non-issuer Upstream EDE Entities. The full list of privacy and security controls that apply to primary EDE Entities are documented in the EDE System Security Plan (SSP) Workbook and the EDE Streamlined Subset NIST 800-53 controls documents on CMS zONE.<sup>80</sup>

The hybrid, non-issuer upstream EDE Entity’s Auditor must evaluate the EDE Entity’s compliance with the EDE privacy and security controls documented in Exhibit 11 (as applicable to the arrangement).

**Exhibit 11: Auditable (Non-Inheritable and Hybrid) Controls**

Control #	Security/Privacy Control Name	Non-Inheritable Controls	Hybrid Controls
<b>Access Control (AC)</b>			
AC-1	Access Control Policy and Procedures		X
AC-2	Account Management		X
AC-2(1)	Automated System Account Management		X
AC-2(2)	Removal of Temporary/Emergency Accounts		X
AC-2(3)	Disable Inactive Accounts		X
AC-2(4)	Automated Audit Actions		X
AC-2(7)	Role-Based Schemes		X
AC-2(10)	Shared / Group Account Credential Termination		X
AC-5	Separation of Duties		X
AC-18	Wireless Access	X	
AC-18(1)	Authentication and Encryption	X	
AC-19	Access Control for Mobile Devices	X	
AC-19(5)	Full-Device / Container-Based Encryption	X	
AC-20	Use of External Information Systems	X	
AC-20(1)	Limits on Authorized Use	X	
AC-20(2)	Portable Storage Devices	X	
AC-21	Information Sharing	X	
AC-22	Publicly Accessible Content	X	
<b>Awareness and Training (AT)</b>			
AT-1	Security Awareness and Training Policy and Procedures	X	
AT-2	Security Awareness Training	X	
AT-2(2)	Insider Threat	X	
AT-3	Role-Based Security Training	X	
AT-4	Security Training Records	X	

<sup>80</sup> These files are available on CMS zONE at the following link: <https://zone.cms.gov/document/privacy-and-security-audit>.

Control #	Security/Privacy Control Name	Non-Inheritable Controls	Hybrid Controls
<b>Audit and Accountability (AU)</b>			
AU-1	Audit and Accountability Policy and Procedures	X	
AU-2	Audit Events		X
AU-2(3)	Reviews and Updates		X
AU-6	Audit Review, Analysis, and Reporting		X
AU-6(1)	Process Integration		X
AU-6(3)	Correlate Audit Repositories		X
AU-7	Audit Reduction and Report Generation		X
AU-7(1)	Automatic Processing		X
AU-8	Time Stamps		X
AU-8(1)	Synchronization with Authoritative Time Source		X
AU-9	Protection of Audit Information		X
<b>Security Assessment and Authorization (CA)</b>			
CA-1	Security Assessment and Authorization Policies and Procedures		X
CA-2	Security Assessments		X
CA-2(1)	Independent Assessors		X
CA-3(5)	Restrictions on External System Connections	X	
CA-5	Plan of Action and Milestones	X	
CA-6	Security Authorization		X
CA-7	Continuous Monitoring	X	
CA-7(1)	Independent Assessment	X	
CA-9	Internal System Connections	X	
<b>Configuration Management (CM)</b>			
CM-1	Configuration Management Policy and Procedures		X
CM-2	Baseline Configuration		X
CM-2(1)	Reviews and Updates		X
CM-2(3)	Retention of Previous Configurations		X
CM-3	Configuration Change Control	X	
CM-3(2)	Test/Validate/Document Changes	X	
CM-4	Security Impact Analysis	X	
CM-4(1)	Separate Test Environments	X	
CM-9	Configuration Management Plan		X
<b>Contingency Planning (CP)</b>			
CP-2	Contingency Plan		X
CP-2(1)	Coordinate with Related Plans	X	
CP-2(3)	Resume Essential Missions/Business Functions	X	
CP-2(8)	Identify Critical Assets	X	
CP-3	Contingency Training	X	
CP-4	Contingency Plan Testing	X	
CP-4(1)	Coordinate with Related Plans	X	

Control #	Security/Privacy Control Name	Non-Inheritable Controls	Hybrid Controls
CP-8	Telecommunications Services		X
CP-8(1)	Priority of Service Provisions		X
CP-8(2)	Single Points of Failure		X
CP-9	Information System Backup	X	
CP-9(1)	Testing for Reliability/Integrity	X	
CP-10	Information System Recovery and Reconstitution		X
CP-10(2)	Transaction Recovery		X
<b>Identification and Authentication (IA)</b>			
IA-1	Identification and Authentication Policy and Procedures	X	
<b>Incident Response (IR)</b>			
IR-1	Incident Response Policy and Procedures	X	
IR-2	Incident Response Training	X	
IR-3	Incident Response Testing	X	
IR-3(2)	Coordination with Related Plans	X	
IR-4	Incident Handling	X	
IR-4(1)	Automated Incident Handling Processes	X	
IR-5	Incident Monitoring	X	
IR-6	Incident Reporting	X	
IR-6(1)	Automated Reporting	X	
IR-7	Incident Response Assistance	X	
IR-7(1)	Automation Support for Availability of Information/Support	X	
IR-8	Incident Response Plan	X	
IR-9	Information Spillage Response	X	
<b>Media Protection (MP)</b>			
MP-1	Media Protection Policy and Procedures		X
MP-2	Media Access		X
MP-3	Media Marking		X
MP-4	Media Storage		X
MP-5	Media Transport		X
MP-5(4)	Cryptographic Protection		X
MP-6	Media Sanitization		X
MP-7	Media Use		X
MP-7(1)	Prohibit Use Without Owner		X
<b>Physical and Environmental Protection (PE)</b>			
PE-1	Physical and Environmental Protection Policy and Procedures		X
PE-2	Physical Access Authorizations		X
PE-2(1)	Access by Position / Role		X
PE-3	Physical Access Control		X
PE-4	Access Control for Transmission Medium		X
PE-5	Access Control for Output Devices		X

Control #	Security/Privacy Control Name	Non-Inheritable Controls	Hybrid Controls
PE-6	Monitoring Physical Access		X
PE-6(1)	Intrusion Alarms/Surveillance Equipment		X
PE-8	Visitor Access Records		X
<b>Planning (PL)</b>			
PL-1	Security Planning Policy and Procedures		X
PL-2	System Security Plan		X
PL-2(3)	Plan/Coordinate with Other Organizational Entities		X
PL-4	Rules of Behavior		X
PL-4(1)	Social Media and Networking Restrictions		X
PL-8	Information Security Architecture		X
<b>Personnel Security (PS)</b>			
PS-1	Personnel Security Policy and Procedures	X	
PS-2	Position Risk Designation	X	
PS-3	Personnel Screening	X	
PS-4	Personnel Termination	X	
PS-5	Personnel Transfer	X	
PS-6	Access Agreements	X	
PS-7	Third-Party Personnel Security	X	
PS-8	Personnel Sanctions	X	
<b>Risk Assessment (RA)</b>			
RA-1	Risk Assessment Policy and Procedure		X
RA-3	Risk Assessment		X
RA-5	Vulnerability Scanning		X
<b>System and Services Acquisition (SA)</b>			
SA-5	Information System Documentation		X
<b>System and Communications Protection (SC)</b>			
SC-28	Protection of Information at Rest	X	
SC-CMS-1	Electronic mail	X	
<b>Accountability, Audit, and Risk Management (AR)</b>			
AR-1	Governance and Privacy Program		X
AR-2	Privacy Impact and Privacy Program		X
AR-4	Privacy Monitoring and Auditing		X
AR-5	Privacy Awareness and Training	X	
AR-8	Accounting of Disclosures	X	
<b>Data Quality and Integrity (DI)</b>			
DI-1	Data Quality		X
DI-1(1)	Validate PII	X	

Control #	Security/Privacy Control Name	Non-Inheritable Controls	Hybrid Controls
<b>Data Minimization and Retention (DM)</b>			
DM-3	Minimization of PII Used in Testing, Training, and Research		X
DM-3 (1)	Minimization of PII Used in Testing, Training, and Research/Risk Minimization Techniques		X
<b>Individual Participation and Redress (IP)</b>			
IP-1	Consent		X
IP-2	Individual Access		X
IP-3	Redress		X
IP-4	Complaint Management		X
IP-4(1)	Complaint Management/Response Times		X
<b>Security (SE)</b>			
SE-1	Inventory of Personally Identifiable Information		X
SE-2	Privacy Incident Response		X
<b>Transparency (TR)</b>			
TR-1	Privacy Notice		X
TR-3	Dissemination of Privacy Program Information		X
<b>Use Limitation (UL)</b>			
UL-1	Internal Use	X	
UL-2	Information Sharing with Third Parties	X	

Exhibit 12 reflects the Inheritable Common Controls that the hybrid, non-issuer upstream EDE Entity can potentially inherit from the primary EDE Entity. The hybrid, non-issuer upstream EDE Entity’s Auditor does not need to independently evaluate the implementation of any inherited common controls implemented by the approved primary EDE Entity.

**Exhibit 12: Inheritable Common Controls**

Control #	Security/Privacy Control Name
<b>Access Control (AC)</b>	
AC-3	Access Enforcement
AC-4	Information Flow Enforcement
AC-6	Least Privilege
AC-6(1)	Authorize Access to Security Functions
AC-6(2)	Non-Privileged Access for Non-Security Functions
AC-6(5)	Privileged Accounts
AC-6(9)	Auditing Use of Privileged Functions
AC-6(10)	Prohibit Non-Privileged Users from Executing Privileged Functions
AC-7	Unsuccessful Logon Attempts
AC-8	System Use Notification
AC-10	Concurrent Session Control
AC-11	Session Lock
AC-11(1)	Pattern-Hiding Displays
AC-12	Session Termination
AC-14	Permitted Actions Without Identification or Authentication
AC-17	Remote Access
AC-17(1)	Automated Monitoring/Control
AC-17(2)	Protection of Confidentiality/Integrity Using Encryption
AC-17(3)	Managed Access Control Points
AC-17(4)	Privileged Commands/Access
AC-17(9)	Disconnect / Disable Access
<b>Audit and Accountability (AU)</b>	
AU-3	Content of Audit Records
AU-3(1)	Additional Audit Information
AU-4	Audit Storage Capacity
AU-5	Response to Audit Processing Failures
AU-5(1)	Audit Storage Capacity
AU-9(4)	Access by Subset of Privileged Users
AU-10	Non-Repudiation
AU-11	Audit Record Retention
AU-12	Audit Generation
<b>Security Assessment and Authorization (CA)</b>	
CA-3	System Interconnections
CA-8	Penetration Testing
CA-8(1)	Independent Penetration Agent or Team



Control #	Security/Privacy Control Name
<b>Configuration Management (CM)</b>	
CM-5	Access Restrictions for Change
CM-5(1)	Automated Access Enforcement/Auditing
CM-5(5)	Limit Production/Operational Privileges
CM-6	Configuration Settings
CM-6(1)	Automated Central Management/ Application/Verification
CM-7	Least Functionality
CM-7(1)	Periodic Review
CM-7(2)	Prevent Program Execution
CM-7(4)	Unauthorized Software/Blacklisting
CM-8	Information System Component Inventory
CM-8(1)	Updates During Installations/Removals
CM-8(3)	Automated Unauthorized Component Detection
CM-8(5)	No Duplicate Accounting of Components
CM-10	Software Usage Restrictions
CM-10(1)	Open Source Software
CM-11	User-Installed Software
<b>Contingency Planning (CP)</b>	
CP-1	Contingency Planning Policy and Procedures
CP-2(2)	Capacity Planning
CP-6	Alternate Storage Site
CP-6(1)	Separation from Primary Site
CP-6(3)	Accessibility
<b>Identification and Authentication (IA)</b>	
IA-2	Identification and Authentication (Organizational Users)
IA-2(1)	Network Access to Privileged Accounts
IA-2(2)	Network Access to Non-Privileged Accounts
IA-2(3)	Local Access to Privileged Accounts
IA-2(8)	Network Access to Privileged Accounts – Replay Resistant
IA-2(11)	Remote Access – Separate Device
IA-3	Device Identification and Authentication
IA-4	Identifier Management
IA-5	Authenticator Management
IA-5(1)	Password-Based Authentication
IA-5(2)	PKI-Based Authentication
IA-5(3)	In-Person or Trusted Third-Party Registration
IA-5(7)	No Embedded Unencrypted Static Authenticators
IA-5(11)	Hardware Token-Based Authentication
IA-6	Authenticator Feedback
IA-7	Cryptographic Module Authentication
IA-8	Identification and Authentication (Non-Organizational Users)

Control #	Security/Privacy Control Name
IA-8(2)	Acceptance of Third-Party Credentials
<b>Maintenance (MA)</b>	
MA-1	System Maintenance Policy and Procedures
MA-2	Controlled Maintenance
MA-3	Maintenance Tools
MA-3(1)	Inspect Tools
MA-3(2)	Inspect Media
MA-3(3)	Prevent Unauthorized Removal
MA-4	Nonlocal Maintenance
MA-4(1)	Auditing and Review
MA-4(2)	Document Nonlocal Maintenance
MA-5	Maintenance Personnel
MA-6	Timely Maintenance
<b>Risk Assessment (RA)</b>	
RA-5(1)	Update Tool Capability
RA-5(2)	Update by Frequency/Prior to New Scan/When Identified
RA-5(5)	Privileged Access
<b>System and Services Acquisition (SA)</b>	
SA-1	System and Services Acquisition Policy and Procedures
SA-2	Allocation of Resources
SA-3	System Development Life Cycle
SA-4	Acquisition Process
SA-4(1)	Functional Properties of Security Controls
SA-4(2)	Design/Implementation Information for Security Controls
SA-4(9)	Functions/Ports/Protocols/Services in Use
SA-8	Security Engineering Principles
SA-9	External Information System Services
SA-10	Developer Configuration Management
SA-11	Developer Security Testing and Evaluation
SA-15	Development Process, Standards, and Tools
SA-17	Developer Security Architecture and Design
SA-22	Unsupported System Components
<b>System and Communications Protection (SC)</b>	
SC-1	System and Communications Protection Policy and Procedures
SC-2	Application Partitioning
SC-4	Information in Shared Resources
SC-5	Denial of Service Protection
SC-6	Resource Availability
SC-7	Boundary Protection
SC-7(3)	Access Points
SC-7(4)	External Telecommunications Services

Control #	Security/Privacy Control Name
SC-7(5)	Deny by Default/Allow by Exception
SC-7(7)	Prevent Split Tunneling for Remote Devices
SC-7(8)	Route Traffic to Authenticated Proxy Servers
SC-7(12)	Host-Based Protection
SC-7(13)	Isolation of Security Tools/Mechanisms/Support Components
SC-7(18)	Fail Secure
SC-8	Transmission Confidentiality and Integrity
SC-8(1)	Cryptographic or Alternate Physical Protection
SC-8(2)	Pre/Post Transmission Handling
SC-10	Network Disconnect
SC-12	Cryptographic Key Establishment and Management
SC-12(2)	Symmetric Keys
SC-13	Cryptographic Protection
SC-17	Public Key Infrastructure Certificates
SC-18	Mobile Code
SC-19	Voice Over Internet Protocol
SC-20	Secure Name/Address Resolution Service (Authoritative Source)
SC-21	Secure Name/Address Resolution Service (Recursive or Caching Resolver)
SC-22	Architecture and Provisioning for Name/Address Resolution Service
SC-23	Session Authenticity
SC-24	Fail in Known State
<b>System and Information Integrity (SI)</b>	
SI-1	System and Information Integrity Policy and Procedures
SI-2	Flaw Remediation
SI-2(2)	Automated Flaw Remediation Status
SI-2(3)	Time to Remediate Flaws / Benchmarks for Corrective Actions
SI-3	Malicious Code Protection
SI-3(2)	Automatic Updates
SI-4	Information System Monitoring
SI-4(1)	System-Wide Intrusion Detection System
SI-4(4)	Inbound and Outbound Communications Traffic
SI-4(5)	System-Generated Alerts
SI-5	Security Alerts, Advisories, and Directives
SI-6	Security Function Verification
SI-7	Software, Firmware, and Information Integrity
SI-7(1)	Integrity Checks
SI-7(7)	Integration of Detection and Response
SI-8	Spam Protection
SI-8(2)	Automatic Updates
SI-10	Information Input Validation
SI-11	Error Handling

Control #	Security/Privacy Control Name
SI-12	Information Handling and Retention
SI-16	Memory Protection
<b>Authority and Purpose (AP)</b>	
AP-1	Authority to Collect
AP-2	Purpose Specification
<b>Accountability, Audit, and Risk Management (AR)</b>	
AR-7	Privacy-enhanced System Design and Development
<b>Data Minimization and Retention (DM)</b>	
DM-1	Minimization of Personally Identifiable Information
DM-1(1)	Minimization of PII/Locate/Remove/Redact/Anonymize PII
DM-2	Data Retention and Disposal
DM-2 (1)	Data Retention and Disposal/System Configuration