Inspections Report

Clinical Laboratory Improvement Amendments (CLIA) Certification

Aetna Better Health of Texas, Community First Health Plans, Driscoll Health Plan, and Parkland Community Health Plan

July 11, 2022
OIG Report No. INS-22-003
Clinical Laboratory Improvement Amendments (CLIA) Certification
Aetna Better Health of Texas, Community First Health Plans, Driscoll Health Plan, and Parkland Community Health 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: Aetna Better Health of Texas, Inc., Community First Health Plans, Inc., Driscoll Health Plan, and Parkland Community Health Plan, Inc.

Key Results
The 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
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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.

The 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 Aetna Better Health of Texas, Community First Health Plans, Driscoll Health Plan, and Parkland Community Health 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 Aetna Better Health of Texas, Community First Health Plans, Driscoll Health Plan, and Parkland Community Health Plan in a draft report dated June 2, 2022. Aetna Better Health of Texas, Community First Health Plans, Driscoll Health Plan, and Parkland Community Health Plan agreed with the inspection’s recommendations. All four 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 Aetna Better Health of Texas, Community First Health Plans, Driscoll Health Plan, and Parkland Community Health 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: Aetna Better Health of Texas, Inc. doing business as Aetna Better Health, Community First Health Plans, Inc., Driscoll Children’s Health Plan, and Parkland Community Health Plan, 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

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\(^3\) 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.” 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.

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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 four 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. When the changes require a revised certificate, laboratories are not eligible for Medicaid until their certificate has been revised.

One of the MCOs has a web-based tracking system that captures the effective and end dates of a CLIA certificate. The system prompts MCO staff to contact the laboratory when a certificate has expired, but it does not automatically stop payments to those facilities. 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.

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7 42 U.S.C. §§ 263a(c)(2) and (d)(1)(A) (Dec. 4, 2012).
Aetna Better Health of Texas Management Response

Action Plan

Providers currently submit CLIA ID on claims to Aetna, and Aetna has processes in place to receive it. Also, Aetna is in receipt of the CMS Crosswalk from TMHP. Therefore, Aetna has 2 of the 3 required components: CLIA ID on the claim and a CPT-to-LC Code crosswalk.

Per Aetna’s request, HHSC is determining if TMHP can provide its CLIA dataset that associates a CLIA ID with specialties, LC codes, and effective/term dates. If TMHP is unable to provide MCOs with its CLIA dataset then Aetna must build its own by gathering the information from all laboratory service providers and logging it. Aetna must develop a process to maintain such dataset on an ongoing basis. Aetna must pend claims from out of network providers until Aetna collects data from the providers.

Based on scope of work and preliminary analysis, Aetna believes it will take until February 2023 to build its own CLIA dataset. Dedicated staff/resources must contact providers, collect the information, log it into the system, and then build the system logic. The logic will be a custom process in QNXT that requires development and testing. Once the dataset exists, Aetna can deny claims for expired CLIA certificates or procedures not covered by the CLIA certificate.

Responsible Manager
Chief Operating Officer
Target Implementation Date

Aetna will provide a detailed project plan after receiving final direction from HHSC. Aetna can revise the project plan if TMHP is able to share its CLIA dataset.

Community First Health Plans Management Response

Community First immediately took action to put procedures in place to collect, document and conduct ongoing monitoring of CLIA certification. In addition to the certification effective and expiration dates, procedures include collection of the two components of CLIA compliance: (a) certification level and (b) certification codes.

Action Plan

A. Review and Collection of CLIA Certificates


2. Create new data fields in the credentialing system to house the CLIA certification level, effective date, end date and CLIA codes and add information to credentialing procedures. Credentialing. Completed.

3. Outreach to collect CLIA certificates and enter new information into the credentialing system. Credentialing. Completed.

4. Enter updated CLIA information into the core administrative and claims processing system. Data Management. Completed.

5. Create an alert in the credentialing system, and test functionality, to facilitate monitoring of expirables for CLIA certifications due to expire within 60 days. Credentialing. Completed.

6. Conduct outreach to providers to obtain up-to-date certificates. Credentialing. Ongoing.

7. Enter CLIA updates into the core claims processing system, including certification expiration. Data Management. Ongoing.

B. Review Possible Contractual Violations

2. Review and revise, as needed, the credentialing policy to outline CLIA certification requirements. Credentialing. Target date: July 31, 2022. In process.

3. Review and revise, as needed, the provider suspension and termination policy to include review of delinquent CLIA certifications. Providers who do not have an up-to-date certification will be referred to the appropriate committee for review of a possible contractual violation, claims denial due to expired certificates and/or termination. Credentialing. Target date: August 31, 2022. In process.

Responsible Managers
- Credentialing Manager
- Data Management Director
- Medicare Plans and Network Management Executive Director
- Corporate Communications and Experience Executive Director

Target Implementation Date
September 1, 2022

Driscoll Health Plan Management Response

Action Plan

DHP [Driscoll Health Plan] will conduct an audit of network provider files to identify active CLIA certificates on file for network providers providing laboratory services. Outreach will be conducted to providers (without an active certificate on file) to obtain an active certificate. CLIA certificate copies will be captured in the DHP Credentialing system and CLIA certificate data including effective/end dates, certificate type, and certification codes, will be loaded into the claim payer system for use in the adjudication of laboratory service claims.

Communications, including Fax Blast, Provider Portal messaging, and updates to the DHP Provider Manual will be sent to network providers advising of upcoming claim payer system changes that will deny services if there is no active CLIA certificate matching the submitted laboratory service.
DHP will adjudicate laboratory services, before the target implementation date, to include an informational code explaining upcoming CLIA certificate requirements; informational codes will appear on provider EOPs.

**Responsible Manager**

Director of Credentialing and Provider Data

**Target Implementation Date**

DHP will align our implementation plan and timeline in accordance with final direction from HHSC.

**Parkland Community Health Plan Management Response**

**Action Plan**

- Develop and implement a procedure and workflow that details the process of obtaining, processing, and capturing CLIA functionality.
- Include CLIA certificates in the ongoing monitoring process to ensure off cycle updates to the CLIA certificates.
- Ensure PCHP [Parkland Community Health Plan] has current CLIA Certificates for each laboratory in the system.

**Responsible Managers**

- Vice President, Information Technology and Business Intelligence
- Senior Medical Director
- Chief Compliance and Ethics Officer

**Target Implementation Date**

December 31, 2022

The final implementation date will align with the further direction from HHSC and the OIG.
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.$^9$, $^10$

One of the four MCOs has 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.

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$^10$ Uniform Managed Care Contract, Attachment A, § 7.02(16), v. 2.31 (Sept. 1, 2020) and v. 2.32 (Mar. 2, 2021).
Aetna Better Health of Texas Management Response

Providers currently submit CLIA ID on claims to Aetna, and Aetna has processes in place to receive it. Also, Aetna is in receipt of the CMS Crosswalk from TMHP. Therefore, Aetna has 2 of the 3 required components: CLIA ID on the claim and a CPT-to-LC Code crosswalk.

Per Aetna’s request, HHSC is determining if TMHP can provide its CLIA dataset that associates a CLIA ID with specialties, LC codes, and effective/term dates. If TMHP is unable to provide MCOs with its CLIA dataset then Aetna must build its own by gathering the information from all laboratory service providers and logging it. Aetna must develop a process to maintain such dataset on an ongoing basis. Aetna must pend claims from out of network providers until Aetna collects data from the providers.

Based on scope of work and preliminary analysis, Aetna believes it will take until February 2023 to build its own CLIA dataset. Dedicated staff/resources must contact providers, collect the information, log it into the system, and then build the system logic. The logic will be a custom process in QNXT that requires development and testing. Once the dataset exists, Aetna can deny claims for expired CLIA certificates or procedures not covered by the CLIA certificate.

**Responsible Manager**
Chief Operating Officer

**Target Implementation Date**

Aetna will provide a detailed project plan after receiving final direction from HHSC. Aetna can revise the project plan if TMHP is able to share its CLIA dataset.
Community First Health Plans Management Response

Utilizing cross-walk information provided by HHSC, Community First researched opportunities to configure the claims payer system to assess whether the lab certification codes listed on providers’ CLIA certificates correspond to procedure codes billed by the providers and are payable.

Action Plan

A. **Match Certification Codes to Services Billed**

1. Research the core administrative and claims processing system functionality to determine if validation of CLIA certification prior to claims adjudication is configurable. Data Management/Chief Operations Officer. Completed. Not a feature of the system at this time.

2. Evaluate functionality of the Claims Editing System (CES) to determine if a claim edit can be configured to assess if services billed are permissible based on a provider’s CLIA certification. Data Management/Chief Operations Officer. Completed. A cross-walk procedure was determined to be a viable option.

3. Create a data extract report of providers to include their CLIA certification and associated lab codes. Data Management. Completed.

4. Utilize the providers’ CLIA certification codes to create a cross-walk to permissible claim services. Claims Editing System vendor/Data Management. Completed. Note: Cross-walk information and updates based on data receipt from HHSC.

5. Create a claims edit for procedure codes to run through the cross-walk to determine if a claim is payable based on the providers’ CLIA certification. Claims Editing System vendor/Data Management. Completed.

B. **Deny Claims When Procedure Codes Do Not Correspond to Certificate Codes**

1. Develop a procedural flowchart to show how laboratory procedure codes will bump up against the claim edit and are forwarded through to claims adjudication if the providers’ approved codes match to the code billed. Risk Management. Target date: June 30, 2022. In process.
2. Test adjudication of laboratory claims. Look for denial of claims from providers who bill for procedures not covered by their CLIA certificate. Data Management/Claims. Target date: July 31, 2022. In process.

3. Create a Special Investigation Unit (SIU) audit, to assess appropriate payment of laboratory claims. The SIU will review Credentialing records for the presence of up-to-date CLIA certificates, monitoring for certificate renewal a minimum of every two years, and changes to the certificate level; ongoing updates of provider data sent to the CES vendor; appropriate claims adjudication based on the providers’ level of certification; and denial of claims when a certificate is expired or procedure codes do not match the certificate level. Risk Management/SIU. Target date: August 31, 2022. In process.


**Responsible Managers**

- Credentialing Manager
- Data Management Director
- Claims Director
- Medicare Plans and Network Management Executive Director
- Corporate Communications and Experience Executive Director
- Business Risk Management Senior Manager
- Audit Services Director

**Target Implementation Date**

September 1, 2022

**Driscoll Health Plan Management Response**

**Action Plan**

**Recommendation 2.1**

DHP [Driscoll Health Plan] will configure the claims payer system to adjudicate laboratory services using validation of the provider's active CLIA certificate. Initially, laboratory services, where a provider has an active CLIA certificate, will
be reimbursed. Laboratory services, where a provider does not have an active CLIA certificate will be denied.

Claim adjudication denials will be monitored to provide additional educational outreach to network providers on full CLIA requirements.

**Recommendation 2.2**

DHP will configure the claims payer system to adjudicate laboratory services against the provider's active CLIA certificate, including the requirement that laboratory services match the provider’s CLIA certificate type and certification codes.

Any laboratory services not fully matching the provider's active CLIA certificate, or where a certificate is not on file or is expired, will be denied.

**Responsible Manager**
Senior Director Claims, Credentialing and Provider Data

**Target Implementation Dates**
DHP will align our implementation plan and timeline in accordance with final direction from HHSC

**Parkland Community Health Plan Management Response**

**Action Plan**

**Recommendation 2.1**

- Develop process to ensure the lab codes listed on the CLIA certificate correspond to the procedure codes in the claim payer system to accurately pay and process claims. Update all policies and procedures.

- Develop and implement a process that uses the provider’s information provided by HHSC to ensure the certification codes listed on the provider’s CLIA certificates correspond to the procedure codes in the claims payer system. Notify providers with a status of “claim denied” for procedures not covered on their CLIA certificate.

- Implement claims system enhancements/ modifications for Claims adjudication and Credentialing segments.
• Review procedures for verification of the CLIA certification waiver(s) and non-waiver(s) approved laboratory codes and categories.

• Training and perform competency assessment for staff.

Recommendation 2.2

• Develop and implement a process that uses the provider’s information provided by HHSC to ensure the certification codes listed on the provider’s CLIA certificates correspond to the procedure codes in the claims payer system. Notify providers with a status of “claim denied” for procedures not covered on their CLIA certificate.

• Create a process that flags/notifies and denies claims for providers that are not credentialed or have an expired certification.

• Notify providers that are within 6 months of certificate expiration. Update provider status in the claim payer system.

• Perform QA checks to ensure provider categories and levels matches levels for CLIA certification.

• Training and perform competency assessment for staff.

Responsible Manager

• Vice President, Information Technology and Business Intelligence

• Senior Medical Director

• Chief Compliance and Ethics Officer

Target Implementation Date

The implementation date will align with the final direction from HHSC and the OIG.

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 314,628 claims paid by the four 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

Report Distribution

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- Cecile Erwin Young, Executive Commissioner
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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
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• Karen Ramirez, Credentialing Manager
• Araceli Flores, Data Management Director
• Martha Gonzalez, Medicare Plans and Network Management Executive Director
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**Driscoll Health Plan**
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• Jennifer Brooks, Vice President of Claims Administration
• Dianna Love, Senior Director of Claims, Credentialing and Provider Data
• Judith Brown, Director Credentialing and Provider Data

**Parkland Community Health Plan**
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• Patricia Ryan, Vice President, Information Technology and Business Intelligence
• Amrita Waingankar, MD, Senior Medical Director
• Nakia Smith, Chief Compliance and Ethics Officer
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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