DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

Common Working File Edits for Unauthorized Laboratory Tests

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INSPECTOR GENERAL

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EXECUTIVE SUMMARY

PURPOSE

To determine whether laboratory payment safeguards have been effective in protecting Medicare program funds.

BACKGROUND

This report focuses on how well the Common Working File (CWF) edits work when processing claims from laboratories holding a CLIA Certificate of Waiver or Certificate for Provider Performed Microscopy Procedures. The CWF scrutinizes claims to ensure that the laboratory services billed are authorized under a provider's CLIA certificate. We did not analyze claims submitted by laboratories certified by CLIA to do moderate or high complexity laboratory testing. These laboratories hold CLIA Certificates of Compliance or Accreditation and the services they bill to Medicare are not yet subject to CWF edits.

FINDINGS

Claim Processing Edits Appear Effective at Detecting And Denying Payment For Services Not Authorized by a Laboratory's CLIA Certificate of Waiver or Certificate For Provider Performed Microscopy Procedures

Only 98 of the 26,456 laboratories (less than 1 percent) in our sample managed to elude CMS's Common Working File claims processing edits and were paid for services not authorized by their CLIA certificate. Based on our sample, it appears that CMS's Common Working File edits were effective and resulted in the correct processing (denial or payment) of nearly all (998 of every 1,000) services billed by 26,456 laboratories holding a Certificate of Waiver or a Certificate for Provider Performed Microscopy Procedures.

Based on our sample, we estimate that, in 1999, about 16,000 laboratory services (out of an estimated 8.1 million services submitted) went undetected by CWF edits. We also estimate that these claims accounted for less than $76,000 of the estimated $31.3 million paid for services submitted by laboratories holding a Certificate of Waiver or a Certificate for Provider Performed Microscopy Procedures.

However, Certain CMS Survey and Certification Policies, in Effect in 1999, Appear to Adversely Affect Common Working File Payment Safeguards

CMS Policy: Permits laboratories that obtain a CLIA Certificate of Registration to bill Medicare before they have been surveyed.

Fifty laboratories in our sample were holding a CLIA Certificate of Registration when Medicare paid them for laboratory services in 1999. These 50 laboratories gained access to Medicare and Medicaid payment systems simply by submitting a CLIA application to CMS indicating that they would be doing moderate or high complexity laboratory tests. Based on unverified application information, they were given a CLIA Certificate of Registration and a CLIA number for use in billing Medicare and Medicaid.

The CMS policy allowed these 50 laboratories to operate without a visit from CLIA surveyors for up to 24 months. During this period, they were allowed to receive payments from Medicare even though they had not paid all of their CLIA fees. Most of these laboratories billed Medicare for less than $1,000 in 1999 and several were paid $10,000 or more. One laboratory was paid nearly $200,000. The CWF processed these claims correctly; however, we question a policy that permits unrestricted access to the Medicare payment system before laboratories have paid their survey and certification fees and been inspected. The CMS is aware of this problem and is considering a change in procedure.

CMS Policy: Prohibits the downgrading of a CLIA certificate until the current certificate has expired.

Analysis of our 5 percent file revealed that 1,104 laboratories had downgraded their CLIA certification sometime during 1999. Medicare paid for more than 13,600 moderate and high complexity services billed by these laboratories in our sample. These services may not have been paid had the CWF received updated information that the laboratory had downgraded its CLIA certification.

When these providers submitted their claims for payment, it was CMS policy not to downgrade CLIA certificate information until the existing CLIA certificate had expired. Some of the paid services may have been denied if updated CLIA certification information had been relayed in a more timely manner to the CWF. The CMS is considering a policy change that would result in more timely updates of laboratory certification information. Based on our sample, a change in procedure could affect the processing of an estimated 275,000 laboratory services.

RECOMMENDATIONS

It appears that CMS's Common Working File has been effective in ensuring that laboratories holding CLIA Certificates of Waiver and Certificates for Provider Performed Microscopy Procedures are paid correctly. Based on the vulnerabilities identified in this report, we encourage CMS to exam and revise its operating procedures to:

- Shorten the length of time allowed between application and onsite survey of new laboratories.

- Prohibit laboratories from billing Medicare until they have paid all of their CLIA fees or been surveyed to ensure compliance with CLIA regulations.

- Downgrade CLIA certificates and transmit the information to the CWF as soon as it becomes known that a laboratory will no longer do moderate or high complexity testing.

AGENCY COMMENTS

We received comments on this report from CMS. They concur with our all of our recommendations and have made changes to their procedures that will help meliorate the common working file edit system by addressing the vulnerabilities identified in this report. Their comments can be found in Appendix A.

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INTRODUCTION

PURPOSE

To determine whether laboratory payment safeguards have been effective in protecting Medicare program funds.

BACKGROUND

The Centers for Medicare & Medicaid Services

The Centers for Medicare & Medicaid Services (CMS) administers Medicare, the nation's largest health insurance program, which covers approximately 39 million Americans. Medicare provides health insurance to people age 65 and over, and to those who have permanent kidney failure and to certain people with disabilities. The CMS also works with the States to provide health insurance to another 35 million Americans enrolled in Medicaid and the State Children's Health Insurance Program.

Clinical Laboratory Improvement Amendments of 1988

In addition to providing health insurance, CMS also performs many quality-focused activities, including regulation of clinical laboratory testing. In 1988, Congress enacted the Clinical Laboratory Improvement Amendments (CLIA). The CLIA established "quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed."

Under current law, all laboratories must be certified under CLIA to perform testing on human specimens.[1] Laboratories enroll in the program by completing an application and paying a certificate fee to CMS. Fees are based on certificate type, annual volume and number of test specialities.

Each laboratory must have a certificate appropriate for the complexity of the testing they conduct. All laboratory test methods are classified based on testing complexity into one of four categories: high, moderate, provider-performed microscopy or waived test

[1] The CLIA regulations define a laboratory as a facility for the . . . 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. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. The regulations allow for some exceptions, including forensic laboratories, research laboratories that "do not report patient-specific results," drug testing laboratories certified by the Substance Abuse and Mental Health Services Administration, and some Federal laboratories.

methods. The type of CLIA certificate a laboratory receives relates to the complexity of testing conducted at that laboratory's site. All laboratories are required to keep CMS informed of major changes in testing, ownership or directorship.

Of the nearly 170,000 laboratory[2] sites certified by CLIA as of July 2000, about 86,500 sites have been issued a Certificate of Waiver. Approximately 36,000 physicians and other approved providers hold Certificates for Provider Performed Microscopy Procedures. These laboratories are permitted to perform specific moderate-complexity microscopy procedures and waived tests. The remaining 41,500 laboratories conduct moderate or high complexity testing.

A CLIA surveyor must inspect laboratories that conduct moderate or high complexity testing before they can receive CLIA certification. These onsite inspections occur after the laboratory has paid its CLIA fees. The CMS allows laboratories up to 24 months from the date of their application to pay CLIA certification fees. In the interim, laboratories are issued a Certificate of Registration and a CLIA number that allows them to conduct testing and bill Medicare and Medicaid until CMS inspects them. Once the laboratory has proven to surveyors that it meets all CLIA requirements, it is issued a Certificate of Compliance or a Certificate of Accreditation. The certificates expire 24 months after issue. All laboratories must renew their CLIA certificate every 24 months.

Medicare Payment

Medicare and Medicaid require CLIA certification as a condition of payment. Medicare has two parts: Hospital Insurance (Part A) and Supplemental Medical Insurance (Part B).

- **Medicare Part A:** Provides coverage of inpatient hospital services, skilled nursing facilities, home health services and hospice care. These providers are required to ensure that the laboratory services furnished to the patients in their care are performed by CLIA certified laboratories. Reimbursement for these laboratory services is included in Medicare's payment to these providers.

- **Medicare Part B:** Helps pay for the cost of physician services, outpatient hospital services, laboratory services, medical equipment and other health care services and supplies. Providers of these services submit itemized bills for the services they provide to Medicare for payment.

Medicare carriers and intermediaries process claims for payment of laboratory services. These fiscal agents ensure that all claims submitted for payment are accurate and complete. Incomplete claims and claims that fail computer system accuracy checks (called edits) are rejected. Claims not rejected by the fiscal agents' payment safeguards are prepared for payment using the Clinical Laboratory Fee Schedule. The Clinical

[2] This includes about 5,800 laboratories in New York and Washington which are exempt States. These States meet CMS requirements to survey and certify laboratories under their State program. The States must pay a fee and show CMS that the State program meets or exceeds the requirements for laboratories under CLIA.

Laboratory Fee Schedule determines the amount Medicare will pay for each laboratory service billed to the program.

Payment Safeguards: Claims Processing and Common Working File Edits

Laboratory claims submitted to Medicare for payment undergo scrutiny by the fiscal agent that received the claim and by the Common Working File maintained by CMS. When intermediaries and carriers receive a claim for payment of clinical laboratory services they process the claim using the information submitted by the provider and information contained in their files. When they have finished processing the claim to the point of payment or denial, they submit the claim to the Common Working File (CWF). The CWF uses its programs and files to decide whether to accept and pay the claim as submitted or reject the claim and deny payment.

The CWF scrutinizes claims for reimbursement of clinical laboratory services to ensure that the provider submitting the claim was certified by CLIA when the service was provided to the patient. If the claim is from a laboratory provider holding a CLIA Certificate of Waiver or Certificate for Provider-Performed Microscopy, the CWF also checks to make sure that the laboratory services billed are authorized under that provider's CLIA certificate. Laboratory services not authorized under the provider's CLIA certificate are denied payment.

Information about a laboratory's CLIA survey and certification is periodically transmitted to the CWF from CMS's Online Survey, Certification and Reporting (OSCAR) system. The OSCAR system relies on laboratory surveyors to update survey and certification information when it becomes known. This updated information is then relayed to the CWF.

METHODOLOGY

We used a claim sample containing all of the claims submitted for 5 percent of Medicare beneficiaries in calendar year 1999. Using this 5 percent sample, we created a file containing all of the laboratory services submitted to Medicare for these patients. We sorted this file on the CLIA laboratory number of the provider.

In April 2000, we obtained data about CLIA certified laboratories from the CLIA Online Survey, Certification and Reporting (OSCAR) system. We used this data to create three other files. One file contained information about laboratories having a CLIA Certificate of Waiver. The second contained information about laboratories holding Certificates for Provider Performed Microscopy Procedures. The third contained information about laboratories certified by CLIA to do moderate or high complexity laboratory testing. We sorted these files on the CLIA laboratory number to facilitate the matching of claim information with CLIA survey and certification information.

Using information from CMS's web site, we created an Access database containing all of the waived procedure codes. A second Access database was created that contained all of the procedure codes for provider-performed microscopy. The provider-performed microscopy file also contained all of the waived laboratory procedure codes.

For our first data run, we used information from the April 2000 CLIA survey and certification file containing information about waived laboratories. We merged this information with the 5 percent sample file containing 1999 claim information. We created a program that enabled us to identify and isolate all of the laboratory services billed to Medicare by the laboratories holding a CLIA Certificate of Waiver. Using our Access database, we identified authorized and unauthorized services billed to Medicare by laboratories holding a CLIA Certificate of Waiver. We also used our program to determine whether CMS paid or denied these services. This process was repeated for the analysis of the services submitted by laboratories holding Provider Performed Microscopy Certificates.

Our sample selection method prevents us from projecting our findings to the universe of laboratories. We selected our laboratories and services from a 5 percent beneficiary file. Consequently, projections as to the number of laboratories affected in the universe would not be reliable. Our sample methodology does enable us to make projections about services and payments.

We derived some information in this report from discussions that we had with CMS and State agency CLIA surveyors. These discussions were held during the winter of 2000/2001 as part of the inspections entitled: *CLIA Regulation of Unestablished Laboratory Tests,* (OEI-05-00-00250) and *Enrollment and Certification Processes in the Clinical Laboratory Improvement Amendments Program* (OEI-05-00-00251).

We conducted our review in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

FINDINGS

Claim processing edits appear effective at detecting and denying payment for services not authorized by a laboratory's CLIA Certificate of Waiver or Certificate For Provider Performed Microscopy Procedures

The CMS has done a good job in developing and implementing claims processing edits for waived and provider-performed microscopy laboratory services. The common working file edits they have developed appear effective in identifying:

- laboratories that attempt to bill Medicare without proper CLIA certification, and
- nearly all laboratory services billed to Medicare but not authorized under a provider's CLIA certificate.

Overall, less than 1 percent of the laboratories in our sample managed to elude CMS's Common Working File claims processing edits and were paid for services not authorized by their CLIA certificate. Based on our sample, it appears that CMS's Common Working File edits were effective and resulted in the correct processing (denial or payment) of nearly all (998 of every 1,000) services billed by laboratories holding a Certificate of Waiver or a Certificate for Provider Performed Microscopy Procedures.

Our 5 percent sample of claims submitted in 1999 shows that Medicare allowed just over $1.5 million in payments to laboratories holding a Certificate of Waiver or a Certificate for Provider Performed Microscopy Procedures. Of this amount, less than 1 percent appears to have been paid incorrectly due to some Common Working File edit failure. Of the nearly 26,000 laboratories in our sample, fewer than 100 by-passed CWF edits and were paid incorrectly. Most of these laboratories were paid for services not covered by their CLIA certificate when they used a procedure code modifier with a laboratory service procedure code.

Based on our sample, we estimate that, in 1999, about 16,000 laboratory services (out of an estimated 8.1 million services submitted) went undetected by CWF edits. We also estimate that these claims accounted for less than $76,000 of the estimated $31.3 million paid for services submitted by laboratories holding a Certificate of Waiver or a Certificate for Provider Performed Microscopy Procedures.

However, Certain CMS survey and certification policies, in effect in 1999, appear to adversely affect common working file payment safeguards

The CWF functioned correctly and CMS correctly paid claims under the policies that existed in 1999. However, the payment decisions made by CMS's Common Working File system may have been affected by CLIA survey and certification information used by the CWF system. Two CMS survey and certification policies (in effect during 1999) may have affected the way CWF edits handled payment decisions on claims submitted by 1,154 laboratories in our sample.

Policy 1: Permits laboratories that obtain a CLIA Certificate of Registration to bill Medicare before they have been surveyed

Permitting laboratories that obtain a CLIA Certificate of Registration to bill Medicare before they have been surveyed may be a vulnerability because it enables laboratories to bypass Common Working File payment safeguards.

The payment decisions made by CMS's Common Working File system may have been affected by the quality of CLIA survey and certification information the CWF system received from CLIA. Based on our analysis, payments to 1,154 laboratories (496 waived and 659 PPM) may have been affected by survey policy and procedures in effect during 1999. Our analysis found that 50 laboratories holding a CLIA Certificate of Registration had billed Medicare during 1999 but were never certified to perform moderate or high complexity tests; yet, they billed Medicare for these tests.

These 50 laboratories had submitted a CLIA application to CMS indicating that they would be doing moderate or high complexity laboratory tests. Based on information provided on their application, CMS gave these laboratories a CLIA Certificate of Registration and a CLIA number. The CLIA registration certificate enabled these laboratories to operate for up to 24 months without verification of the information provided on the application. Information about these laboratories was then provided to CMS's CWF system. The CWF system then used that information in its payment decisions.

These 50 laboratories submitted their claims for payment during a time when CMS policy allowed them to operate without a survey for up to 24 months. They had not paid all of their CLIA certification fees. Laboratory surveyors had not made any visits to the laboratory to ensure compliance with CLIA regulatory requirements. These laboratories were given access to the Medicare payment system that enabled them to bypass many CWF edits.

Of the 50 laboratories paid while holding a Certificate of Registration, 45 had not billed Medicare extensively for moderate or high complexity tests. Medicare paid most of these laboratories less than $1,000 and several laboratories were paid $10,000 or more. One laboratory was paid nearly $200,000. The CWF processed these claims correctly under

the policy that existed at the time provider submitted the claims. We have no reason to suspect wrong doing by any of these laboratories. However, we are concerned about the potential for an unscrupulous provider to gain unchecked access to the Medicare and Medicaid payment systems. Some State laboratory surveyors have told us that they have issued CLIA numbers to laboratories that apparently did not exist. These laboratories used the 24 months they were permitted to operate under a CLIA Certificate of Registration to obtain Medicare and Medicaid payments.

We do not mean to infer that all laboratories that downgrade their applications to a Certificate of Waiver or a Certificate for Provider Performed Microscopy Procedures are unscrupulous. Many reasons, including the cost of CLIA certification, inability to meet CLIA standards, competition in the marketplace and other factors, could explain why laboratories do not follow through and obtain a CLIA Certificate of Compliance or a Certificate of Accreditation.

The CMS is aware of this vulnerability and is considering procedural changes to reduce Medicare's exposure to unscrupulous providers who would seek to defraud Medicare and Medicaid. Requiring payment of all CLIA certification and survey fees ensures more timely onsite visits to laboratories. Earlier onsite visits will help to ensure that the quality of testing done at a laboratory meets CLIA standards before Medicare and Medicaid make any substantial payments for substandard or poor laboratory testing. It will also make it more difficult for nonexistent providers to defraud Medicare and Medicaid.

Policy 2: Prohibits the downgrading of a CLIA certificate until the current certificate has expired

Untimely changes to a laboratory's CLIA certificate information create a vulnerability that may affect Common Working File payment safeguards. More than 13,600 (out of 18,200 plus) laboratory services in our sample got through the Common Working File edits because they were billed by providers whose CLIA Certificate of Compliance or Certificate of Accreditation was still shown as valid in CMS systems. Our sample contained 1,104 providers who changed their laboratory certification from moderate and high complexity testing to provider performed microscopy or waived testing at some point during 1999.

During the time period these 1,104 laboratories submitted their claims for payment, CMS did not update information about downward changes in a laboratory's CLIA certification until the laboratory's higher level CLIA certification had expired. For example, a laboratory issued a Certificate of Compliance effective January 1, 1998 could continue to bill for moderate and high complexity testing until January 2000 even if they had notified CMS that effective January 2, 1998 they would only be doing waived tests.

We did not contact the State surveyors to determine exactly when they were notified that the laboratory would no longer be doing moderate or high complexity tests. Some of these laboratories may have elected to change their certification when their certificates came up for renewal. Others may have had trouble meeting CLIA certification requirements during their re-certification visit. Some may have sent notice to CMS that

they had ceased conducting moderate and high complexity testing before their CLIA certificate expired. Finally changes in a laboratory's certification may not become apparent until a laboratory surveyor discovers that moderate and high complexity testing had ceased at some earlier point in time and the laboratory failed to notify CMS of the change.

The CMS is considering a new procedure that will result in the Common Working File having more accurate and timely information about a laboratory's CLIA certification. This change in procedure could help prevent payment of moderate and high complexity services billed by laboratory providers whose CLIA certificates are changed to either a Certificate of Waiver or a Certificate for Provider Performed Microscopy Procedures. Based on our sample, this change could affect the processing of an estimated 275,000 laboratory services.

RECOMMENDATIONS

It appears that the CMS's Common Working File has been effective in ensuring that providers holding CLIA Certificates of Waiver and Certificates for Provider Performed Microscopy Procedures are paid only for tests authorized under their CLIA certificate.

We believe that the CMS survey and certification policies and procedures discussed in this report create vulnerabilities in Medicare claims processing. Therefore, we encourage CMS to examine and revise its operating procedures to:

- Shorten the length of time allowed between application and onsite survey of new laboratories.
- Prohibit laboratories from billing Medicare until they have paid all of their CLIA fees or been surveyed to ensure compliance with CLIA regulations.
- Downgrade CLIA certificates and transmit the information to the CWF as soon as it becomes known that a laboratory will no longer do moderate or high complexity testing.

The first of these three recommendations was also made the the OIG in an earlier report entitled, "Enrollment and Certification Processes in the Clinical Laboratory Improvement Amendments Program."

AGENCY COMMENTS

We received comments on this report from CMS. They concur with our all of our recommendations and have made changes to their procedures that will help meliorate the common working file edit system by addressing the vulnerabilities identified in this report. Their comments can be found in Appendix A.

APPENDIX A

CMS Comments on this Report

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Service

Administrator
Washington, DC 20201

RECEIVED
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OFFICE OF INSPECTOR GENERAL

DATE: NOV 27 2001

TO: Janet Rehnquist
Inspector General

FROM: Thomas A. Scully
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: *Common Working File Edits for Unauthorized Laboratory Tests* (OEI-05-00-00050)

We appreciate the opportunity to review the above-mentioned OIG draft report. We are pleased the inspection found the Common Working File (CWF) edits appear to be working well.

We acknowledge, despite the success of these edits, there are certain agency policies that may have affected CWF payment safeguards. Correspondingly, the OIG recommends that the Centers for Medicare & Medicaid Services (CMS) change the operations manuals and notify the contractors to remedy the vulnerabilities created by Clinical Laboratory Improvement Amendments of 1998 (CLIA) survey and certification policies. The CMS concurs with the OIG's recommendations. To alleviate concerns of CWF payment safeguards, we have implemented various policy changes. Specifically, we survey a new lab approximately 3 months after the application process is complete and the lab's certification fee is paid. We have prohibited laboratories from billing Medicare until they have paid their CLIA fees or have been surveyed. Additionally, we have modified our database to accept immediately most status changes from any laboratory that downgrades its CLIA certificate of compliance or certificate of accreditation to a certificate that permits only waived tests or provider-performed microscopy procedures.

We thank the OIG for their efforts in this inspection and look forward to working with the OIG in the future. With regard to the specific OIG recommendations, our comments are as follows:

OIG Recommendation
CMS should shorten the length of time allowed between application and onsite survey of new laboratories.

CMS Response
We concur. Our policy is to survey a new lab approximately 3 months after the application process is complete and the lab's certification fee is paid.

OIG Recommendation
CMS should prohibit laboratories from billing Medicare until they have paid all of their CLIA fees or have been surveyed to ensure compliance with CLIA regulations.

CMS Response
We concur. Since August 11, 1999, any laboratory applying for participation in the CLIA program for the first time must pay the appropriate CLIA fee(s) in full before receiving a CLIA certificate. After the fees are fully paid, the CLIA certificate information is sent to the Medicare and Medicaid claims processors. Similarly, any laboratory that renews its current CLIA certificate or requests a change in the level of certificate must pay the new CLIA fees in full before the laboratory is allowed to receive reimbursement for the tests performed under new certification.

OIG Recommendation
CMS should downgrade CLIA certificates and transmit the information to the CWF as soon as it becomes known that a laboratory will no longer do moderate or high complexity testing.

CMS Response
We concur. In December 11, 2000, the CLIA database was reprogrammed to accept immediately most status changes from any laboratory that downgrades its CLIA certificate of compliance or certificate of accreditation to a certificate that permits only waived tests or provider-performed microscopy procedures. If, however, a laboratory has been surveyed for its next 2-year certificate of compliance, the date the downgraded certificate becomes effective is when the new 2-year certificate period begins. In most cases, there is not a long lag time between the survey and the end of the certificate.