

Inspections Report

Clinical Laboratory Improvement Amendments (CLIA) Certification

Texas Medicaid and Healthcare Partnership
(TMHP)



**Inspector
General**

Texas Health
and Human Services

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Clinical Laboratory Improvement Amendments (CLIA) Certification

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Results in Brief

Why OIG Conducted This Inspection

The Texas Health and Human Services (HHS) Office of Inspector General (OIG) Audit and Inspections Division (OIG Inspections) conducted an inspection of Texas Medicaid and Healthcare Partnership (TMHP) processes to ensure laboratory service providers have the appropriate Clinical Laboratory Improvement Amendments (CLIA) certification prior to paying submitted claims.

OIG Inspections conducted work to determine whether MCOs controls ensure payments made to laboratories were only for services covered under the laboratory's CLIA certification level. OIG conducted this additional work to determine whether controls were in place for fee-for-service claims paid by TMHP.

Summary of Review

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

The inspection scope covered TMHP processes and claims from September 1, 2021, through November 30, 2021.

Key Results

Texas Medicaid and Healthcare Partnership (TMHP) has processes for obtaining the Clinical Laboratory Improvement Amendments (CLIA) certificate information at the time a laboratory enrolls in Texas Medicaid. TMHP receives a file from Centers for Medicare and Medicaid Services (CMS) weekly, which is used in an automated process to update CLIA information in its claims payer system. TMHP has automated edits to check the CLIA certification type but does not have processes for denying claims from laboratory providers that bill for laboratory procedures not covered by their CLIA certificate.

Recommendations

The TMHP claims payer system should include lab certification codes in its claims adjudication process and deny claims for procedure codes that do not correspond to the lab certification codes listed on the provider's CLIA certificate.

TMHP should ensure procedure codes in its claims payer system correspond to the lab certification codes listed on the providers' CLIA certificate.

Management Response

OIG Inspections presented preliminary inspection results, observations, and recommendations to TMHP in a draft report dated June 22, 2022. TMHP agreed with the inspection's recommendations. TMHP's management response is included in the report following the recommendations.

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

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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 Texas Medicaid and Healthcare Partnership (TMHP) processes to ensure laboratory service providers have the appropriate Clinical Laboratory Improvement Amendments (CLIA) certification prior to paying submitted claims.

TMHP has processes for obtaining the CLIA certificate information at the time a laboratory enrolls in Texas Medicaid. TMHP receives a file from Centers for Medicare and Medicaid Services (CMS) weekly, which is used in an automated process to update CLIA information in its claims payer system. TMHP has automated edits to check the CLIA certificate type but does not have processes for denying claims from laboratory providers that bill for laboratory procedures not covered by their CLIA certificate.

OIG Inspections offered recommendations to TMHP, which, if implemented, will help ensure TMHP makes payments to laboratories based on their CLIA certification level and lab certification codes.

OIG Inspections presented preliminary inspection results, observations, and recommendations to TMHP in a draft report dated June 22, 2022. TMHP agreed with the inspection's recommendations. TMHP's management response is included in the report following the recommendations.

For instances of noncompliance identified in the inspection report, the Texas Health and Human Services Commission (HHSC) may consider tailored contractual remedies to compel TMHP 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 TMHP for their cooperation and assistance during this inspection.

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

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

Objective

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

Scope

The inspection scope covered TMHP processes and claims from September 1, 2021, through November 30, 2021.

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

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.^{4,5}

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).

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.

⁴ 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).

⁵ 42 C.F.R. § 493.5 (Apr. 24, 1995).

What Prompted This Inspection

OIG Inspections conducted work to determine whether MCOs' controls ensure payments made to laboratories were only for services covered under the laboratory's CLIA certification level. OIG conducted this additional work to determine whether controls were in place for fee-for-service claims paid by TMHP.

Detailed Results

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

Observation 1: TMHP's Claims Payer System Does Not Use CLIA Laboratory Certification Codes in Its Claims Adjudication Process

TMHP's claims payer system has automated edits to check the CLIA certificate type and contains the CLIA lab certification codes needed to identify CLIA claims that should be paid. However, TMHP does not apply the lab certification codes when adjudicating claims. As a result:

- TMHP made payments without verifying lab certification codes.
- In some instances, TMHP made payments for procedure codes that did not fall under the lab certification codes on laboratories' CLIA certificates.

TMHP may only reimburse for laboratory procedures that a laboratory is certified to perform.⁶

TMHP has a weekly automated process that uses the confidential Provider of Service File – Clinical Laboratories from CMS⁷ to update the CLIA lab certification codes. TMHP matches the file with the CLIA identification numbers it has on file to update its claims payer system. However, TMHP's claims payer system does not compare the lab certification codes to allowable procedure codes. The automated edits within TMHP's claims payer system cannot appropriately approve or deny laboratory claims without matching the procedure codes to the corresponding lab certification codes listed on the CLIA certificate.

Recommendation 1.1

The TMHP claims payer system should include laboratory certification codes in its claims adjudication process and deny claims for procedure codes that do not correspond to the lab certification codes listed on the provider's CLIA certificate.

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

⁷ The confidential file is sent from CMS to HHSC Information Technology. HHSC makes the file available to TMHP, which uses the file to update its claims payer system.

Recommendation 1.2

TMHP should ensure procedure codes in its claims payer system correspond to the lab certification codes listed on the providers' CLIA certificate.

TMHP Management Response

Action Plan

TMHP will coordinate with HHSC Stakeholders to identify and implement the necessary system updates to the claims payer system and the Master Provider File via a Service Request Initiation (SRI). Once solution(s) and prioritization of the updates are agreed upon, TMHP will implement changes as required.

Responsible Manager

Director and Senior Architect/Lead of Base Enhancement Team

Target Implementation Date

December 2022

Appendix A: Methodology and Standards

Methodology

The inspection team collected data for this inspection by:

- Conducting interviews with TMHP
- Reviewing policies and procedures for claims adjudication
- Reviewing selected CLIA certificates with TMHP
- Analyzing claims data from September 1, 2021, through November 30, 2021

The OIG Fraud Analytics and Data Operations Division provided claims data for laboratory procedures for the date range of September 1, 2021, through November 30, 2021, which identified 222,889 claims paid by TMHP.

To accomplish the inspection objective, inspectors:

- Analyzed claims data to identify incorrect payments.
- Interviewed TMHP to determine why incorrect payments were made.

The inspection team analyzed claims 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
- Jeffrey Fullam, Team Lead for Inspections
- Charlene Anderson, CTCM, Team Lead for Inspections
- Casey Gibson, Senior Inspector
- Mo Brantley, Senior Audit Operations Analyst

Report Distribution

Health and Human Services

- Cecile Erwin Young, Executive Commissioner
- Kate Hendrix, Chief of Staff
- Maurice McCreary, Jr., Chief Operating Officer
- Jordan Dixon, Chief Policy and Regulatory Officer
- Karen Ray, Chief Counsel
- Michelle Alletto, Chief Program and Services Officer
- Nicole Guerrero, Director of Internal Audit
- Stephanie Stephens, Chief Medicaid and CHIP Services Officer, Medicaid and CHIP Services
- Emily Zalkovsky, Deputy State Medicaid Director, Medicaid and CHIP Services
- Shannon Kelley, Associate Commissioner for Managed Care, Medicaid and CHIP Services

- 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
- Leslie Smart, Director of Medical and Dental Benefits Policy

Texas Medicaid and Healthcare Partnership (TMHP)

- Terry Westropp, Chief Executive Officer
- John Spann, Chief Financial Officer
- Larry Castillo, External Audit Coordinator
- Kim Hatton, Director, Base Enhancement Team
- Peggy Daniels, Senior Architect/Lead, Base Enhancement Team

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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- Phone: 1-800-436-6184

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