



AUG 22 2008

TO: Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services

FROM: Daniel R. Levinson *Daniel R. Levinson*
Inspector General

SUBJECT: Medical Review of Claims for the Fiscal Year 2006 Comprehensive Error Rate Testing Program (A-01-07-00508)

The attached final report provides the results of our audit of the medical review of claims for the fiscal year (FY) 2006 Comprehensive Error Rate Testing (CERT) program. As part of the Medicare error rate process, the CERT contractor conducts medical review of a sample of paid claims for durable medical equipment, prosthetics, orthotics, and supplies (DME). The Centers for Medicare & Medicaid Services (CMS) requires the CERT contractor to perform medical review in accordance with CMS's written policies.

For the FY 2006 error rate process, CMS's written policies required the CERT contractor to review beneficiaries' medical records, including pertinent records from physicians, to support claims from DME suppliers. The records requested from DME suppliers included physicians' orders, certificates of medical necessity, and proof-of-delivery documentation. CMS orally instructed the CERT contractor to deviate from written policies by (1) making determinations based primarily on the limited medical records available from suppliers, (2) applying clinical inference when reviewing supplier medical records to reasonably infer that the DME provided was medically necessary, and (3) not counting lack of proof of delivery as an error if that was the only issue with a claim. Based on the CERT contractor's medical review, CMS reported that the FY 2006 DME error rate was 7.5 percent, or about \$700 million in improper payments.

We contracted with KePRO, an independent medical review contractor, to perform two reviews of a sample of 363 claims from the CERT sample of 7,955 claims that the CERT contractor had reviewed in determining the FY 2006 DME error rate.

Our objectives were to determine (1) the adequacy of the CERT contractor's FY 2006 medical review of DME claims using CMS's procedures, which relied primarily on supplier records; and (2) the impact of reviewing additional medical records and conducting beneficiary and provider interviews on the FY 2006 DME error rate.

Using the same procedures and medical records as the CERT contractor, KePRO found that medical review was adequate for 324 of the 363 sampled claims, including 23 claims that both the CERT contractor and KePRO determined to be erroneous. However, KePRO identified an additional 39 erroneous claims that the CERT contractor had not identified. The CERT contractor agreed with 18 of the additional error determinations and disagreed with 21. We attributed these review discrepancies to the CERT contractor's inadequate review of available documentation and to CMS's lack of written policies and procedures on the appropriate use of clinical inference. Based on the 23 errors that both the CERT contractor and KePRO found and the additional 39 errors that KePRO found, we estimated that the error rate in the FY 2006 CERT DME sample was 17.3 percent.

KePRO's second review, using additional medical records from physicians and other health care providers and, in some instances, information obtained from beneficiary and provider interviews, confirmed 20 of the 23 errors that the CERT contractor had found and identified 73 errors that the CERT contractor had not found. Specifically, KePRO confirmed 34 of the 39 errors identified in its initial review and determined that another 39 claims were erroneous because the additional documentation either did not support the items' medical necessity or delivery or showed that the items were not medically necessary. We attributed these review discrepancies to the CERT contractor's reliance on clinical inference rather than additional medical records available from health care providers, CMS's inconsistent policies regarding proof-of-delivery documentation, physicians' lack of understanding of documentation requirements, and CMS's lack of procedures for obtaining information on high-risk DME items from beneficiaries. Based on the 20 errors that both the CERT contractor and KePRO found and the additional 73 errors that KePRO found, we estimated that the error rate in the FY 2006 CERT DME sample was 28.9 percent.

We recommend that CMS:

- require the CERT contractor to review all available supplier documentation;
- establish a written policy to address the appropriate use of clinical inference;
- require the CERT contractor to review all medical records (including, but not limited to, physicians' records) necessary to determine compliance with applicable requirements on medical necessity;
- document oral guidance that conflicts with written policies, such as guidance on the need for proof-of-delivery documentation in making medical review determinations;
- instruct its Medicare contractors to provide additional training to physicians that focuses on improving their medical record documentation to support ordered DME items; and
- require the CERT contractor to contact the beneficiaries named on high-risk claims, such as claims for power mobility devices, to help determine whether the beneficiaries received these items and the items were medically necessary.

In its comments on our draft report, CMS generally concurred with our findings and recommendations.

Pursuant to the principles of the Freedom of Information Act, 5 U.S.C. § 552, as amended by Public Law 104-231, Office of Inspector General reports generally are made available to the public to the extent the information is not subject to exemptions in the Act (45 CFR part 5). Accordingly, this report will be posted on the Internet at <http://oig.hhs.gov>.

Please send us your final management decision, including any action plan, as appropriate, within 60 days. If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact Joseph J. Green, Assistant Inspector General for Financial Management and Regional Operations, at (202) 619-1157 or through e-mail at Joe.Green@oig.hhs.gov. Please refer to report number A-01-07-00508 in all correspondence.

Attachment

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICAL REVIEW OF CLAIMS
FOR THE FISCAL YEAR 2006
COMPREHENSIVE ERROR RATE
TESTING PROGRAM**



Daniel R. Levinson
Inspector General

August 2008
A-01-07-00508

Office of Inspector General

<http://oig.hhs.gov>

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

EXECUTIVE SUMMARY

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) established the Comprehensive Error Rate Testing (CERT) program to produce a Medicare error rate for all provider claims other than inpatient hospital claims. To determine the error rate, the CERT contractor conducts medical review of a sample of paid claims. CMS requires the CERT contractor to make medical review decisions in accordance with CMS's written policies.

For the fiscal year (FY) 2006 error rate process, CMS's written policies required the CERT contractor to review beneficiaries' medical records, including pertinent records from physicians, to support claims from suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DME). The records requested from DME suppliers included physicians' orders, certificates of medical necessity, and proof-of-delivery documentation. CMS orally instructed the CERT contractor to deviate from written policies by (1) making determinations based primarily on the limited medical records available from suppliers, not the full medical records available from physicians; (2) applying clinical inference when reviewing supplier medical records to reasonably infer that the DME provided was medically necessary; and (3) not counting lack of proof of delivery as an error if that was the only issue with a claim. Based on the CERT contractor's medical review, CMS reported that the FY 2006 DME error rate was 7.5 percent, or about \$700 million in improper payments.

We contracted with KePRO, an independent medical review contractor, to perform two reviews of a sample of 363 claims from the CERT sample of 7,955 claims that the CERT contractor had reviewed in determining the FY 2006 DME error rate.

OBJECTIVES

Our objectives were to determine (1) the adequacy of the CERT contractor's FY 2006 medical review of DME claims using CMS's procedures, which relied primarily on supplier records; and (2) the impact of reviewing additional medical records and conducting beneficiary and provider interviews on the FY 2006 DME error rate.

SUMMARY OF FINDINGS

Initial Review: Using the same procedures and medical records as the CERT contractor, KePRO found that medical review was adequate for 324 of the 363 sampled claims, including 23 claims that both the CERT contractor and KePRO determined to be erroneous. However, KePRO identified an additional 39 erroneous claims that the CERT contractor had not identified. The CERT contractor agreed with 18 of the additional error determinations and stated that it had not classified these claims as errors because it had not adequately reviewed the available documentation. The CERT contractor did not agree with the remaining 21 additional error determinations because it believed that the documentation was sufficient to infer that the DME was medically necessary, as CMS had orally authorized. However, KePRO concluded that the documentation provided was not sufficient to make the same clinical inferences.

We attributed these review discrepancies to the CERT contractor's inadequate review of available documentation and to CMS's lack of written policies and procedures on the appropriate use of clinical inference. Based on the 23 errors that both the CERT contractor and KePRO found and the additional 39 errors that KePRO found, we estimated that the error rate in the FY 2006 CERT DME sample was 17.3 percent.

Second Review: KePRO's second review, using additional medical records from physicians and other health care providers and, in some instances, information obtained from beneficiary and provider interviews, confirmed 20 of the 23 errors that the CERT contractor had found and identified 73 errors that the CERT contractor had not found. Specifically, KePRO confirmed 34 of the 39 errors identified in its initial review and determined that another 39 claims were erroneous because the additional documentation either did not support the items' medical necessity or delivery or showed that the items were not medically necessary.

We attributed these review discrepancies to the CERT contractor's reliance on clinical inference rather than additional medical records available from health care providers, CMS's inconsistent policies regarding proof-of-delivery documentation, physicians' lack of understanding of documentation requirements, and CMS's lack of procedures for obtaining information on high-risk DME items from beneficiaries. Based on the 20 errors that both the CERT contractor and KePRO found and the additional 73 errors that KePRO found, we estimated that the error rate in the FY 2006 CERT DME sample was 28.9 percent.

RECOMMENDATIONS

We recommend that CMS:

- require the CERT contractor to review all available supplier documentation;
- establish a written policy to address the appropriate use of clinical inference;
- require the CERT contractor to review all medical records (including, but not limited to, physicians' records) necessary to determine compliance with applicable requirements on medical necessity;
- document oral guidance that conflicts with written policies, such as guidance on the need for proof-of-delivery documentation in making medical review determinations;
- instruct its Medicare contractors to provide additional training to physicians that focuses on improving their medical record documentation to support ordered DME items; and
- require the CERT contractor to contact the beneficiaries named on high-risk claims, such as claims for power mobility devices, to help determine whether the beneficiaries received these items and the items were medically necessary.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In comments on our draft report, CMS generally concurred with our findings and recommendations. CMS noted that our recommendations would expand the CERT review process significantly and would affect the cost of the CERT program and the time required to conduct reviews. CMS stated that it would like to assess how to best integrate CERT reviews with its ongoing integrity reviews to strengthen its fraud-fighting efforts in DME as well as to improve its measurement activities. CMS stated that it would like to explore with us the possibility of testing these new review procedures during the FY 2009 review cycle and that it would like to work with us in developing a plan to adopt our recommendations. CMS also provided more specific responses to our six recommendations.

Appendix C contains CMS's comments, excluding technical comments.

OFFICE OF INSPECTOR GENERAL RESPONSE

We recognize CMS's willingness to adopt changes in the CERT program to enhance Medicare program integrity efforts, and we would be pleased to review CMS's corrective action plan to adopt our recommendations. We acknowledge that expanding the review process may increase the cost of the CERT program and the time required to conduct reviews but, based on our findings, such an expansion is necessary to ensure an accurate measurement of DME payment errors. Accordingly, we continue to recommend that CMS obtain all medical records (including, but not limited to, physicians' records) for DME claims and contact the beneficiaries named on high-risk claims.

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INTRODUCTION

BACKGROUND

Medicare Error Rate Program

In fiscal year (FY) 2000, the Centers for Medicare & Medicaid Services (CMS) initiated two programs to develop a Medicare fee-for-service error rate. The Hospital Payment Monitoring Program was established to produce an error rate for inpatient acute-care hospital claims. The Comprehensive Error Rate Testing (CERT) program, which is the subject of this report, was established to produce an error rate for all provider claims other than inpatient hospital claims. When aggregated, those error rates produce an overall Medicare fee-for-service paid claim error rate. An error is the difference between the amount that Medicare paid to a provider and the amount that it should have paid.

Using the results of its error rate programs, CMS annually submits to Congress an estimate of the amount of improper payments for Medicare fee-for-service claims pursuant to the Improper Payments Information Act of 2002 (Public Law 107-300).

Durable Medical Equipment

Durable medical equipment, prosthetics, orthotics, and supplies (DME) include items such as wheelchairs, hospital beds, oxygen, and medical and surgical supplies. Pursuant to the “Medicare Claims Processing Manual,” Publication 100-04, Chapter 20, section 10.1.1, Medicare Part B covers DME. CMS defines DME as equipment that can withstand repeated use, is primarily and customarily used to serve a medical purpose, generally is not useful to a person in the absence of an illness or injury, and is appropriate for use in the home.

Medical Review of Claims

Medical review is the examination of information on a provider claim and any supporting documentation associated with the claim to determine whether a beneficiary’s medical condition meets Medicare coverage criteria. Pursuant to CMS’s “Medicare Program Integrity Manual” (Integrity Manual), Publication 100-08, Chapter 3, section 3.4.1.2, when conducting medical review, contractors must review and consider all documentation provided. The documentation must support the medical necessity of the item(s) or service(s) provided. This documentation may include physician progress notes, other written physician evaluations, therapist evaluations, and other information about a beneficiary’s clinical condition and treatment(s).

Medical Review of Claims in the Comprehensive Error Rate Testing Program

CMS’s CERT contractor is AdvanceMed, a program safeguard contractor (PSC). As part of the Medicare error rate process, the CERT contractor conducts medical review of a sample of paid claims. CMS’s contract requires that the CERT contractor make medical review decisions in accordance with the Integrity Manual and section 7 of the PSC Umbrella Statement of Work. Section 7 requires PSCs to perform medical review using guidance such as National Coverage

Determinations (NCD), Local Coverage Determinations (LCD), and CMS coding manuals. CMS develops NCDs to describe the circumstances for nationwide Medicare coverage of specific medical services, procedures, and devices. Medicare contractors develop LCDs to specify the clinical circumstances under which services are considered reasonable and necessary in their jurisdictions.

CMS's contract for FY 2006 and the Integrity Manual required the CERT contractor to review beneficiaries' medical records, including pertinent records from physicians, to support DME claims. However, CMS orally instructed the CERT contractor to deviate from written policies by making determinations based primarily on the limited medical records available from suppliers (generally the physicians' orders and certificates of medical necessity¹), not the full medical records available from physicians, and by applying clinical inference when reviewing supplier medical records to reasonably infer that the DME provided was medically necessary.

The CERT contractor issues CMS-approved letters to DME suppliers requesting medical records to support sampled claims. For the FY 2006 error rate period, the letters requested that suppliers submit the physician order/prescription, the certificate of medical necessity, proof-of-delivery documentation, and any additional documentation to support a claim. CMS later orally advised the CERT contractor not to count lack of proof of delivery as an error if that was the only issue with the claim.

Fiscal Year 2006 Medicare Error Rate

In its November 2006 "Improper Fee-for-Service Payments Long Report," CMS reported that the aggregate Medicare fee-for-service error rate for FY 2006 was 4.4 percent and that the DME error rate was 7.5 percent, or about \$700 million in improper DME payments.² The FY 2006 DME error rate represented a decline from the previous 3 years (13.6 percent in FY 2003, 11.1 percent in FY 2004, and 8.6 percent in FY 2005). The FY 2007 DME error rate increased to 10.3 percent.

OBJECTIVES, SCOPE, AND METHODOLOGY

Objectives

Our objectives were to determine (1) the adequacy of the CERT contractor's FY 2006 medical review of DME claims using CMS's procedures, which relied primarily on supplier records, and (2) the impact of reviewing additional medical records and conducting beneficiary and provider interviews on the FY 2006 DME error rate.

¹The certificate of medical necessity is a form required for specified DME items to help document medical necessity and other coverage criteria.

²The FY 2006 CERT error rate was based on claims submitted by providers from April 1, 2005, to March 31, 2006.

Scope

We reviewed a sample of 363 claims from the CERT sample of 7,955 paid DME claims that the CERT contractor had reviewed in determining the FY 2006 DME error rate (Appendix A). The CERT contractor found that 27 of the 363 claims contained payment errors totaling \$37,630.

Our review included determining whether paid claims were for DME that was reasonable, medically necessary, sufficiently documented, and correctly coded. We limited our review of internal controls to obtaining an understanding of CMS's written and oral policies regarding medical review, as well as the requirements detailed in the Integrity Manual and the PSC Umbrella Statement of Work.

We performed our fieldwork at CMS; the CERT contractor's location; and various supplier, physician, and beneficiary locations nationwide from March through December 2007.

Methodology

To accomplish our objectives, we:

- reviewed applicable Medicare requirements and CMS guidance on medical review;
- selected a stratified random sample of 300 claims from the CERT sample of 7,955 DME claims, with the first stratum containing Medicare paid amounts of \$0 to \$200 and the second containing Medicare paid amounts of \$200.01 to \$1,800;
- selected from two additional strata another 63 claims that comprised all DME claims (1) for which the Medicare paid amounts exceeded \$1,800 and (2) that included power mobility devices, such as power wheelchairs and power-operated vehicles;
- determined that 170 of the 363 selected claims were at high risk of improper payment because of the type of DME (e.g., power mobility devices and orthotics), the dollar value of the item, or the location of the supplier;
- contracted with KePRO, an independent medical review contractor, to perform two reviews of the 363 sampled claims: an initial review to determine the adequacy of the CERT contractor's medical review using CMS's existing procedures and limited medical records and a second review to determine the impact on the FY 2006 DME error rate of reviewing additional medical records from physicians and other providers (and, for the 170 high-risk claims, the impact of conducting beneficiary, supplier, and physician interviews);
- obtained, for KePRO's initial review of the 363 claims, the medical records and other documentation that the CERT contractor used to determine whether the items were medically necessary and the Medicare payments were appropriate;

- obtained, for KePRO's second review of the 363 claims, additional medical records and other information from physicians and other providers through telephone, facsimile, and mail (and, for the 170 high-risk claims, additional information through interviews with and site visits to beneficiaries, suppliers, and physicians);
- obtained the CERT contractor's written comments on KePRO's initial error determinations;
- estimated the effect of the results from both of KePRO's reviews on the error rate in the FY 2006 CERT DME sample (Appendix B); and
- discussed the results of our review with CMS officials.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

FINDINGS AND RECOMMENDATIONS

Initial Review: Using the same procedures and medical records as the CERT contractor, KePRO found that medical review was adequate for 324 of the 363 sampled claims, including 23 claims that both the CERT contractor and KePRO determined to be erroneous. However, KePRO identified an additional 39 erroneous claims that the CERT contractor had not identified. The CERT contractor agreed with 18 of the additional error determinations and stated that it had not classified these claims as errors because it had not adequately reviewed the available documentation. The CERT contractor did not agree with the remaining 21 additional error determinations because it believed that the documentation was sufficient to infer that the DME was medically necessary, as CMS had orally authorized. However, KePRO concluded that the documentation provided was not sufficient to make the same clinical inferences.

We attributed these review discrepancies to the CERT contractor's inadequate review of available documentation and to CMS's lack of written policies and procedures on the appropriate use of clinical inference. Based on the 23 errors that both the CERT contractor and KePRO found and the additional 39 errors that KePRO found, we estimated that the error rate in the FY 2006 CERT DME sample was 17.3 percent.

Second Review: KePRO's second review, using additional medical records from physicians and other health care providers and, in some instances, information obtained from beneficiary and provider interviews, confirmed 20 of the 23 errors that the CERT contractor had found and identified 73 errors that the CERT contractor had not found. Specifically, KePRO confirmed 34 of the 39 errors identified in its initial review and determined that another 39 claims were erroneous because the additional documentation either did not support the items' medical necessity or delivery or showed that the items were not medically necessary.

We attributed these review discrepancies to the CERT contractor's reliance on clinical inference rather than additional medical records available from health care providers, CMS's inconsistent policies regarding proof-of-delivery documentation, physicians' lack of understanding of documentation requirements, and CMS's lack of procedures for obtaining information on high-risk DME items from beneficiaries. Based on the 20 errors that both the CERT contractor and KePRO found and the additional 73 errors that KePRO found, we estimated that the error rate in the FY 2006 CERT DME sample was 28.9 percent.

PROGRAM REQUIREMENTS

Medicare Payment Requirements

Section 1862(a)(1)(A) of the Social Security Act states that no Medicare payment may be made for items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Pursuant to 42 CFR § 424.57(c)(12), the Integrity Manual, and supplier manuals, suppliers must maintain documentation showing that items were delivered to the beneficiaries. Suppliers must make proof-of-delivery documentation available upon request. The Integrity Manual states that any DME claim that does not have proof of delivery from the supplier should be denied and the overpayment recovered. Suppliers that consistently do not provide documentation to support services or items may be referred to the Office of Inspector General (OIG) for investigation and/or imposition of sanctions.

Medical Review of Durable Medical Equipment Claims

Pursuant to the Integrity Manual, Chapter 5, section 5.7, for any DME item to be covered by Medicare, the medical record must contain sufficient documentation of the beneficiary's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement. The information should include the beneficiary's diagnosis and other pertinent information, including, but not limited to, duration of the condition, clinical course, prognosis, nature and extent of functional limitations, other therapeutic interventions and results, and past experience with related items. Neither a physician's order nor a certificate of medical necessity by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician. Information in the medical record must support the item's medical necessity and substantiate the answers on the certificate of medical necessity.

CMS's contract requires that the CERT contractor make medical review decisions in accordance with the Integrity Manual. The CERT contractor is also required to comply with section 7 of the PSC Umbrella Statement of Work, which states that PSCs will perform medical review using guidance such as NCDs, LCDs, and CMS coding manuals.

CMS's written policies require the CERT contractor to review beneficiaries' medical records, including pertinent records from physicians, to support DME claims. CMS's oral guidance deviated from its written policies by instructing the CERT contractor to (1) make determinations based primarily on the limited medical records available from suppliers (generally the

physicians' orders and certificates of medical necessity), not the full medical records available from physicians; (2) consider the available supplier medical records and apply clinical inference to reasonably infer that the DME provided was medically necessary; and (3) not to count lack of proof of delivery as an error if that was the only issue with a claim.

INITIAL REVIEW: ADEQUACY OF MEDICAL REVIEW USING EXISTING PROCEDURES AND LIMITED MEDICAL RECORDS

Using the same procedures and medical records as the CERT contractor, KePRO found that medical review was adequate for 324 of the 363 sampled DME claims, including 23 claims that both the CERT contractor and KePRO determined to be erroneous.³ However, KePRO identified an additional 39 erroneous claims that the CERT contractor had not identified. In response to our request to review KePRO's determinations on the 39 claims, the CERT contractor agreed with 18 determinations and disagreed with 21.

Agreement on 18 Claims

For the 18 claims on which it concurred with KePRO's determinations, the CERT contractor told us that it had not classified these claims as errors because it had not adequately reviewed the supporting documentation. Specifically, the CERT contractor agreed that:

- Thirteen claims for items such as power mobility devices, hospital bed accessories, and nebulizer drugs had insufficient documentation to support the medical necessity and/or utilization requirements specified by the applicable LCDs.
- Five claims for items such as diabetic testing supplies and drugs were not accompanied by valid physician orders (i.e., the orders were missing, not signed, or not updated).

Clinical Inference of Medical Necessity Disputed on 21 Claims

For the 21 claims on which the CERT contractor disagreed with KePRO's determinations, the main area of dispute involved reliance on clinical inference instead of the specific medical records required by CMS written policies. The CERT contractor did not dispute that these claims lacked the medical records required by applicable LCDs. However, the CERT contractor maintained that the available documentation (e.g., physicians' orders, certificates of medical necessity, or beneficiary claim histories) was sufficient to infer, as CMS had orally authorized, that the DME was medically necessary under applicable LCD requirements. CMS's policy manuals and Integrity Manual do not address the extent to which the CERT contractor should use clinical inference in the absence of required documentation.

We asked KePRO to review the CERT contractor's written response to the 21 error determinations and to determine whether it agreed that clinical inference could be used instead of the specific documentation required by the LCDs to support the medical necessity of the DME.

³The CERT contractor identified 27 erroneous claims, but KePRO disagreed with 4 of the CERT contractor's error determinations.

KePRO concluded that the documentation provided for the 21 claims was not sufficient to meet applicable LCD requirements or to make the clinical inference of medical necessity.⁴

The 21 disputed claims comprised 8 claims for oxygen and/or equipment; 5 claims for diabetic testing supplies; 3 claims for nebulizers and/or supplies; and 1 claim each for parenteral/enteral nutrition, diabetic shoes/inserts, prosthetics or orthotics, eyeglasses (lenses and frames), and wheelchairs. Following are details and examples from the three largest categories: oxygen and/or equipment, diabetic testing supplies, and nebulizers and/or supplies.⁵

Oxygen and/or Equipment

CMS's "Coverage Issue Manual," part 60-4, and LCD requirements for oxygen and oxygen equipment specify that claims for oxygen must be supported by documentation in the beneficiary's medical record that specifies the diagnosis of the disease requiring home use of oxygen; the oxygen flow rate; and an estimate of the frequency of use, duration of use, and duration of need. The LCD also states that the certificate of medical necessity may act as a substitute for a written physician's order only if it contains sufficient detail (e.g., the means of oxygen delivery and the specifics of varying oxygen flow rates). Without this detail, the order is incomplete.

KePRO found that for 8 of the 21 claims, the physicians' orders and/or certificates of medical necessity did not sufficiently document the flow rate, frequency, or means of oxygen delivery. For example, for one claim that had no physician's order, KePRO determined that the certificate of medical necessity was not an acceptable substitute for a physician's order because it did not include the means of oxygen delivery or the varying oxygen flow rates. The CERT contractor believed that diagnostic codes in the beneficiary's claim history could reasonably be used to infer the medical necessity for oxygen. KePRO responded that clinical inference should not be applied to an incomplete order.

Diabetic Testing Supplies

The LCD requires that refills of diabetic testing supplies be supported by documentation in the physician's or supplier's records that specifies the required frequency of testing to justify the quantity of supplies ordered. The LCD also requires that the medical records document that the physician evaluated the beneficiary within 6 months before ordering quantities of testing supplies that exceed the utilization guidelines.

KePRO determined that five claims for diabetic testing supplies were erroneous because the claims were not accompanied by updated physicians' orders that specified the frequency of testing or by evidence that the physician had evaluated the beneficiary in the last 6 months. For example, KePRO classified one claim as erroneous because the physician order did not specify the required frequency of testing. The CERT contractor stated that it was able to infer that the

⁴KePRO's second review using additional medical records sustained 18 of the 21 disputed errors.

⁵For the examples provided in this report, the LCDs that KePRO used to determine reasonableness and medical necessity applied to DME suppliers nationwide.

physician intended the beneficiary to test her blood glucose levels at the accepted schedule for an insulin-dependent patient because the signed physician order indicated that the beneficiary was insulin dependent and because the testing supplies ordered did not exceed the LCD guidelines for an insulin-dependent patient. KePRO responded that the LCD specifically states that orders for diabetic testing supplies must include the frequency of testing.

Nebulizers and/or Supplies

According to the LCD, Medicare covers nebulizers when they are medically necessary for administering drugs to manage conditions such as chronic pulmonary disease. The LCD requires that the supplier receive a written, signed, and dated physician's order before submitting a nebulizer claim.

KePRO determined that the documentation was insufficient to determine the medical necessity of two claims for nebulizer rentals and that the physician's order was inadequate to support one claim for nebulizer drugs. For example, for one claim for a nebulizer rental, KePRO determined from its review of the beneficiary's claim history in the National Claims History File that the rental was not medically necessary because the beneficiary had not received any nebulizer drugs for at least 3 years. The CERT contractor maintained that as part of its medical review, it would have reviewed the beneficiary's claim history in CMS's Common Working File (which is based on the same data as the National Claims History File) for covered drugs to support the medical necessity of the nebulizer rental. The CERT contractor also stated that the claim history from the Common Working File was archived and that it no longer had access to the archived claims. We reviewed the 3 years of claim history that KePRO reviewed and did not identify any nebulizer drugs billed to Medicare.

Causes of Initial Review Discrepancies

We attributed the initial review discrepancies to the CERT contractor's inadequate review of available documentation and CMS's lack of written policies and procedures on the appropriate use of clinical inference.

Effect of Initial Review Determinations on Error Rate

Based on the 23 errors that both the CERT contractor and KePRO found and the additional 39 errors that KePRO found, we estimated that the error rate in the FY 2006 CERT DME sample was 17.3 percent.

SECOND REVIEW: IMPACT OF REVIEWING ADDITIONAL MEDICAL RECORDS

The FY 2006 DME error rate likely would have been significantly higher if the CERT contractor had reviewed additional medical records from physicians and other health care providers and, in some instances, information obtained from beneficiary interviews. The additional documentation included physicians' progress notes, diagnostic test results, and therapy evaluations. KePRO's review of this additional documentation confirmed 20 of the 23 errors

that the CERT contractor had found and identified 73 erroneous claims that the CERT contractor had not found. Specifically, KePRO confirmed 34 of its initial 39 error determinations and identified another 39 errors for which the additional documentation either did not support the items' medical necessity or delivery or showed that the items were not medically necessary.

Confirmation of Most Initial Error Determinations

During its second review using additional medical records, KePRO confirmed 34 of the 39 error determinations made during its initial review. For these 34 claims, KePRO concluded that the physicians' orders, certificates of medical necessity, and beneficiary medical records did not contain sufficient documentation to support the CERT contractor's clinical inferences that the items were medically necessary. Specifically, 18 of the 21 claims on which the CERT contractor did not agree and 16 of the 18 claims on which the CERT contractor agreed with KePRO's initial error determinations remained errors because the additional documentation did not support the medical need or utilization requirements for the items as defined by LCDs. KePRO attributed the insufficient medical records to physicians' lack of understanding of the type and extent of documentation required to substantiate the need for DME items. KePRO reversed its determinations on 5 of the 39 claims that it had initially found to be errors because the additional medical records clearly justified the medical need for the items.

Additional Error Determinations

Based on its review of additional documentation, KePRO determined that an additional 39 claims that it had initially determined to be proper were actually erroneous because the items were not medically necessary or lacked proof of delivery.

Clinical Inference of Medical Necessity Not Supported

KePRO classified 34 of the 39 claims as errors because the additional medical records obtained from physicians did not support the CERT contractor's clinical inferences that the DME was medically necessary under applicable LCD requirements. We are most concerned about the significant number of claims for which clinical inference, rather than actual medical records, was used to determine medical necessity. Without adequate guidance on the extent to which clinical inference should be used as an acceptable substitute for actual medical records, CMS cannot ensure that DME medical review determinations are consistent. As a result, the DME error rate could be compromised.

The 34 claims comprised 15 claims for oxygen and/or equipment, 4 claims for power mobility devices, 3 claims for enteral/parenteral nutrition, 3 claims for diabetic testing supplies, and 9 claims for other types of DME. Following are details and examples from the four largest categories: oxygen and/or equipment, power mobility devices, enteral/parenteral nutrition, and diabetic testing supplies.

Oxygen and/or Equipment: One LCD requires that certificates of medical necessity for beneficiaries who qualify for oxygen based only on a sleep oximetry study must contain the lowest oxygen saturation value identified by the sleep study. Another LCD requires

that, for oxygen to be covered based on an oxygen study obtained during exercise, three oxygen studies must be documented in the beneficiary's medical record.

KePRO classified 15 oxygen and/or accessory claims as errors because the medical records did not support the information provided on the certificates of medical necessity. For one claim, for example, the oxygen saturation level recorded on the certificate of medical necessity met the requirements for oxygen coverage. However, the medical records contained no evidence of an oximetry study. As a result, KePRO concluded that the medical records did not support the clinical inference that the CERT contractor made based on the information on the certificate of medical necessity.

Power Mobility Devices: The LCD requires that beneficiaries who receive power mobility devices, such as electric wheelchairs, have a mobility limitation that significantly impairs their ability to participate in mobility-related activities of daily living, such as eating, dressing, and bathing.

KePRO classified four claims for power mobility devices as errors because information from our interviews with the providers and beneficiaries did not support the items' medical necessity. For example, for one claim for a power wheelchair, the ordering physician, as identified by the billing supplier, denied ordering the wheelchair and had no knowledge of the beneficiary or the supplier. The beneficiary told us that he knew neither the ordering physician nor the supplier. He also showed us a second power wheelchair that had been prescribed for his wife. The beneficiary and his wife were both ambulatory and had never used the wheelchairs.

Enteral/Parenteral Nutrition: The LCD requires that, to support the medical necessity of enteral/parenteral nutrition, beneficiaries' medical records must document a permanent nonfunction or disease that restricts food consumption.

KePRO classified three claims for enteral/parenteral nutrition as errors because the additional documentation did not support medical necessity. For example, the certificate of medical necessity for one claim for enteral nutrition stated that the beneficiary had a diagnosis of dysphagia (inability to swallow). However, the physician progress notes indicated that the beneficiary was able to eat but ate little because of behavioral disturbances. Because the medical records did not support the diagnosis of dysphagia, KePRO concluded that enteral nutrition was not medically necessary.

Diabetic Testing Supplies: The LCD requires that refills of diabetic testing supplies be supported by documentation in the physician's or supplier's records that specifies the required frequency of testing to justify the quantity of supplies ordered. The LCD also requires that the medical records document that the physician evaluated the beneficiary within 6 months before ordering quantities of testing supplies that exceed the utilization guidelines.

KePRO classified three claims for diabetic testing supplies as errors because the additional medical records did not meet LCD requirements. For example, for one claim

for diabetic testing supplies, the documentation did not support the frequency of testing recorded on the physician's order. As a result, KePRO determined that the supplies were not medically necessary.

Lack of Proof of Delivery

KePRO classified 5 of the 39 claims as errors because the claims had no proof-of-delivery documentation or other support to confirm delivery of the DME to the beneficiary.⁶ The CERT contractor did not consider these claims to be in error because, inconsistent with CMS's written policy, CMS had orally advised the CERT contractor not to count lack of proof of delivery as an error if that was the only issue with a claim.

Identification of Potential Fraud

Medicare claims from DME suppliers have historically been more vulnerable to billing fraud and abuse than claims from other providers because of weak Medicare payment controls and inadequate oversight to ensure that suppliers are legitimate. During our site visits to collect medical records and information on the 170 high-risk claims, we identified 11 claims that may have involved billing fraud. Seven of these claims were for expensive DME items, such as power mobility devices and collagen dressings. We identified the potential fraud through unannounced visits to the billing suppliers and ordering physicians and through beneficiary interviews. For 8 of the 11 claims, the beneficiary stated that he or she did not know the physician whose name was on the order. For five of the claims, the beneficiary stated that he or she never received the item. We referred the 11 claims to the OIG Office of Investigations.

Causes of Second Review Discrepancies

We attributed the second review discrepancies to the CERT contractor's reliance on clinical inference rather than additional medical records available from health care providers, CMS's inconsistent policies regarding proof-of-delivery documentation, physicians' lack of understanding of documentation requirements, and CMS's lack of procedures for obtaining information on high-risk DME items from beneficiaries.

Effect of Second Review Determinations on Error Rate

Based on the 20 errors that both the CERT contractor and KePRO found and the additional 73 errors that KePRO found, we estimated that the error rate in the FY 2006 CERT DME sample was 28.9 percent.

RECOMMENDATIONS

We recommend that CMS:

- require the CERT contractor to review all available supplier documentation;

⁶This issue was the subject of a memorandum that we issued to CMS on March 17, 2008.

- establish a written policy to address the appropriate use of clinical inference;
- require the CERT contractor to review all medical records (including, but not limited to, physicians' records) necessary to determine compliance with applicable requirements on medical necessity;
- document oral guidance that conflicts with written policies, such as guidance on the need for proof-of-delivery documentation in making medical review determinations;
- instruct its Medicare contractors to provide additional training to physicians that focuses on improving their medical record documentation to support ordered DME items; and
- require the CERT contractor to contact the beneficiaries named on high-risk claims, such as claims for power mobility devices, to help determine whether the beneficiaries received these items and the items were medically necessary.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In comments on our draft report, CMS generally concurred with our findings and recommendations. CMS noted that our recommendations would expand the CERT review process significantly and would affect the cost of the CERT program and the time required to conduct reviews. CMS stated that it would like to assess how to best integrate CERT reviews with its ongoing integrity reviews to strengthen its fraud-fighting efforts in DME as well as to improve its measurement activities. CMS stated that it would like to explore with us the possibility of testing these new review procedures during the FY 2009 review cycle and that it would like to work with us in developing a plan to adopt our recommendations. CMS also provided more specific responses to our six recommendations.

Appendix C contains CMS's comments, excluding technical comments.

OFFICE OF INSPECTOR GENERAL RESPONSE

We recognize CMS's willingness to adopt changes in the CERT program to enhance Medicare program integrity efforts, and we would be pleased to review CMS's corrective action plan to adopt our recommendations. We acknowledge that expanding the review process may increase the cost of the CERT program and the time required to conduct reviews but, based on our findings, such an expansion is necessary to ensure an accurate measurement of DME payment errors. Accordingly, we continue to recommend that CMS obtain all medical records (including, but not limited to, physicians' records) for DME claims and contact the beneficiaries named on high-risk claims.

APPENDIXES

SAMPLING METHODOLOGY

SAMPLING OBJECTIVES

Our objectives were to determine (1) the adequacy of the Comprehensive Error Rate Testing (CERT) contractor's fiscal year (FY) 2006 medical review of claims for durable medical equipment, prosthetics, orthotics, and supplies (DME) using Centers for Medicare & Medicaid Services procedures, which relied primarily on supplier records; and (2) the impact of reviewing additional medical records and conducting beneficiary and provider interviews on the FY 2006 CERT sample error rate.

SAMPLING FRAME

The sampling frame consisted of 7,955 DME claims valued at \$1,213,093 that the CERT contractor had reviewed in determining the FY 2006 DME error rate.

SAMPLE DESIGN

We designed a random sample by dividing our frame into two strata. The first stratum consisted of DME claims for which Medicare paid \$0 to \$200. The second stratum consisted of DME claims for which Medicare paid \$200.01 to \$1,800. Additionally, we reviewed all claims for which Medicare payments exceeded \$1,800 (stratum 3) or that contained a Healthcare Common Procedure Coding System code representing power mobility devices (stratum 4).

Sample Design

Stratum	Description	Number of Claims	Paid Amounts
1	Payments of \$0 to \$200.00	5,776	\$343,727
2	Payments of \$200.01 to \$1,800	2,116	677,104
3	Payments greater than \$1,800	33	103,353
4	Claims for power mobility devices	30	88,909
Total		7,955	\$1,213,093

SAMPLE SIZE

The sample consisted of 363 DME claims: 135 claims from the first stratum, 165 claims from the second stratum, 33 claims from the third stratum, and 30 claims from the fourth stratum.

SAMPLE RESULTS AND ESTIMATES

CERT Contractor Sample Results

Sample Size	Value of Sampling Frame	Number of Claims in Error	Value of Claims in Error	Error Rate (Value of Claims in Error/Value of Sampling Frame)
7,955	\$1,213,093	479	\$80,954	6.7% ¹

KePRO and CERT Contractor Sample Results

Stratum	Sample Size	Value of Sample	Errors Found by	Number of Claims in Error		Value of Claims in Error	
				Initial Review	Second Review	Initial Review	Second Review
Payments of \$0 to \$200.00	135	\$7,844	KePRO CERT contractor	15	17	\$1,057	\$1,147
				16	13	810	478
Payments of \$200.01 to \$1,800	165	51,659	KePRO CERT contractor	19	44	6,101	15,700
				3	3	1,335	1,335
Payments greater than \$1,800	33	103,353	KePRO CERT contractor	2	5	5,458	14,351
				3	3	15,564	15,564
Claims for power mobility devices	30	88,909	KePRO CERT contractor	3	7	7,752	26,766
				1	1	5,589	5,665
Total	363	\$251,765		62²	93³	\$43,666	\$81,006

¹The 6.7 percent is the percentage of dollars reviewed by the CERT contractor that were found to be in error. To obtain the FY 2006 DME error rate of 7.5 percent, the errors found in the sample were weighted consistent with the CERT sample design. The two percentages are not directly comparable.

²The 62 claims consisted of 23 claims that the CERT contractor found to be in error and that KePRO confirmed, plus 39 additional claims that KePRO found to be in error.

³The 93 claims consisted of 20 claims that the CERT contractor found to be in error and that KePRO confirmed, 34 claims that KePRO found to be in error in its first review and confirmed in its second review, and 39 additional claims that KePRO found to be in error in its second review.

Estimated Value of Erroneous Claims Identified in Initial Review
(Limits Calculated for a 90-Percent Confidence Interval)

	Estimated Improper Payments in Frame of 7,955 Claims	Estimated Error Rate in Frame (Estimated Improper Payments/Value of Sampling Frame)
Point estimate	\$209,600	17.3%
Lower limit	\$163,262	13.5%
Upper limit	\$255,938	21.1%

Estimated Value of Erroneous Claims Identified in Second Review
(Limits Calculated for a 90-Percent Confidence Interval)

	Estimated Improper Payments in Frame of 7,955 Claims	Estimated Error Rate in Frame (Estimated Improper Payments/Value of Sampling Frame)
Point estimate	\$350,334	28.9%
Lower limit	\$285,309	23.5%
Upper limit	\$415,358	34.2%



Administrator
Washington, DC 20201

RECEIVED
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OFFICE OF INSPECTOR GENERAL

DATE: AUG 01 2008

TO: Daniel R. Levinson
Inspector General

FROM: Kerry Weems
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Medical Review of Claims for the Fiscal Year 2006 Comprehensive Error Rate Testing Program," (A-01-07-00508)

Thank you for the opportunity to review and comment on the OIG draft report entitled "Medical Review of Claims for the Fiscal Year 2006 Comprehensive Error Rate Testing (CERT) Program." We appreciate the effort that went into drafting this report, and the recommendations made by OIG on how it sees improvement could be made to the CERT program.

This report evaluated the adequacy of the CERT contractor's fiscal year (FY) 2006 medical review of durable medical equipment (DME) claims using the Centers for Medicare & Medicaid Services' (CMS) procedures, determined the potential impact of reviewing additional medical records, and conducted beneficiary and provider interviews on the FY 2006 DME error rate. Using an independent medical review contractor, the OIG completed two levels of review on a sample of 363 DME claims that had been reviewed by the CERT contractor. First, the OIG reviewed the sampled claims using the medical records submitted to the CERT contractor. Second, the OIG reviewed the claims using additional records from physicians and other care providers and beneficiary interviews. OIG identified 39 errors that had not been identified by the CERT contractor at the first level of review. The level of review confirmed 34 of the 39 errors and identified an additional 39 erroneous claims. The OIG estimated that the additional errors would have increased the FY 2006 DME error rate by 24 percentage points, from 7.5 percent to 31.5 percent. OIG attributed these discrepancies to the CERT contractor's reliance on clinical inference rather than medical record documentation, CMS' inconsistent policies regarding proof-of-delivery documentation, physicians' lack of understanding about documentation requirements, and CMS' lack of procedures for obtaining information on high-risk DME items from beneficiaries.

As you know, CMS relies on the CERT program to fulfill two very important missions. First, it allows us to meet the compliance requirements of the Improper Payments Information Act of 2002, which requires Medicare to publish a fee-for-service national error rate. Second, it provides CMS with substantial performance information at the contractor and benefit category

level to help us determine how well our contractors are processing claims and where particular program vulnerabilities might exist. In fact, the ability to estimate the DME specific error rate is a direct result of CMS' implementation of the CERT program.

Given its centrality to CMS' financial oversight mission, we are eager to adopt any meaningful changes to the program that will help enhance measurement efforts in particular, and our overall program integrity efforts in general.

Thus, we would like to work with you to develop a plan to adopt your recommendations in the most efficient manner possible. As you can imagine, your recommendations expand the current CERT review process significantly and will impact the cost of the CERT program as well as the time we have to conduct reviews. While we cannot quantify how much longer it will take to complete reviews using your recommendations, we can estimate that in terms of cost, we would be looking at a 10-20 percent increase, or \$1.25-\$2.5 million, in our CERT budget to implement these changes.

We would like to explore with you the possibility of testing these new review procedures during the FY 2009 review cycle, to determine their impact on cost and timeliness and to assess how to best integrate CERT reviews – which are conducted on a random sample of claims – with our ongoing integrity reviews in high vulnerability geographic areas like Los Angeles and Southern Florida. The best outcome is to strengthen our fraud fighting efforts in DME, as well as improve our measurement activities. To that end, we want to ensure that any new program integrity investments are directed at highly vulnerable providers and geographic areas and leverage enrollment and enforcement activities, in addition to measurement activities.

As you know, CMS has been quite aggressive over the past 3 years in our efforts to combat unscrupulous DME providers. We issued regulations that clarify and strengthen provider enrollment requirements and standards and increased efforts to deactivate or, when necessary, revoke billing privileges for providers and suppliers that are inactive or do not meet program requirements. Additionally, we have initiated three demonstration projects that target fraudulent DME business practices. The demonstrations focus on billing by suppliers of DME, prosthetics, orthotics, and supplies in Florida and southern California, home health agencies in the greater Los Angeles and Houston areas, and infusion therapy providers in south Florida. Overall, these efforts have resulted in the revocation of nearly 900 provider numbers with billings of \$157 million, and improved the public's confidence in our ability to address this growing threat. Finally, we are reorganizing our DME oversight efforts to better focus and align our resources in reaction to vulnerabilities identified by our own data analysis, Medicare contractor findings, and results from the CERT report.

Listed below are more detailed comments on your recommendations. In addition, we have included one technical comment that addresses how OIG arrived at calculating a DME error rate based on its new findings.

OIG Recommendations

- Require the CERT contractor to review all available supplier documentation.

- Require the CERT contractor to review all medical records (including, but not limited to, physicians' records) necessary to determine compliance with applicable requirements on medical necessity.
- Require the CERT contractor to contact the beneficiaries named on high-risk claims, such as claims for power mobility devices, to help determine whether the beneficiaries received these items and the items were medically necessary.

CMS Response

The CMS concurs in part. Late in 2006, CMS revised the CERT process for DME reviews. From 2003-2006, CERT did not request additional information from ordering physicians. Instead, CERT requested a certificate of medical necessity (CMN) from suppliers who submitted DME claims. The CMN was designed to reduce documentation requirements on physicians; it included information needed to assess compliance with Medicare payment and coverage rules. By 2007, CMS' requirements for CMNs had been eliminated in favor of ensuring that ordering physicians maintained documentation needed to support coverage and payment for DME. Beginning with the 2007 improper payment report period, CERT has been asking physicians, as well as the supplier, for supporting information on DME claims.

As mentioned above, there are timing and cost considerations surrounding these expansive reviews, including interviewing beneficiaries. However, your findings make a strong argument for testing the validity of this recommendation on a national scale. Therefore, beginning with the 2009 measurement cycle, we intend to adopt this recommendation for the review of claims for diabetic test strips, oxygen, and powered mobility devices. We will publish the results of our findings in the 2009 annual CERT report. We would like to work together with your staff in planning the best implementation plan for this test.

OIG Recommendation

Establish a written policy to address the appropriate use of clinical inference.

CMS Response

We concur. CMS issued direction on the use of clinical inference in the Program Integrity Manual and via training to contractor medical review staff.

The Program Integrity Manual, IOM 100-08, 3.4.5.C, states, "While the medical review staff must follow national coverage determinations and local coverage determinations, they are expected to use their expertise to make clinical judgments when making medical review determinations. They must take into consideration the clinical condition of the beneficiary as indicated by the beneficiary's diagnosis and medical history when making these determinations."

In 2004, CMS provided training to contractor medical review staff, including the CERT contractor, on the use of clinical judgment in medical claims review. Reviewers were instructed that medical record documentation: must *reflect* the care provided; is not expected to record every aspect of the care provided; and, at a minimum, must enable a clinical reviewer to

reasonably infer the care that was provided. Reasonable inference was defined as: 1) a conclusion made by a reviewer with clinical experience in the area under review; and 2) an interpretation of the claim after considering the totality of the circumstances.

OIG Recommendation

Document oral guidance that conflicts with written policies, such as guidance on the need for proof-of-delivery documentation in making medical review determinations.

CMS Response

We concur. CMS agrees that guidance to the CERT contractor should be consistent with written policy and documented in the appropriate program and/or contract documents. We will ensure that all oral guidance, policy clarifications, and technical direction is followed by written direction.

OIG Recommendation

Instruct its Medicare contractors to provide additional training to physicians that focus on improving their medical record documentation to support ordered DME items.

CMS Response

We concur. As part of CMS' corrective action plan to reduce payment errors, CMS requires the Medicare claims processing contractors to reduce the error rate by giving Medicare providers the information they need to understand the program, be informed timely about changes and bill correctly. We give contractors a fair bit of flexibility to allow them to be creative and target educational efforts on problems in their jurisdiction that are identified by CERT and other monitoring activities.