



2016 Transitional Reinsurance (RI) Program Payment Audit Report

for

Harken Health Insurance Company (UnitedHealthcare)

HIOS Issuer ID 78463

September 10th, 2025

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I. EXECUTIVE SUMMARY

The 2016 Transitional Reinsurance (RI) Program Payment Audit Report is an assessment of Harken Health Insurance Company's (UnitedHealthcare) compliance with the applicable federal requirements related to payments made under the Transitional Reinsurance Program established under section 1341 of the Patient Protection and Affordable Care Act (ACA)¹ and implementing regulations.^{2,3} This report details the audit procedures⁴ and the resulting findings and/or observations for the Benefit Year (BY) 2016 RI payment audit (RI audit) of UnitedHealthcare.

Background

UnitedHealthcare, HIOS ID 78463, is a health insurance issuer that received BY 2016 RI payments consistent with the BY 2016 national RI payment parameters.⁵ UnitedHealthcare submitted enrollment, medical, and pharmacy claims data to its External Data Gathering Environment (EDGE) Server for calculation of the BY 2016 RI payments. The payments are reflected in the issuer's BY 2016 EDGE Reinsurance Detailed Enrollee Report (BY 2016 RIDE Report). This issuer's BY 2016 RI payments totaled \$12,272,904.28.

Audits to Determine Compliance with the Transitional RI Program

Under title 45 of the Code of Federal Regulations (C.F.R.) § 153.410(d), the Department of Health and Human Services (HHS) may audit issuers to assess compliance with the applicable federal requirements related to the transitional RI program. HHS designated CMS to conduct these audits, which are designed to achieve the following:

- Safeguard federal funds;
- Instill confidence amongst regulated entities concerning data quality, soundness, and robustness;
- Evaluate health insurance issuers' compliance with federal program rules and regulations; and

¹ The ACA (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the ACA, was enacted on March 30, 2010. In this report, we refer to the two statutes collectively as the “Patient Protection and Affordable Care Act” or “ACA.”

² See 42 U.S.C. 18061. Also see 45 C.F.R. Part 153, Subparts A, C, E, H.

³ Consistent with section 1321(c)(1) of ACA, the HHS Secretary is responsible for operating the transitional reinsurance program on behalf of any state that elected not to do so. For the 2016 benefit year, HHS operated the reinsurance program in all 50 states and the District of Columbia. See <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Transitional-Reinsurance-Program—CMS-to-Begin-Operating-on-behalf-of-the-State-of-Connecticut.pdf>.

⁴ To provide the flexibility needed when reviewing compliance with program requirements and to ensure that issuers can provide CMS with their most accurate data, audit protocols allow for dialogue between auditor and issuer to identify and correct errors in data submission that differ somewhat from some independence and reporting standards set forth under Generally Accepted Government Auditing Standards (GAGAS). These procedures were defined and executed consistent with the competence, integrity, and analytical discipline required for “performance audits” as defined by GAGAS.

⁵ The final BY 2016 national RI payment parameters consisted of a \$90,000 attachment point and \$250,000 cap. See HHS Notice of Benefit and Payment Parameters for 2016; Final Rule, 80 Fed. Reg. 10749 at 10777 (Feb. 27, 2015). See also the *Summary Report on Transitional Reinsurance and Permanent Risk Adjustment Transfers for the 2016 Benefit Year* (June 30, 2017), available at: <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/Summary-Reinsurance-Payments-Risk-2016.pdf>. After accounting for actionable late-filed discrepancies related to reinsurance overpayments and overlapping claims, including some additional adjustments that occurred after CMS published the Summary Report for the 2016 Benefit Year, the final BY 2016 coinsurance rate was 53.16%.

- Develop a successful and coordinated risk-based audit program that maximizes resources.

This RI audit is part of CMS's program to validate the BY 2016 enrollee-level data submitted to selected issuers' EDGE servers as of May 1, 2017^{6,7} and to analyze controls and policies related to BY 2016 RI payments. Claims that were not submitted to the EDGE server or claims that were submitted to the EDGE server whose issuer paid claims values increased after the final BY 2016 EDGE data submission deadline will not be considered for additional RI payments. The results of findings identified during the claims-level audit can only result in a payment from the issuer to CMS.⁸

CMS findings and observations from this RI audit for the BY 2016 RI payments made to UnitedHealthcare are documented below.

- *Finding*: Results from cases of confirmed non-compliance or discovery of evidence suggesting non-compliance with applicable federal requirements related to the transitional RI program, which require a recoupment of RI payments.
 - Example: Claim level discrepancies identified within the issuer's claims data extract and the issuer's BY 2016 RIDE Report, associated with an enrollee, that result in a recoupment of RI payments.
- *Observation*: Results from the identification of areas for improvement when there is no evidence of actual non-compliance with applicable federal requirements related to the transitional RI program, or when there may be evidence of non-compliance with applicable federal requirements related to the transitional RI program that does not require recoupment of RI payments.
 - Example: Claim level discrepancies identified within the issuer's claims data extract and the issuer's BY 2016 RIDE Report, associated with enrollees where the claim adjustment would not result in a recoupment of RI payments.

Results of Review

CMS identified zero (0) findings and two (2) observations during UnitedHealthcare's BY 2016 RI audit. The results of the BY 2016 RI audit do not require a recoupment of amounts the issuer received for BY 2016 RI payments.

The results of the two (2) observations do not require a recoupment of the issuer's BY 2016 RI payments. In some instances, an observation may also affect an enrollee who received an RI payment but not result in an impact to the RI payment for that enrollee (e.g., the issuer's aggregated paid claims

⁶ See 45 C.F.R. § 153.730. When April 30th has fallen on a weekend or holiday, CMS extended the EDGE data submission deadline to the following business day. This practice resulted in the BY 2016 deadline shifting to May 1, 2017. See REGTAP FAQ 14472a, available at https://regtap.cms.gov/faq_viewu.php?id=14472.

⁷ Issuers were required to submit attestations and report discrepancies for the BY 2016 EDGE submission during a window from May 8, 2017, to May 22, 2017. See 45 C.F.R. § 153.710(d). See also the *Risk Adjustment (RA) and Reinsurance (RI) Attestation and Discrepancy Reporting Process for the 2016 Benefit Year* presentation slides (May 9, 2017 & May 11, 2017), available at https://regtap.cms.gov/reg_library_openfile.php?id=2094&type=1. To execute the procedures described in this audit report, CMS will always review an issuer's final benefit year data submission upon which final RI payments were calculated for the issuer.

⁸ As communicated in the Entrance Conference, additional RI payments will not be provided for underpayments identified during the BY 2016 RI audits. See 45 C.F.R. §§ 153.420, 153.710(g).

for the enrollee, after correcting the observation and application of the BY 2016 RI payment parameters, results in the same or a larger⁹ RI payment for the enrollee).¹⁰

Please note that issuers may be required to submit late-filed discrepancies and update EDGE server data as necessary to allow CMS to assess the impact of the observations in this report.

Please refer to Section II.D below for details on the observations noted above.

⁹ See supra note 8.

¹⁰ Please refer to [Section II C. Findings](#) to view the aggregated amount of paid claim differences associated with each audit procedure, used for calculating the “Total Financial Impact.”

II. REINSURANCE PAYMENT PROGRAM ASSESSMENT

A. BACKGROUND, OBJECTIVES, SCOPE, and METHODOLOGY

1. Background

Section 1341 of the ACA established a transitional RI program to stabilize premiums in the individual market inside and outside of the Exchanges for benefits years 2014 through 2016.¹¹ The transitional RI program collected contributions from contributing entities to fund RI payments to issuers of non-grandfathered individual market reinsurance-eligible plans,¹² the administrative costs of operating the program, and the General Fund of the U.S. Treasury. The program helped reduce the uncertainty of insurance risk in the individual market as the federal ACA insurance market requirements and Exchanges were implemented by partially offsetting issuers' claims associated with high-cost enrollees.¹³ Under the program, payments were made to issuers of RI-eligible plans for a percentage of covered claims (coinsurance rate) above the attachment point and below the RI cap.¹⁴ For BY 2016, the attachment point was \$90,000, the RI cap was \$250,000, and the final coinsurance rate was 53.16%.¹⁵

HHS implemented a distributed data collection (DDC) approach where issuers of RI-eligible plans were required to establish external data gathering environment (EDGE) servers to make accessible data required to calculate RI payments when HHS was responsible for operating the transitional RI program.^{16,17} Issuers were required to submit enrollee and claims data on their EDGE servers by April 30th or, if April 30th fell on a weekend or holiday, of the year following the applicable benefit year.¹⁸ Non-orphan claims (i.e., those that are linked to enrollees in a valid individual market RI-eligible plan) were selected for the RI calculation and considered as a request for payment pursuant to 45 C.F.R. § 153.410. Each issuer's EDGE server calculated the issuer's estimated RI payment, while the EDGE Calculation Module (ECM), a CMS internal system, calculated the amount of each issuer's actual RI payment, taking into consideration total available RI contributions.

HHS has the authority to conduct audits to confirm successful implementation of, and adherence to, the applicable federal requirements related to the transitional RI program.¹⁹ As such, CMS, on behalf of HHS, established this RI audit program. CMS developed audit protocols to assess issuers' compliance with the following applicable federal regulations governing the transitional RI program:

- 45 C.F.R. § 153.410: Requests for reinsurance payment; and

¹¹ See *supra* note 3.

¹² See 45 C.F.R. § 153.20 for a definition of "reinsurance-eligible plan."

¹³ See, e.g., Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2014 and Amendments to the HHS Notice of Benefit and Payment Parameters for 2014; Final Rules; Patient Protection and Affordable Care Act; Establishment of Exchange and Qualified Health Plans; Small Business Health Options Program; Proposed Rule, 78 Fed. Reg. 15410 (March 11, 2013) (2014 Payment Notice); and the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2015; Final Rule, 79 Fed. Reg. 13743 (March 11, 2014); HHS Notice of Benefit and Payment Parameters for 2016; Final Rule, 80 Fed. Reg. 10749 (Feb. 27, 2015).

¹⁴ *Ibid.* Also see *supra* note 5.

¹⁵ See *supra* note 5.

¹⁶ See 45 C.F.R. §§ 153.420 and 153.700.

¹⁷ See *supra* note 3.

¹⁸ See *supra* note 6.

¹⁹ See 45 C.F.R. § 153.410(d).

- 45 C.F.R. § 153.420: Data collection; and
- 45 C.F.R. § 153.700, et seq.: Distributed data collection for HHS-Operated Programs.

Please refer to [Appendix 3 – Applicable Federal Regulations](#) for further details.

2. Objectives

The objectives of this audit are to:

- (1) Evaluate issuer-submitted enrollment and claims files against applicable federal requirements related to the transitional RI program for compliance and completeness;
- (2) Assess validity and compliance of issuer-submitted plan reference data and associated enrollee data;
- (3) Evaluate whether issuer-submitted data supports the BY 2016 RIDE Report²⁰ data at the enrollee level;
- (4) Evaluate accuracy of the RI payments as calculated by the EDGE server,²¹ in instances where there is a deviation in the detailed enrollee and claims submission to the EDGE server;
- (5) Assess issuer controls, policies, and procedures surrounding data submission to the EDGE server for the transitional RI program; and
- (6) Assess compliance with maintenance of records requirements in 45 C.F.R. § 153.410(c) (i.e., 10 years of file retention).

3. Scope and Methodology

CMS selected UnitedHealthcare for an audit to assess the issuer's compliance with the applicable federal requirements related to the transitional RI program for BY 2016. CMS evaluated UnitedHealthcare's information and activities related to the BY 2016 (January 1, 2016, through December 31, 2016) enrollee and claim-level data submitted to the issuer's EDGE server as of May 1, 2017, to support RI payments received.

CMS sent UnitedHealthcare an electronic letter on June 20, 2023, to notify them of this audit. CMS's audit contractor sent a follow-up letter on June 22, 2023, which identified the data requests and other requirements related to conducting the audit. CMS's audit contractor reviewed UnitedHealthcare's documentation, including an issuer-provided data extract, and used CMS's applicable audit procedures to assess compliance with applicable federal requirements related to the transitional RI program.

CMS's audit contractor applied CMS's RI audit protocols to identify findings and observations. The contractor performed audit procedures on data and information for 100 percent of known on-Exchange and off-Exchange enrollees in UnitedHealthcare's RI-eligible plans that received a BY 2016 RI payment. For more detail on CMS's audit procedures please review [Appendix 2 – Procedure Criteria & Effect](#).

²⁰ The RIDE report contains enrollee-level plan and claim details used for the RI payment calculation and is made available only to issuers through EDGE servers.

²¹ Issuer EDGE servers process enrollment and claims data according to the EDGE Server Business Rules (ESBR) to select claims to be included in RI payment calculations. See 45 C.F.R. §§ 153.410, 153.420, 153.700, 153.710, and 153.720.

B. RESULTS OF REVIEW

CMS assessed UnitedHealthcare's compliance with applicable federal requirements related to the transitional RI program for BY 2016 using the following procedures: Unreconciled Claims Review, RI-Eligible Plan Review, Claim Coverage Period Validation, Paid Claim Amount Validation, BY 2016 Cross Year Claim Validation, Duplicate Claim Validation, Enrollee Validation, Issuer RI Policies and Procedures Review, Issuer RI Attestation Review, and Issuer Compliance with Maintenance of Records and Audit Requirements. Below are the results of this review.²²

(1) Unreconciled Claims Review

No findings resulted from the review of UnitedHealthcare's claims data extract to determine if the claims reported on the BY 2016 RIDE Report existed in the data extract.

(2) RI-Eligible Plan Review

No findings and no observations resulted from the review of UnitedHealthcare's claims data extract to determine if the enrollee's plan ID matched the corresponding enrollee's plan ID reported in the issuer's BY 2016 RIDE Report and if the claim was paid by an RI-eligible plan.

(3) Claim Coverage Period Validation

No findings resulted from the review of UnitedHealthcare's claims data extract to determine if the service begin date of claims were within the enrollee's coverage period.

(4) Paid Claim Amount Validation

No findings and no observations resulted from the review of UnitedHealthcare's claims data extract to determine if the claim paid amount matched the corresponding claim paid amount in the issuer's BY 2016 RIDE Report.

(5) BY 2016 Cross Year Claim Validation

No findings resulted from the review of UnitedHealthcare's claims data extract to identify cross year claims and determine if the service end date of claims fell within the applicable benefit year.

(6) Duplicate Claim Validation

No findings resulted from the review of UnitedHealthcare's claims data extract to determine if claims were reported more than once on the EDGE server.

(7) Enrollee Validation

No findings resulted from the review of UnitedHealthcare's claims data extract to determine if the enrollee and related claims included in the issuer's claims data extract matches the enrollee associated with the applicable claim on the EDGE server.

(8) Issuer RI Policies and Procedures Review

One (1) observation resulted from the review of UnitedHealthcare's RI policies and procedures to determine compliance with applicable CMS rules, regulations, and policies. Please refer to Observation No. 1 included in Section II.D below for details on the observation related to the transitional RI program.

²² This review was primarily focused on the BY 2016 RIDE Report titled: 78463.RIDE.D20170504T001146.P.xml.

(9) Issuer RI Attestation Review

No observations resulted from the review of UnitedHealthcare's RI Attestation to validate that the issuer provided a completed attestation signed by the Chief Executive Officer (CEO), Chief Financial Officer (CFO) or other authorized official who has reviewed the documentation submitted for this RI audit.

(10) Issuer Compliance with Maintenance of Records and Audit Requirements

One (1) observation resulted from the review of UnitedHealthcare's compliance with the applicable CMS audit requirements, including an assessment of the completeness of audit documentation, and maintenance of records regulations for the BY 2016 RI payment audit. Please refer to Observation No. 2 included in Section II.D below for details on the observation related to the transitional RI program.

C. FINDINGS

A finding results from cases of confirmed non-compliance or discovery of evidence suggesting non-compliance with applicable federal requirements related to the transitional RI program, which require a recoupment of all or a portion of an issuer's total RI payment. In BY 2016, for an issuer to be eligible to receive RI payments for an enrollee, the enrollee must have had claims paid by the issuer in an amount that fell between the attachment point of \$90,000 and the RI cap of \$250,000. The amount of total paid claims was then required to be adjusted downward for enrollees for whom the issuer also received a 2016 advance CSR payment (a process collectively referred to as the CSR Maximum Out-of-Pocket (MOOP) adjustment). CMS's audit contractor considered the MOOP adjustment amounts reported in the issuer's BY 2016 RIDE Report, the BY 2016 coinsurance rate of 53.16%, as well as the paid claim amount differences identified from the claim-level audit procedures, for purposes of determining the financial impact of the findings in UnitedHealthcare's BY 2016 RI audit. Please refer to the Findings Summary Results table below to view the aggregated amount of paid claim differences associated with each audit procedure.

Findings Summary Results:

Findings			
Finding No.	Claim Level Procedures	Total	
		Total Count of Claims	Total Claim Level Differences
No Findings Noted.			

Based on the claim-level audit procedures performed, zero (0) findings were identified for enrollees associated with a BY 2016 RI payment. These claim-level procedures resulted in a total of \$0.00 paid claim amount differences, and the differences were further aggregated at the enrollee level for final recalculation of the issuer's BY 2016 RI payment, which resulted in a total financial impact of \$0.00. Please refer to the Findings Summary Results table above to view the aggregated amount of paid claim differences associated with each audit procedure used for calculating the "Total Financial Impact" amount shown in the table below.

Financial Impact Summary Results:

	Total RI Payment Amount
Total RI Payment per UnitedHealthcare's BY 2016 Final Coinsurance Rate	\$12,272,904.28
Total RI Payment as Recalculated	\$12,272,904.28
Total Financial Impact²³	\$0.00

The financial impact of the zero (0) findings is subject to recoupment by HHS in the amount of \$0.00.

Please review [Appendix 2 – Procedure Criteria & Effect](#) for more information.

D. OBSERVATIONS

An observation results from the identification of areas for improvement when there is no evidence of actual non-compliance with the applicable federal requirements related to the transitional RI program or when there may be evidence of non-compliance with the applicable federal requirements related to the transitional RI program that does not require recoupment of RI payments. CMS is making UnitedHealthcare's management aware of these areas by bringing the identified observations to their attention.

Based on the claim-level audit procedures performed, no observations were identified for enrollees associated with a BY 2016 RI payment. Additionally, one (1) observation was identified for the Issuer RI Policies and Procedures Review and one (1) observation was identified for Issuer Compliance with Maintenance of Records and Audit Requirements. Please review the Observations Summary Results table below for more information on the observations identified.

²³ Financial impact derived from BY 2016 RI payment audits only includes findings where funds are subject to recoupment by HHS. These amounts will be collected as part of the next available monthly payment cycle consistent with 45 C.F.R. § 156.1210 and the netting regulation at 45 C.F.R. § 156.1215 after this report is finalized. If all or part of the recoupment amount is unable to be netted, CMS will send an invoice to the issuer to establish the debt and collect the remaining amount owed to the federal government. See 45 C.F.R. § 156.1215(c).

Observations Summary Results:

Observations		
Observation No.	Claim Level Procedures	Total
		Total Count of Claims
No Observations Noted.		
Observation No.	Policies and Procedures	
Observation No. 1	Issuer RI Policies and Procedures Review	
Observation No.	Issuer Compliance with Maintenance of Records and Audit Requirements	
Observation No. 2	Issuer Compliance with Maintenance of Records and Audit Requirements	

III. ISSUER MANAGEMENT RESPONSES

UnitedHealthcare's completed attached [Appendix 1 – Issuer Management Response](#) is due within **thirty (30) calendar days from the date of this draft audit report**. If CMS does not receive UnitedHealthcare's management response within this timeframe, we will assume your management's agreement and issue the final audit report.

Agreement

If UnitedHealthcare's management agrees with the reported finding(s), observation(s), and recoupment amount (if applicable) the issuer should initial "Agree", sign, and submit the attached Appendix 1.

Disagreement

If UnitedHealthcare's management disagrees with the reported finding(s), observation(s), and/or recoupment amount (if applicable) and requests a review of additional information that may impact the results of the audit, the issuer should initial "Disagree", sign, and submit the attached Appendix 1. UnitedHealthcare must provide a written explanation with any such additional documentation within thirty (30) calendar days of the date of this draft audit report along with a completed Appendix 1. If this option is selected, CMS will consider this draft only a preliminary audit report. CMS will review the written explanation and supporting documentation submitted as part of UnitedHealthcare's response to this report to determine if the report can be amended in a mutually acceptable manner. CMS maintains discretion to determine whether amendments to the report are appropriate. UnitedHealthcare's response(s) to this report will be included in the final published audit report.

Regardless of whether the issuer agrees or disagrees with the reported finding(s) and observation(s), UnitedHealthcare's management should review and return the draft audit report, including completed Appendix 1, within thirty (30) calendar days from the date of this draft audit report. Review of this draft report is the final opportunity to provide information to correct any inaccuracies or address concerns before it is finalized. CMS will provide UnitedHealthcare a copy of the final audit report and publish the final report on the Center for Consumer Information and Insurance Oversight (CCIIO) website, including the recoupment amount(s) (if applicable) along with an updated Appendix 1, after receipt of UnitedHealthcare's management's response. CMS will finalize and process the final adjustment recoupment amount consistent with 45 C.F.R. § 156.1210 and the netting regulation at 45 C.F.R. § 156.1215 in the next available monthly payment cycle. If all or part of the adjustment amount was unable to be netted, CMS will send an invoice to establish the debt and collect the remaining adjustment amount owed to the federal government. See 45 C.F.R. § 156.1215(c).

Corrective Action Plan

UnitedHealthcare's management must initial that it agrees to provide a corrective action plan (CAP) to CMS, if requested. Under 45 C.F.R. § 153.410(d)(4), if a finding is included in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by CMS, on behalf of HHS, and the issuer must: (1) within 45 days of the issuance of the final audit report submit a CAP for approval, (2) implement the plan, and (3) provide written documentations of the corrective actions once taken.

Appendix 1 – Issuer Management Response

Issuer ID: 78463

Issuer Name: Harken Health Insurance Company

The undersigned Chief Executive Officer (CEO), Chief Financial Officer (CFO), or other individual with authority to legally and financially bind this issuer, has reviewed the information included in the BY 2016 Transitional Reinsurance (RI) Payment Audit (RI audit) Report of the issuer's compliance with applicable federal requirements related to Department of Health and Human Services (HHS)-operated transitional reinsurance (RI) program through which payments were made to the issuer for benefit year (BY) 2016 RI. This audit resulted in no payment adjustment.

Agreement/Disagreement

(INITIAL) JC *Agrees* with the recoupment amount (if applicable) for this issuer's BY 2016 RI audit, confirming the reported observations, as such this report will be considered a final RI audit report and will be published. If this option is selected, you must return this response within thirty (30) calendar days of the date of this draft RI audit report. The issuer's response(s) to this report will be included in the final published audit report.

Or

(INITIAL) _____ *Disagrees* and requests a review of additional information that may impact the reported observations and recoupment amount (if applicable) for this issuer's BY 2016 RI audit. If a review is requested, CMS will consider this draft only a preliminary RI audit report. If this option is selected, you must provide a written explanation with any additional supporting documentation that may impact the results of the RI audit when you return this response within thirty (30) calendar days of the date of this draft audit report. CMS will review the written explanation and any supporting documentation submitted as part of the issuer's response to this report to determine if the report can be amended in a mutually acceptable manner. CMS maintains discretion to determine whether amendments to the report are appropriate. The issuer's response(s) to this report will be included in the final published BY 2016 RI Payment audit report.

Corrective Action Plan

(INITIAL) JC If requested, the issuer *Agrees* to provide a Corrective Action Plan (CAP) to CMS for approval within 45 days of issuance of the final RI audit report if the audit resulted in at least one finding as required under 45 C.F.R. § 153.410(d)(4).

Signed: J-Clark _____

Printed Name: Joe Clark _____

Title: CFO E&I _____

Direct Telephone Number: 952-205-6030 _____

Date: 10/09/2025 _____

Appendix 2 – Procedure Criteria & Effect

Procedure	Criteria	Effect
Unreconciled Claims Review	RI eligible claims submitted to the EDGE server only include claims the issuer can substantiate in its claims system. See 45 C.F.R. §§ 153.410, 153.420, 153.700, and 153.710. See the RI Reference Guide (Version 2.0 March 17, 2016)²⁴	The inclusion of unreconciled claims in the BY 2016 RIDE Report results in a finding and a change to the issuer's BY 2016 RI payments.
RI-Eligible Plan Review	RI eligible claims submitted to the EDGE server only include claims incurred and paid by an applicable RI-eligible plan. See 45 C.F.R. §§ 153.410, 153.420, 153.700, and 153.710. See the RI Reference Guide (Version 2.0 March 17, 2016)²⁵	The inclusion of claims that were not paid by an RI-eligible plan results in a finding and a change to the issuer's BY 2016 RI payments. The inclusion of claims reported as paid by an incorrect RI-eligible plan results in an observation and no change to the issuer's BY 2016 RI payments.
Claim Coverage Period Validation	RI eligible claims submitted to the EDGE server only include claims incurred during the active enrollment period for the enrollee within the applicable BY. See 45 C.F.R. §§ 153.410, 153.420, 153.700, and 153.710. See the RI Reference Guide (Version 2.0 March 17, 2016)²⁶	The inclusion of claims that were not incurred within the enrollee's coverage period results in a finding and a change to the issuer's BY 2016 RI payments.
Paid Claim Amount Validation	RI eligible claims submitted to the EDGE server only include the amounts paid by the issuer. See 45 C.F.R. §§ 153.410, 153.420, 153.700, and 153.710. See the RI	The inclusion of claims with overstated paid claim amounts results in a finding and a change to the issuer's BY 2016 RI payments. The inclusion of claims with understated paid claim amounts results in an observation and no

²⁴ [EDGE Server: Reinsurance \(RI\) Quick Reference Guide \(hhs.gov\)](https://www.hhs.gov/edge-server/reinsurance-ri-quick-reference-guide)

²⁵ See supra note 24.

²⁶ See supra note 24.

Procedure	Criteria	Effect
	Reference Guide (Version 2.0 March 17, 2016) ²⁷	change to the issuer's BY 2016 RI payments. ²⁸
BY 2016 Cross Year Claim Validation	RI eligible claims submitted to the EDGE server only include claims that have a service end date within the applicable BY. See 45 C.F.R. §§ 153.410, 153.420, 153.700, and 153.710. See the RI Reference Guide (Version 2.0 March 17, 2016) ²⁹	The inclusion of claims that were reported in the incorrect BY results in a finding and a change to the issuer's BY 2016 RI payments.
Duplicate Claim Validation	RI eligible claims submitted to the EDGE server only include claims the issuer can substantiate in its claims system and should only be reported one time. See 45 C.F.R. §§ 153.410, 153.420, 153.700, and 153.710. See the RI Reference Guide (Version 2.0 March 17, 2016) ³⁰	The inclusion of duplicate claims results in a finding and a change to the issuer's BY 2016 RI payments.
Enrollee Validation	RI eligible claims submitted to the EDGE server should only include claims associated with the appropriate eligible enrollee ID. See 45 C.F.R. §§ 153.410, 153.420, 153.700, and 153.710. See the RI Reference Guide (Version 2.0 March 17, 2016) ³¹	The inclusion of claims associated with an enrollee that does not match the enrollee reported to the BY 2016 RIDE Report results in a finding and a change to the issuer's BY 2016 RI payments.
Issuer RI Policies and Procedures Review	Issuers should implement policies and procedures that adequately address and document their implementation and compliance with the federal requirements related to the HHS-operated transitional RI program and	The absence of adequate documentation regarding the issuer's RI policies and procedures results in an observation and no change to the issuer's BY 2016 RI payments.

²⁷ See supra note 24.

²⁸ See supra note 8.

²⁹ See supra note 24.

³⁰ See supra note 24.

³¹ See supra note 24.

Procedure	Criteria	Effect
	the EDGE server data submission process. See 45 C.F.R. § 153.410	
Issuer Compliance with Maintenance of Records and Audit Requirements	Issuers should adhere to audit specifications, documentation requests, and timelines outlined by CMS at the onset of the transitional RI Audit. Issuers must maintain documents and records for each BY for at least 10 years and must make those documents and records available to substantiate the request for RI payments. See 45 C.F.R. § 153.410(c) and (d)	The failure to comply with applicable CMS maintenance of records or audit requirements, including the failure to provide complete audit documentation in accordance with maintenance of records and audit requirements, results in an observation and will not result in a change to the issuer's BY 2016 RI payments if this deficiency does not impact CMS's ability to adequately substantiate the issuer's payment amounts.

Appendix 3 – Applicable Federal Regulations

The following table identifies select regulatory requirements related to the transitional RI audits.

Citation	Regulatory Text
45 C.F.R. § 153.410 – Requests for Reinsurance Payments	(a) <i>General requirement.</i> An issuer of a reinsurance-eligible plan may make a request for payment when that issuer's claims costs for an enrollee of that reinsurance-eligible plan has met the criteria for reinsurance payment set forth in subpart B of this part and the HHS notice of benefit and payment parameters and State notice of benefit and payment parameters for the applicable benefit year, if applicable. (b) <i>Manner of request.</i> An issuer of a reinsurance-eligible plan must make requests for payment in accordance with the requirements of the annual HHS notice of benefit and payment parameters for the applicable benefit year or the State notice of benefit and payment parameters described in subpart B of this part, as applicable. (c) <i>Maintenance of records.</i> An issuer of a reinsurance-eligible plan must maintain documents and records, whether paper, electronic, or in other media, sufficient to substantiate the requests for reinsurance payments made pursuant to this section for a period of at least 10 years, and must make those documents and records available upon request from HHS, the OIG, the Comptroller General, or their designees, or, in a State where the State is operating reinsurance, the State or its designee, to any such entity, for purposes of verification, investigation, audit, or other review of reinsurance payment requests. (d) <i>Audits and compliance reviews.</i> HHS or its designee may audit or conduct a compliance review of an issuer of a reinsurance-eligible plan to assess its compliance with the applicable requirements of this subpart and subpart H of this part. Compliance reviews conducted under this section will follow the standards set forth in § 156.715 of this subchapter. (1) <i>Notice of audit.</i> HHS will provide at least 30 calendar days advance notice of its intent to conduct an audit of an issuer of a reinsurance-eligible plan. (i) <i>Conferences.</i> All audits will include an entrance conference at which the scope of the audit will be presented and an exit conference at which the initial audit findings will be discussed.

Citation	Regulatory Text
	(2) <i>Compliance with audit activities.</i> To comply with an audit under this section, the issuer must: (i) Ensure that its relevant employees, agents, contractors, subcontractors, downstream entities, and delegated entities cooperate with any audit or compliance review under this section; (ii) Submit complete and accurate data to HHS or its designees that is necessary to complete the audit, in the format and manner specified by HHS, no later than 30 calendar days after the initial audit response deadline established by HHS at the entrance conference described in paragraph (d)(1)(i) of this section for the applicable benefit year; (iii) Respond to all audit notices, letters, and inquiries, including requests for supplemental or supporting information, as requested by HHS, no later than 15 calendar days after the date of the notice, letter, request, or inquiry; and (iv) In circumstances in which an issuer cannot provide the requested data or response to HHS within the timeframes under paragraph (d)(2)(ii) or (iii) of this section, as applicable, the issuer may make a written request for an extension to HHS. The extension request must be submitted within the timeframe established under paragraph (d)(2)(ii) or (iii) of this section, as applicable, and must detail the reason for the extension request and the good cause in support of the request. If the extension is granted, the issuer must respond within the timeframe specified in HHS's notice granting the extension of time. (3) <i>Preliminary audit findings.</i> HHS will share its preliminary audit findings with the issuer, who will then have 30 calendar days to respond to such findings in the format and manner specified by HHS. (i) If the issuer does not dispute or otherwise respond to the preliminary findings, the audit findings will become final. (ii) If the issuer responds and disputes the preliminary findings, HHS will review and consider such response and finalize the audit findings after such review. (4) <i>Final audit findings.</i> If an audit results in the inclusion of a finding in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by HHS, and the issuer must complete all of the following:

Citation	Regulatory Text
	(i) Within 45 calendar days of the issuance of the final audit report, provide a written corrective action plan to HHS for approval. (ii) Implement that plan. (iii) Provide to HHS written documentation of the corrective actions once taken. (5) Failure to comply with audit activities. If an issuer fails to comply with the audit activities set forth in this subsection in the manner and timeframes specified by HHS: (i) HHS will notify the issuer of reinsurance payments received that the issuer has not adequately substantiated; and (ii) HHS will notify the issuer that HHS may recoup any payments identified in paragraph (5)(i) of this section.
45 C.F.R. § 153.420 – Data Collection	(a) Data requirement. To be eligible for reinsurance payments, an issuer of a reinsurance-eligible plan must submit or make accessible all required reinsurance data in accordance with the reinsurance data collection approach established by the State, or by HHS on behalf of the State. (b) Deadline for submission of data. An issuer of a reinsurance-eligible plan must submit or make accessible data to be considered for reinsurance payments for the applicable benefit year by April 30 of the year following the end of the applicable benefit year.
45 C.F.R. § 153.700(a) – Distributed data environment	(a) Dedicated distributed data environments. For each benefit year in which HHS operates the risk adjustment or reinsurance program on behalf of a State, an issuer of a risk adjustment covered plan or a reinsurance-eligible plan in the State, as applicable, must establish a dedicated data environment and provide data access to HHS, in a manner and timeframe specified by HHS, for any HHS-operated risk adjustment and reinsurance program.
45 C.F.R. § 153.710(a)-(d) – Data requirements	(a) Enrollment, claims, and encounter data. An issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, must provide to HHS, through the dedicated data environment, access to enrollee-level plan enrollment data, enrollee claims data, and enrollee encounter data as specified by HHS.

Citation	Regulatory Text
	(b) <i>Claims data</i> All claims data submitted by an issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, must have resulted in payment by the issuer (or payment of cost sharing by the enrollee). (c) <i>Claims data from capitated plans.</i> An issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, that does not generate individual enrollee claims in the normal course of business must derive the costs of all applicable provider encounters using its principal internal methodology for pricing those encounters. If the issuer does not have such a methodology, or has an incomplete methodology, it must supplement the methodology in a manner that yields derived claims that are reasonable in light of the specific service and insurance market that the plan is serving. (d) <i>Final dedicated distributed data environment report.</i> Within 15 calendar days of the date of the final dedicated distributed data environment report from HHS, the issuer must, in a format specified by HHS, either: (1) Confirm to HHS that the information in the final report accurately reflects the data to which the issuer has provided access to HHS through its dedicated distributed data environment in accordance with §153.700(a) for the benefit year specified in the report; or (2) Describe to HHS any discrepancy it identifies in the final dedicated distributed data environment report.
45 C.F.R. § 153.730 – Deadline for submission of data	A risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, must submit data to be considered for risk adjustment payments and charges and reinsurance payments for the applicable benefit year by April 30 of the year following the applicable benefit year or, if such date is not a business day, the next applicable business day. ³²

³² Recognizing there are years when April 30th does not fall on a business day, 45 C.F.R. § 153.730 was amended to provide that when April 30 falls on a non-business day, the deadline for issuers to submit the required data would be the next applicable business day. See the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023; Final Rule, 87 Fed. Reg. 27208 at 27258 (May 6, 2022). When this occurred in prior benefit years, CMS exercised enforcement discretion to shift the deadline to the next applicable business day. See *supra* note 6.