



Inspections Report

Clinical Laboratory Improvement Amendments (CLIA) Certification

Cook Children's Health Plan, El Paso
Health, and Superior HealthPlan



**Inspector
General**

Texas Health
and Human Services

July 12, 2022
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Clinical Laboratory Improvement Amendments (CLIA) Certification

Cook Children's Health Plan, El Paso Health, and Superior HealthPlan

Results in Brief

Why OIG Conducted This Inspection

The Texas Health and Human Services (HHS) Office of Inspector (OIG) General Audit and Inspections Division (OIG Inspections) conducted an inspection of managed care organization (MCO) processes for ensuring laboratory service providers have the appropriate Clinical Laboratory Improvement Amendments (CLIA) certification prior to paying submitted claims.

OIG previously conducted work related to laboratories that incorrectly billed Medicaid and received payment for procedure codes not covered by the laboratory's CLIA certificate. The payment of incorrect claims by MCOs indicated a systemic issue with the processing of claims for laboratory services.

Summary of Review

The inspection objective was to determine whether MCOs have controls to ensure payments made to laboratories are only for services covered under the laboratory's CLIA certification level.

The inspection scope covered MCO processes and claims from January 1, 2021, through March 31, 2021, for the following MCOs: Cook Children's Health Plan, El Paso Health, and Superior HealthPlan.

Key Results

One of the three inspected MCOs had processes for obtaining a provider's CLIA certificate at the time of credentialing and recredentialing in the MCO's provider network. However, the MCOs did not have consistent processes for:

- Obtaining and maintaining current provider CLIA certificates
- Denying claims from laboratories with expired CLIA certificates
- Denying claims from providers that billed for procedures not covered by their CLIA certificate

Recommendations

The MCOs should:

- Ensure they obtain and maintain the current CLIA certificate for each laboratory in its provider network billing CLIA procedure codes.
- Use the information provided by HHSC to develop processes to ensure the lab certification codes listed on providers' CLIA certificates correspond to procedure codes in their claims payer system.
- Ensure their claims payer system denies claims for procedure codes that do not correspond to the laboratory certificate codes listed on a provider's CLIA certificate.

Management Response

The MCOs agreed with the inspection's recommendations and indicated they are working with HHSC on implementation.

For more information, contact: OIGInspectionsReports@hhs.texas.gov

Table of Contents

Inspection Overview	1
Overall Results	1
Objectives	2
Scope	2
Background	2
What Prompted This Inspection	3
Detailed Results	4
Observation 1: MCOs Do Not Have Processes to Ensure They Have Current CLIA Certificates for Laboratories in Their Provider Networks	4
Observation 2: MCOs Do Not Maintain Lab Certification Codes from CLIA Certificates in Their Claims Payer Systems	8
Appendix A: Methodology and Standards	12
Appendix B: Report Team and Distribution	14
Appendix C: OIG Mission, Leadership, and Contact Information ...	16

Inspection Overview

Overall Results

The Texas Health and Human Services (HHS) Office of Inspector General (OIG) Audit and Inspections Division (OIG Inspections) conducted an inspection of managed care organization (MCO) processes for ensuring laboratory service providers have the appropriate Clinical Laboratory Improvement Amendments (CLIA) certification prior to paying submitted claims.

One of the three inspected MCOs had processes for obtaining a laboratory's CLIA certificate at the time of credentialing and recredentialing in the MCO's provider network. However, the MCOs did not have consistent processes for:

- Obtaining and maintaining current provider CLIA certificates
- Denying claims from laboratories with expired CLIA certificates
- Denying claims from providers that billed for laboratory procedures not covered by their CLIA certificate

OIG Inspections offered recommendations to Cook Children's Health Plan, El Paso Health, and Superior HealthPlan, which, if implemented, will help to ensure the MCOs make appropriate payments to laboratories based on the laboratory's CLIA certification level and lab certification codes.

OIG Inspections presented preliminary inspection results, observations, and recommendations to Cook Children's Health Plan, El Paso Health, and Superior HealthPlan in a draft report dated June 2, 2022. Cook Children's Health Plan, El Paso Health, and Superior HealthPlan agreed with the inspection's recommendations. All three MCOs' management responses are included in the report following each recommendation.

For instances of noncompliance identified in the inspection report, the Texas Health and Human Services Commission (HHSC) may consider tailored contractual remedies to compel MCOs to meet contractual requirements. In addition,

inspection findings in the report may be subject to OIG administrative enforcement measures,¹ including administrative penalties.²

OIG Inspections thanks management and staff at Cook Children's Health Plan, El Paso Health, and Superior HealthPlan for their cooperation and assistance during this inspection.

Objective

The inspection objective was to determine whether MCOs have controls to ensure payments made to laboratories are only for services covered under the laboratory's CLIA certification level.

Scope

The inspection scope covered MCO processes and claims from January 1, 2021, through March 31, 2021, for the following MCOs: Cook Children's Health Plan, El Paso First Health Plans, Inc. doing business as El Paso Health, and Superior HealthPlan, Inc.

Background

CLIA regulations include federal standards applicable to all U.S. facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease.³

The Centers for Medicare and Medicaid Services (CMS) sent a letter in 2000 to state Medicaid directors, stating "each State must ensure that all laboratories used for testing Medicaid beneficiaries are CLIA certified. . . . All states were alerted at the onset of CLIA to include contract requirements that laboratories paid with

As used in this section, the term "laboratory" means a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings, as defined in 42 U.S. Code § 263a (2012).

¹ Tex. Admin. Code § 371.1603 (May 20, 2020).

² Tex. Hum. Res. Code § 32.039 (Apr. 2, 2015).

³ 42 C.F.R. § 493.3(b) (Apr. 24, 2003) identifies the following exemptions: forensic laboratories, drug testing laboratories certified by the Substance Abuse and Mental Health Services Administration, and laboratories that do not report patient specific results.

Medicaid funds be CLIA certified.”⁴ In addition, CMS issues CLIA laboratory certificates.

Laboratories must apply for a CLIA certificate and identify their specialty and sub-specialty areas through CMS. These specialty and sub-specialty certification codes, in turn, correspond to specific procedure codes that the laboratory is certified to perform. Certificates are valid for two years. The Food and Drug Administration categorizes tests as falling into one of three levels of complexity: waived, moderate (which includes the provider-performed microscopy subcategory), and high.^{5,6}

What Prompted This Inspection

OIG previously conducted work related to laboratories that incorrectly billed Medicaid and received payment for procedure codes not covered by the laboratory’s CLIA certificate. The payment of incorrect claims by MCOs indicated a systemic issue with the processing of claims for laboratory services.

⁴ U.S. Department of Health and Human Services, “Medicaid Clinical Laboratory Improvement Amendments (CLIA) Implementation,” Release No. 35 (July 13, 2000).

⁵ U.S. Food and Drug Administration, “Clinical Laboratory Improvement Amendments (CLIA),” <https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clinical-laboratory-improvement-amendments-clia> (accessed Nov. 11, 2021).

⁶ 42 C.F.R. § 493.5 (Apr. 24, 1995).

Detailed Results

The following sections of this report provide additional detail about the instances of noncompliance observed by OIG Inspections.

Observation 1: MCOs Do Not Have Processes to Ensure They Have Current CLIA Certificates for Laboratories in Their Provider Networks

During the review of the three MCOs, the inspection team found the MCOs did not have controls in place to ensure laboratories provided updated certificates, as required.

Laboratories are required to renew their CLIA certificates every two years. When laboratories change the type, methodology of examinations, or other procedures they must provide notice describing the changes within six months after the change was effective.⁷ When the changes require a revised certificate, laboratories are not eligible for Medicaid until their certificate has been revised.⁸

None of the MCOs have processes to ensure laboratories provide updated certificates. MCOs either rely on each laboratory's credentialing and recredentialing process to verify CLIA certificates or verify certificate information on the CMS website. This process may not provide MCOs with the most current CLIA certificate; therefore, MCOs cannot ensure they only pay for laboratory procedures the laboratory is certified to perform.

Recommendation 1

MCOs should ensure they obtain and maintain the current CLIA certificate for each laboratory in their provider network billing for CLIA procedure codes.

⁷ 42 U.S.C. §§ 263a(c)(2) and (d)(1)(A) (Dec. 4, 2012).

⁸ 42 C.F.R. § 493.1809 (Sept. 1, 1992).

Cook Children's Health Plan Management Response

Action Plan

Collect the CLIA certificate with the lab certification codes at the time of credentialing and monitor expiration date of the CLIA certificate for in network laboratories and require CLIA certificate to be submitted with claim for out-of-network providers.

Responsible Manager

Manager Network Development

Target Implementation Date

January 1, 2023

El Paso Health Management Response

Action Plan

El Paso Health has updated the Contract Set up Standard Operating Procedure (SOP) to include the following processes.

El Paso Health's Contracting and Credentialing Representatives (CCRs) will ensure that Providers that notify El Paso Health (EPH) of a CLIA certification, provide the most current and up to date CLIA certificate. Each practice location should have its own CLIA. The CLIA certificate will indicate the level of certification and specific codes in accordance to the level. All pages of the certificate will be required. Only those codes applicable to the level will be added to the Providers or Facility contract. The CLIA number, level, effective and expiration dates are housed in EPH's Claims Payer System under the Credentialing Module.

Obtain the current CLIA for each laboratory in the provider network

1. When adding a new Provider, if the Provider has a CLIA, the CCRs will ensure that the Providers CLIA certificate is available. If the CLIA certificate is not available, the provider will be added with a "No CLIA contract" until the Provider provides a CLIA certificate.
2. Once the Provider provides the current CLIA certificate, then the CCRs will request to System Configuration to add the CLIA level to the providers contract. The CCR will provide to EPH's System Configuration team a link to the CLIA certificate in order for System Configuration to validate the level

and codes according to the certification and set up the contract accordingly. The CLIA certificate will be applicable to the clinic location and will include all Providers under that clinic location, Facility or group practice.

Maintain the current CLIA Certificate for each laboratory in the provider network

As part of the ongoing monitoring and maintenance of CLIA certificates, the CCRs will run a report on a monthly basis from the Credentialing Module of EPH's Claims Payer System. The report will be based on the CLIA expiration for each credentialed provider or facility and identify any expired or soon to be expired CLIAs. If the CLIA has expired, the CCRs will send a notification to the System Configuration Department to ensure that the CLIA is terminated and no claims will be paid under an expired CLIA. The termination date will be the date of expiration of CLIA. The CCRs will reach out to Providers and obtain the current CLIA certificate. Once the providers submit to EPH the current CLIA certificate, the CCRs will then update the information in the Credentialing module of EPH's Claims Payer System and provide to EPH Configuration team the link for the updated CLIA certificate. EPH's System Configuration team will update the providers contract in accordance to the CLIA certificate provided.

All network providers will be educated on CLIA requirements for claims payment.

Responsible Manager

Contracting and Credentialing Manager

Target Implementation Date

Implementation date will align with any final direction from HHSC/OIG in collaboration with all MCOs.

Superior HealthPlan Management Response

Action Plan

Superior's current initial and re-credentialing procedures include requirements for applicable providers, including laboratories, to submit a copy of the CLIA certificate(s), along with all other credentialing documents required for credentialing the provider. Superior has initiated the identification of all in network providers billing CLIA-applicable codes to isolate the universe of providers that will require receipt of current paper CLIA certificates, outside of the provider's normal recredentialing cycle. The requested electronic provider data file will alleviate the provider and MCO burden to supply on a more

frequent basis (and to multiple requested MCOs) as well as increase accuracy of claims payment.

Responsible Manager

Credentialing Director

Target Implementation Date

March 31, 2023

Observation 2: MCOs Do Not Maintain Lab Certification Codes from CLIA Certificates in Their Claims Payer Systems

The MCOs' claims payer systems did not contain the CLIA lab certification codes, which are needed to identify CLIA claims that should be paid. As a result:

- MCOs made payments without verifying lab certification codes.
- In some instances, MCOs incorrectly made payments for procedure codes that did not fall under the lab certification codes on the laboratory's CLIA certificate.

MCOs may only reimburse for laboratory procedures that a laboratory is certified to perform.^{9,10}

The MCOs all have a partial process in their claims payer system that includes the CLIA certificate expiration date, the CLIA number, and the level of the certificate. However, none of the MCOs' claims payer systems identified lab certification codes, which are necessary to compare with allowable procedure codes. The automated edits within the MCOs' claims payer systems cannot appropriately approve or deny laboratory claims without aligning the procedure codes to the corresponding lab certification codes listed on the CLIA certificate.

During the inspection, HHSC developed a process to provide information to the MCOs that will assist them with aligning procedure codes to lab certification codes.

Recommendation 2.1

MCOs should use the information provided by HHSC to develop processes to ensure the lab certification codes listed on providers' CLIA certificates correspond to procedure codes in their claims payer system.

Recommendation 2.2

MCOs should ensure their claims payer system denies claims for procedure codes that do not correspond to the laboratory certificate codes listed on the provider's CLIA certificate.

⁹ 42 C.F.R. § 493.1809 (Sept. 1, 1992).

¹⁰ Uniform Managed Care Contract, Attachment A, § 7.02(16), v. 2.31 (Sept. 1, 2020) and v. 2.32 (Mar. 2, 2021).

Cook Children's Health Plan Management Response

Action Plan

Configure claims system to deny payment for codes not applicable to CLIA lab certification.

Responsible Managers

- Manager Benefits and Reimbursement
- Director Epic Applications
- Manager Claims

Target Implementation Date

January 1, 2023

El Paso Health Management Response

Action Plan

El Paso Health (EPH) will download HHSC's crosswalk and use it to map the lab certification codes to lab procedure codes. The Configuration team will use HHSC's crosswalk to build service groups within their core claims payer system (MIS) that will be used to add ONLY the allowed lab procedures into a Provider's contract for reimbursement.

EPH's Contracting Department will submit all Provider CLIA certificates to the Configuration team for system updates within our MIS. The Configuration team will review the lab certification codes listed on the provider's CLIA certificate and will create a contract term reimbursement containing only the allowed lab certification codes mapped within service groups. This task will be completed using HHSC's laboratory crosswalk as a guide which maps lab certification codes to lab procedure codes.

EPH's Configuration team will configure specific contract terms containing service groups with mapped lab certification codes to lab procedure codes. This process ensures that only allowed lab services listed within a Provider's contract will be reimbursed. Any code not listed within a Provider's contract (not corresponding to laboratory certificate codes listed in Provider's CLIA and mapped using HHSC's crosswalk) will not be reimbursed and will DENY, in EPH's Claim Payer System.

Responsible Manager

- Director of IS Applications
- Chief Information Officer

Target Implementation Date

Implementation date will align with any final direction from HHSC/OIG in collaboration with all MCOs.

Superior HealthPlan Management Response

Action Plan

Recommendation 2.1

Superior appreciates HHSC's support in creating a more efficient process by providing the procedure codes to lab certification codes process. We are currently reviewing for implementation into our processes. To further the efficiency and accuracy, the requested electronic provider data file will ensure the HHSC provided process is optimized by utilizing the most up to date provider CLIA certification data.

Recommendation 2.2

Superior's claims payer system currently has capabilities to deny claims submitted with invalid lab certification codes, as well as claims billed with missing lab certification codes. Additionally, Superior's claims payer system has capabilities, currently live-in other states where there is a state-provided electronic provider CLIA certification file, to deny claims for procedure codes that do not correspond to the provider's laboratory certification codes listed on their CLIA certificate. In the absence of the requested HHSC provided data file, Superior has initiated the identification of all in network providers billing CLIA-applicable codes to isolate the universe of providers that will require receipt of current paper CLIA certificates, outside of the provider's normal recredentialing cycle. Due to the manual nature of the process to obtain and maintain provider's CLIA certificates, Superior anticipates a delay from the time the certifications are requested to when they are in our systems to leverage the system enhancement to deny claims as described above. We are in the initial stages of planning for the system enhancement and, in order to avoid a high volume of inappropriate denials related, we are also evaluating the timing of the system enhancement to allow our teams and providers the opportunity to update applicable certification

information into our system prior to inappropriate denial. As described before, the system enhancement could more quickly be implemented with the provision of the requested electronic provider data file.

Responsible Manager

Vice President Claims Support

Target Implementation Date

March 31, 2023

OIG Inspections Comment

OIG Inspections thanks the MCOs for taking steps to address the issues identified in this report and recognizes that MCOs are working with HHSC on implementation of the recommendations. OIG Inspections does not direct MCO management actions and supports the MCOs continuing to work with HHSC to address the issues identified in the inspection.

Appendix A: Methodology and Standards

Methodology

The inspection team collected data for this inspection by:

- Conducting interviews and two surveys with the MCOs
- Reviewing policies and procedures for claims adjudication
- Reviewing selected CLIA certificates provided by MCOs
- Analyzing encounter data from January 1, 2021, through March 31, 2021

The OIG Fraud Analytics and Data Operations Division provided encounter data for laboratory procedures for the date range of January 1, 2021, through March 31, 2021, which identified 739,599 claims paid by the three MCOs.

To accomplish the inspection objective, inspectors:

- Analyzed encounter data to identify incorrect payments
- Interviewed MCOs to determine why incorrect payments were made

The inspection team analyzed encounter data using two approaches:

- Reviewing claims for moderate and high complexity procedures paid to laboratories with a Certificate of Waiver or Certificate of Provider-Performed Microscopy Procedures.
- Reviewing lab certification codes from certificates of Registration, Accreditation, and Compliance to determine if procedures were paid that were not covered by a provider's CLIA certificate.

There are two components of CLIA compliance: (a) level of certification and (b) specific certification codes.

Laboratories that hold a Certificate of Provider-Performed Microscopy Procedures may be reimbursed for a limited number of moderate complexity procedures, as well as all waived procedures. Laboratories that hold a Certificate of Waiver are only allowed to perform waived tests.

Laboratory certification codes are identified on the certificate of any provider performing moderate to high complexity procedures.

The inspection team used risk-based sampling to select patient control numbers and procedure codes for testing.

Standards

OIG Inspections conducts inspections of Texas HHS programs, systems, and functions. Inspections are designed to be expeditious, targeted examinations into specific programmatic areas to identify systemic trends of fraud, waste, or abuse. Inspections typically result in observations and may result in recommendations to strengthen program effectiveness and efficiency. OIG Inspections conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

Appendix B: Report Team and Distribution

Report Team

OIG staff members who contributed to this inspection report include:

- Kacy J. VerColen, CPA, Deputy Inspector General of Audit and Inspections
- Bruce Andrews, CPA, CISA, Director of Inspections
- James Aldridge, Manager of Inspections
- Charlene Anderson, CTCM, Team Lead for Inspections
- Jeffrey Fullam, Senior Inspector
- Casey Gibson, Senior Inspector
- Mo Brantley, Senior Audit Operations Analyst

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- Emily Zalkovsky, Deputy State Medicaid Director, Medicaid and CHIP Services
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- Dana Collins, Interim Deputy Executive Commissioner for Operations, Medicaid and CHIP Services
- Katherine Scheib, Deputy Associate Commissioner, Medicaid and CHIP Services
- Michelle Erwin, Deputy Associate Commissioner for Office of Policy
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- Karen Love, President
- Traci Simmons, Manager Network Development
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- David Shaffer, Director Epic Applications
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- Janel Lujan, Interim Chief Executive Officer
- Jourdan Norman, Special Investigative Unit Program Manager
- Sharon Perkins, Chief Information Officer
- Javier Sanchez, Director of IS Applications
- Evelin Lopez, Contracting and Credentialing Manager

Superior HealthPlan

- Mark D. Sanders, Chief Executive Officer
- Teresa Kahan, Director Compliance
- Karen Westbay, Vice President Claims Support
- Jason Gajewski, Credentialing Director

Appendix C: OIG Mission, Leadership, and Contact Information

The mission of OIG is to prevent, detect, and deter fraud, waste, and abuse through the audit, investigation, and inspection of federal and state taxpayer dollars used in the provision and delivery of health and human services in Texas. The senior leadership guiding the fulfillment of OIG's mission and statutory responsibility includes:

- Sylvia Hernandez Kauffman, Inspector General
- Audrey O'Neill, Principal Deputy Inspector General, Chief of Audit and Inspections
- Susan Biles, Chief of Staff, Chief of Policy and Performance
- Erik Cary, Chief Counsel
- Christine Maldonado, Chief of Operations and Workforce Leadership
- Steve Johnson, Chief of Investigations and Reviews

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