



Centers for Medicare & Medicaid Services

Change Notification Form for Enhanced Direct Enrollment Entities Information Technology Systems

Version 2.0

October 13, 2022

PRA DISCLOSURE: According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-NEW, expiration date is XX/XX/20XX. The time required to complete this information collection is estimated to take up to 56,290 hours annually for all direct enrollment entities. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. ****CMS Disclosure**** Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact Brittany Cain at Brittany.Cain@cms.hhs.gov.

1. Introduction

As part of the continuing efforts to protect the confidentiality, integrity, and availability (CIA) of the information collected, used, disclosed, and/or retained by the Enhanced Direct Enrollment (EDE) Entity's information technology (IT) systems, EDE entities must implement a configuration change control process as part of the configuration management control family described in the EDE system security and privacy plan (SSP). Any system changes that include new, enhanced, or updated hardware and software capabilities; or that apply patches for correcting software flows and new security threats; or that execute changes to business functions and data collection, may cause changes to system configurations as well as the security and privacy posture of the EDE Entity's information systems. Consequently, EDE entities must document system changes and evaluate the scope and nature of the changes in terms of the potential security and privacy impact as an essential aspect of its own change management and continuous monitoring activities.

All changes must be tested, validated, and documented before implementing the changes in the EDE operational environment. If an EDE Entity is planning to make category 1, 2, or 3 changes to its approved EDE environment, the EDE Entity must notify the Centers for Medicare & Medicaid Services (CMS) prior to implementing these changes. CMS provides guidance on EDE Entity-initiated change requests and categorization in the *Change Notification Procedures for Enhanced Direct Enrollment Entity Information Technology Systems* (hereinafter CN Procedures).

1.1 Purpose

The purpose of this document is to provide the EDE System Security and Privacy Change Notification Form that an EDE Entity completes when making changes to its EDE environments. It is applicable to any EDE Entity responsible for managing and administering the security and privacy of the IT systems.

1.2 Instructions

The EDE entities must review and complete the form using the instructions outlined in each section of this form, and the CN Procedures. The form should be submitted to CMS via the Entity's DE/EDE PME Site with an accompanying notification email to the [DE Help Desk](#) with the email subject line starting with "EDE Entity initiated CR – Category [1, 2, or 3] Change".

The EDE entities must submit additional documentation, as required, through their Entity-specific DE/EDE PME Site.

1.3 EDE Entity System Security and Privacy Change Notification Form

Entity-Initiated Change Request (EICR) Summary		
Name of EDE Entity:	Entity Type:	EDE Phase: <i>(If a Primary Entity)</i>
Submission Date:	Planned Implementation Date:	
Title of Proposed Change:	Proposed Change Category: <i>(See EDE Change Procedures, Section 2.2.1)</i>	
Description of Proposed Change:		
Scope of Proposed Change		
1. Is this proposed change a new upstream arrangement? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>If yes, please answer questions 2-3. If no, please move to question 6.</i>		
2. Indicate the type of upstream Entity. <i>Select one. For more information, see the EDE Guidelines, Section IV.B.</i> <input type="checkbox"/> White Label Issuer <input type="checkbox"/> Hybrid Issuer <input type="checkbox"/> Hybrid Issuer using Single Sign-On <input type="checkbox"/> Hybrid Non-Issuer		
3. Will the proposed upstream Entity conduct identity-proofing? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>If yes, please answer question 4. If no, please move to question 5.</i>		
4. Indicate the type(s) of identity-proofing conducted by the proposed upstream Entity. <i>Check all that apply. For more information, see the EDE Guidelines, Section VI.</i> <input type="checkbox"/> Consumer Identity Proofing Implementation <input type="checkbox"/> Agent and Broker Identity Proofing Verification		
5. Will the proposed upstream Entity conduct any business requirement functions included in the EDE Business Requirements audit? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>If yes, please describe below.</i>		
6. Does the proposed change include an upstream Entity adding functionality or systems beyond the boundary of the most recent EDE ISCM privacy and security audit scope? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>If yes, please describe below.</i>		
7. Does the proposed change include the exchange of data? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>If yes, please answer questions 8-9.</i>		
8. Indicate the type(s) of data exchanged. <input type="checkbox"/> Consumer-Provided Data <input type="checkbox"/> Exchange-Provided Data <i>Check all that apply.</i>		

Sensitive and Confidential Information – For Official Use Only

9. Are the systems receiving/collecting/storing data as part this proposed change included within the audit boundary of the most recent EDE ISCM privacy and security audit scope?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Impact of Proposed Change		
10. Business Impact: Summarize the results of the Business Impact Analysis (BIA) below.		
11. Security Impact: Summarize the results of the Security Impact Analysis (SIA) below. <i>Please indicate which security and privacy control families are impacted and provide a copy of the detailed SIA report. (Note: See Section 2.3 of the EDE Change Notification Procedures)</i>		
12. Privacy Impact: Describe how the changes will impact privacy, for example, PII Data Collection, Use, or Disclosure below.		
13. Does the privacy impact require an updated Privacy/TPWA Questionnaire? <i>If yes, include an updated Privacy/TPWA Questionnaire.</i>		
14. Does the privacy impact require an updated website privacy policy or terms of service for the Primary and/or Upstream Entity? <i>If yes, include a Word document or PDF with the proposed changes highlighted.</i>		

Entity-Initiated Change Request Documentation Checklist

Please complete the checklist below to confirm the necessary documentation is included in your EICR submission. The form should be submitted to CMS via the Entity’s DE/EDE PME Site with an accompanying notification email to the [DE Help Desk](#) with the email subject line starting with “EDE Entity initiated CR – Category [1, 2, or 3] Change”.

EICR Document	Required?	Included EICR Package
✓ Entity-Initiated Change Request Form	Yes, for all EICRs	
✓ Security Impact Analysis	Yes, for all EICRs	
✓ ISA Appendix B	Only proposed upstream arrangements	
✓ UI mock-up, screenshots, and/or diagram compiled in MS PowerPoint	Any EICR that proposes data exchange, changes to or additional systems, new functionality, and UI modifications.	
✓ Privacy Questionnaire	Only if the Primary Entity identified a privacy impact (Question 11 above)	
✓ Website Privacy Policy or Terms of Service	Only if the Primary Entity identified a privacy impact (Question 12 above)	