



Inspections Report

Clinical Laboratory Improvement Amendments (CLIA) Certification

Amerigroup, Blue Cross and Blue Shield of Texas, Dell Children's Health Plan, Molina Healthcare of Texas, and United Healthcare Community Plan



**Inspector
General**

Texas Health
and Human Services

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Clinical Laboratory Improvement Amendments (CLIA) Certification

Amerigroup, Blue Cross and Blue Shield of Texas, Dell Children's Health Plan, Molina Healthcare of Texas, and United Healthcare Community Plan

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: Amerigroup, Blue Cross and Blue Shield of Texas, Dell Children's Health Plan, Molina Healthcare of Texas, and United Healthcare Community Plan.

Key Results

Four of the five inspected MCOs had processes for obtaining a provider's CLIA certificate at the time of credentialing and recertification 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

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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 managed care organization (MCO) processes for ensuring laboratory service providers have the appropriate Clinical Laboratory Improvement Amendments (CLIA) certification prior to paying submitted claims.

Four of the five 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 Amerigroup, Blue Cross and Blue Shield of Texas, Dell Children's Health Plan, Molina Healthcare of Texas, and UnitedHealthcare Community Plan, 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 Amerigroup, Blue Cross and Blue Shield of Texas, Dell Children's Health Plan, Molina Healthcare of Texas, and UnitedHealthcare Community Plan in a draft report dated June 2, 2022. Amerigroup, Blue Cross and Blue Shield of Texas, Dell Children's Health Plan, Molina Healthcare of Texas, and UnitedHealthcare Community Plan agreed with the inspection's recommendations. All five 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 Amerigroup, Blue Cross and Blue Shield of Texas, Dell Children's Health Plan, Molina Healthcare of Texas, and UnitedHealthcare Community Plan 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: Amerigroup Texas, Inc. doing business as Amerigroup Community Care of Texas; Health Care Service Corporation doing business as Blue Cross and Blue Shield of Texas; Seton Health Plan, Inc., doing business as Dell Children's Health Plan; Molina Healthcare of Texas, Inc.; and UnitedHealthcare Community Plan of Texas, L.L.C. doing business as UnitedHealthcare Community Plan.

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

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

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

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).

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}

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. 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).

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.

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 five 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).

Amerigroup Management Response

Action Plan

Amerigroup currently collects CLIA certificates during the initial credentialing and recredentialing (at least once every three years) process. Amerigroup will develop and distribute a provider notice to participating laboratory providers informing them of the requirements to provide new copies of updated CLIA certificates prior to the CLIA certificate expiration date and when a change to their lab certification code occurs. Amerigroup will work to collect, house, and monitor termination dates and changes of CLIA certifications for each participating laboratory in the provider network.

Responsible Manager

Director of Operations

Target Implementation Date

November 1, 2022

Blue Cross and Blue Shield of Texas Management Response

Action Plan

BCBSTX [Blue Cross and Blue Shield of Texas] will create a CLIA tracking process that includes certification codes and expiration dates. Copies of current CLIA certificates will be kept to demonstrate employment of claim denials based on certification code sets and expiration of the certificate.

Responsible Manager

Interim Executive Director, Texas Medicaid

Target Implementation Date

December 1, 2022

Dell Children's Health Plan Management Response⁹

Action Plan

Amerigroup currently collects CLIA certificates during the initial credentialing and recredentialing (at least once every three years) process. Amerigroup will develop and distribute a provider notice to participating laboratory providers informing

⁹ Amerigroup manages claims for Dell Children's Health Plan.

them of the requirements to provide new copies of updated CLIA certificates prior to the CLIA certificate expiration date and when a change to their lab certification code occurs. Amerigroup will work to collect, house, and monitor termination dates and changes of CLIA certifications for each participating laboratory in the provider network.

Responsible Manager

Amerigroup Director of Operations

Target Implementation Date

November 1, 2022

Molina Healthcare of Texas Management Response

Action Plan

Molina validated that our system is able to store the CLIA information, and we have the necessary fields to house this data. The activities necessary for implementation are dependent upon whether Molina will be able to obtain the CLIA certification information for each provider electronically (through a single file as recommended above) or if a manual/image solution will be required.

Outlined below are the actions needed for each option (electronic or manual):

Option A- electronic file received by a single source of truth

For a data exchange sourced single file, the required actions are to validate the data exchange specifications and compare to our existing custom solution file format to determine if any changes will be needed.

Option B – manual process for collection of CLIA certification

Additional actions are required if the CLIA certification information must be obtained directly from providers with copies or images of the individual certificates and any updates that would be submitted by providers. This will require the development of new capability to collect and house the CLIA certifications in either an existing or new document repository. We would evaluate an imaging solution and ICR/OCR technology to automatically capture the information from the certificates. We will also design and implement a new workflow driven process for accessing the certifications and entering the required information into our system, or validating the information captured through the imaging process, if applicable. After this work is complete, we estimate an

implementation schedule and develop a project plan to determine the entire implementation effort.

Responsible Manager

Health Plan Operations/Vice President

Target Implementation Date

Depending on discussions with HHSC and whether Option A or Option B is appropriate, Molina will work with HHSC to implement the project as agreed. Molina also recommends a 6-month CLIA collection period after deployment for recommendation A prior to implementing the claims adjudication recommendation.

UnitedHealthcare Community Plan Management Response

Action Plan

UHC [UnitedHealthCare] currently has a process to ensure we have current CLIA certificates for laboratories in our Provider networks. UHC does not obtain the paper certificates, but we do ensure that the CLIA certificates for all claims billed on HCFA [Health Care Financing Administration, the former name for the Centers for Medicare and Medicaid Services (CMS)] forms are valid/current based on the quarterly QIES [Quality Improvement and Evaluation System] file from CMS and weekly data pulls from the CDC website. UHC looks forward to working with CMS and HHSC to develop a more robust process that will assist MCOs with compliance with contractual requirements.

Responsible Manager

Payment Integrity Operations

Target Implementation Date

UHC will work in collaboration with HHSC to meet deadlines for any necessary updates to the claims payer system, once reports and tools are created for implementation. Completion of this work will depend on the details and scope of the project for implementation. However, UHC will work aggressively to meet any and all deadlines for completion.

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.^{10,11}

Two of the five MCOs have a partial process in their claims payer systems 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.

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

¹¹ Uniform Managed Care Contract, Attachment A, § 7.02(16), v. 2.31 (Sept. 1, 2020) and v. 2.32 (Mar. 2, 2021).

Amerigroup Management Response

Action Plan

Amerigroup will develop and distribute a provider notification informing providers that Amerigroup will deny procedure codes that do not correspond with the lab certification codes on their CLIA certification. Amerigroup will configure the lab certification codes for each provider, based on the providers CLIA certification. Amerigroup will create a process to receive, and update on an ongoing basis, the lab certification codes and the crosswalk of the corresponding procedure codes provided by HHSC. This crosswalk will be used to configure our claims payment system to pay or deny claims based on the procedure code listed on the crosswalk and the corresponding lab certification code that is on the laboratory's CLIA certificate.

Responsible Manager

Director of Operations

Target Implementation Date

Between six to nine months

Blue Cross and Blue Shield of Texas Management Response

Action Plan

- BCBSTX [Blue Cross and Blue Shield of Texas] Medicaid initiated a project on May 13, 2022 to develop a new CLIA editing process. This process will include validating that the providers' CLIA certificate information (i.e., type of certificate, LC codes) corresponds to the laboratory services billed. In instances where the claim does not correspond to the laboratory certificate type or laboratory certificate codes listed on the provider's CLIA certificate, the BCBSTX Medicaid claim engine will deny the claim.
- Claims Processing Policy for CLIA to be created by December 1, 2022
- Education with staff (i.e., Customer Service, Provider Network) regarding claims processing update to be completed by December 1, 2022

Responsible Manager

Interim Executive Director, Texas Medicaid

Target Implementation Date

December 1, 2022

Dell Children's Health Plan Management Response¹²

Action Plan

Amerigroup will develop and distribute a provider notification informing providers that Amerigroup will deny procedure codes that do not correspond with the lab certification codes on their CLIA certification. Amerigroup will configure the lab certification codes for each provider, based on the providers CLIA certification. Amerigroup will create a process to receive, and update on an ongoing basis, the lab certification codes and the crosswalk of the corresponding procedure codes provided by HHSC. This crosswalk will be used to configure our claims payment system to pay or deny claims based on the procedure code listed on the crosswalk and the corresponding lab certification code that is on the laboratory's CLIA certificate.

Responsible Manager

Amerigroup Director of Operations

Target Implementation Date

Between six to nine months

Molina Healthcare of Texas Management Response

Action Plan

Recommendation 2.1:

The first activity is to review the HHSC specifications and any sample cross walk files to document the requirements for receiving the data from HHSC and evaluate modifications needed to our current custom solution. During this process we would review the system changes needed to ingest, store, and access the crosswalk information in our system to support claims processing. Once complete we estimate timelines and develop a project plan.

Recommendation 2.2:

Molina will review HHSC's specifications and requirements to document the requirements for claim processing logic, pay/pend/deny decisions. The claims processing team will work side by side with the technical staff to automate this process. We will identify all procedures that need to be updated and the training

¹² Amerigroup handles claims for Dell Children's Health Plan.

needs for impacted staff (claims, appeals & grievance, call center, provider services, etc.) The Texas provider outreach and education team will be engaged to plan communications and outreach to support the initiative and educate providers. Once all data is collected, we will estimate the timeline and develop the project plan.

Responsible Manager

Health Plan Operations/Vice President

Target Implementation Date

Molina will work with HHSC and determine the implementation timetable according to HHSC requirements.

UnitedHealthcare Community Plan Management Response

Action Plan

The requirement to maintain lab certification codes from CLIA in the claims payer system is not possible to implement currently, because of the lack of “source of truth” data and provider billing timelines associated with CMS CLIA certificate update concessions.

The Centers for Medicare & Medicaid Services (CMS), maintains CLIA editing regulations and is the current source of truth for MCOs. CMS does not publish an accurate list of procedure codes under each LC [laboratory code] which is required in order to automate editing against claims data creating a challenge for MCOs.

Under CMS guidelines, providers maintain a 6-month concession time period to update the LC code list associated with their active CLIA certificate. Under CMS guidelines, a provider who has submitted a request to modify the LC codes in their current CLIA certification is allowed to perform and bill for procedures under LC codes not yet on their certificate for a 6-month period. Should MCOs implement editing to deny claims for LC codes not on the provider’s certificate, there may be significant provider abrasion during the 6-month concession time period.

In order to implement this requirement with minimal member and provider abrasion, UHC [UnitedHealthcare] will work with HHSC to initiate a Texas Medicaid specific process that will provide the CLIA data required to meet the goal of maintaining certificates in the claims payer system. This would allow all

MCOs to implement consistent editing across all health plans and maintain a consistent message to providers regarding their claims processing.

Responsible Manager

Payment Integrity Operations

Target Implementation Date

UHC will work in collaboration with HHSC to meet deadlines for any necessary updates to the claims payer system, once reports and tools are created for implementation. Completion of this work will depend on the details and scope of the project for implementation. However, UHC will work aggressively to meet any and all deadlines for completion.

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 937,809 claims paid by the five 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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- 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

Amerigroup

- Greg Thompson, President and Chief Executive Officer
- Tiffany Zook, Business Consultant
- Jessica McFarlin, Director of Operations

Blue Cross and Blue Shield of Texas

- Victor Santillan, Interim Chief Executive Officer and Executive Director
- John Bacot, Senior Manager, SIU

Dell Children's Health Plan

- Marinan Williams, President and Chief Executive Officer
- Amy Miller, Director Regulatory Compliance

Molina Healthcare of Texas

- Chris Coffey, Plan President
- Mark Shaffer, Vice President of Health Plan Operations
- Lovey Barnes, Director of Government Contracts

UnitedHealthcare Community Plan

- Shaun Viola, Chief Operating Officer
- Deborah Deska, RN, Compliance Officer
- Brandi MacFarlane, Payment Integrity Operations

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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