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PERMANENT SUBCOMMITTEE ON INVESTIGATIONS

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**MEDICARE VULNERABILITIES:
THE USE OF DIAGNOSIS CODES
IN DME CLAIMS**

MINORITY STAFF REPORT

**PERMANENT SUBCOMMITTEE
ON INVESTIGATIONS**

UNITED STATES SENATE



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Medicare Vulnerabilities: *The Use of Diagnosis Codes in DME Claims*

I. INTRODUCTION

The Medicare program was established to provide health insurance for the elderly and the disabled. In 2007, Medicare paid more than \$400 billion to cover more than 43 million beneficiaries.¹ Despite its noble intentions, the Medicare program has faced a pervasive and persistent problem with fraud, waste, and abuse. For instance, the Government Accountability Office (GAO) has designated the Medicare program as high risk, due to its size, complexity, and vulnerability to mismanagement and improper payments, for every year since 1990.² In its fiscal year 2005 performance and accountability report, the Department of Health and Human Services (HHS) reported that it paid an estimated \$12.1 billion in improper payments for Medicare claims in that year alone.³ The improper payments for fiscal year 2004 were even larger, amounting to an estimated \$21.7 billion.⁴

Medicare Part B, the component in which Medicare pays for certain durable medical equipment and supplies (commonly called DME or DMEPOS), is particularly susceptible to abuse. According to the Centers for Medicare and Medicaid Services (CMS), the federal agency that administers the Medicare program, abuses related to DME claims cost billions of dollars each year.⁵ On March 8, 2007, CMS's Chief Financial Officer testified before a Congressional committee, "[t]he fraudulent business practices of unscrupulous durable medical equipment, prosthetics, orthotics, and supplies suppliers continue to cost the Medicare program billions of dollars."⁶ In 2007, GAO reported that CMS estimated that Medicare made improper payments based on mistakes, abuse, or fraud totaling approximately \$700 million for DME supplies in a single year. According to GAO, these types of payments represented approximately 7.5 percent of its total payments for DME items.⁷

In light of reports of waste and abuse in the Medicare program, the United States Senate Permanent Subcommittee on Investigations (the Subcommittee) initiated an investigation into fraud, waste, and abuse in the Medicare program, with a particular focus on the diagnosis codes on DME claims. The Subcommittee's inquiry also examined the effectiveness of CMS's use of the codes.

¹ See 2008 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, at pg. 2.

² See GAO-07-310, High-Risk Series: An Update, January 2007.

³ See U.S. Department of Health and Human Services, Fiscal Year 2005 Performance and Accountability Report, at pg. IV.C.8.

⁴ See *id.*

⁵ The Centers for Medicare and Medicaid Services was formerly called the Health Care Financing Administration (HCFA), until the entity was redesignated in 2001.

⁶ See Testimony of CMS Chief Financial Officer Timothy B. Hill before the House Ways and Means Subcommittees on Health and Oversight, March 8, 2007.

⁷ See GAO 07-59, Medicare: Improvements Needed to Address Improper Payments for Medical Equipment and Supplies, January 31, 2007.

Over the course of its investigation, Subcommittee staff examined extensive data concerning millions of DME claims submitted between 1995 and 2006. The Subcommittee also interviewed numerous officials from CMS, Medicare contractors, the Department of Justice Fraud Division, investigators from the Department of Health and Human Services Office of the Inspector General (HHS/OIG), as well as physicians, representatives of DME suppliers, and Medicare beneficiaries. In conjunction with that investigation, the Subcommittee held a hearing and released a bipartisan staff report on July 9, 2008, entitled *Medicare Vulnerabilities: Payments for Claims Tied to Deceased Doctors*.⁸ That report estimated that, from 2000 through 2007, Medicare had paid up to \$100 million for DME claims containing identification numbers assigned to doctors who had died between one and fifteen years before the claims.

In addition to its review of DME claims tied to deceased physicians, the Subcommittee examined the use of diagnosis codes associated with DME claims. This report presents the Subcommittee staff's findings and minority staff's recommendations with respect to that analysis.

II. EXECUTIVE SUMMARY

This report examines several aspects of the Medicare DME benefit, with a particular focus on the requirement for and use of diagnosis codes. Diagnosis codes are the numeric or alphanumeric designations on a Medicare DME claim that identify the beneficiary's ailment. The Subcommittee's investigation found that the laws governing the use of diagnosis codes on most DME claims have been inconsistent from 1991 through 2003, including certain rules that appear contradictory. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) mandated the establishment and use of standardized codes (contained in the International Classification of Diseases, Ninth Revision, with Clinical Modification (ICD-9-CM)) on claims and CMS issued a regulation consistent with this requirement, which became effective in 2003.

Although diagnosis codes have been required on most DME claims since at least 2003, the Subcommittee found that CMS and its claims review contractors are not effectively utilizing the codes. For example, the Medicare claims review process examines claims to ensure that valid diagnosis codes are present, but does not review the claims to determine whether the diagnoses are remotely related to the purchased medical equipment. In short, the Subcommittee's investigation found that the diagnosis code requirement appears to be a mandate with little substantive purpose.

The Subcommittee examined data related to millions of DME claims in order to determine whether diagnosis codes submitted on claims could be utilized for beneficial purposes, including to identify questionable or improper payments and hence augment Medicare's efforts to uncover fraud, waste, and abuse. The Subcommittee's analysis of these claims identified many instances in which examining the diagnosis codes on DME claims could be a valuable tool to uncover fraudulent or abusive claims. For instance, the Subcommittee uncovered numerous claims in which the diagnosis code section contained a valid ICD-9-CM code, but the diagnosis appeared highly questionable and unrelated to the purchased medical equipment. For example, the Subcommittee reviewed hundreds of thousands of claims paid by Medicare for blood glucose test strips, which are used by diabetics to test their blood-sugar levels, and found that many contained questionable diagnoses that appear wholly unrelated to diabetes. The Subcommittee also uncovered hundreds of thousands of claims for blood glucose test strips in which the stated diagnosis was chronic airway obstruction, bubonic plague, leprosy, typhoid, or cholera. Experts interviewed by the Subcommittee – including representatives of the Centers for Disease Control

⁸ See U.S. Senate Permanent Subcommittee on Investigations, *Medicare Vulnerabilities: Payments for Claims Tied to Deceased Doctors* (July 9, 2008).

and Prevention, a prominent manufacturer of blood glucose strips, and a well-known medical school – universally confirmed that such diagnoses were not appropriate for that product. The Subcommittee’s analysis of blood glucose test strips and 17 other DME items found millions of claims that contained questionable diagnosis codes totaling more than \$1 billion.

The Subcommittee also examined claims data from 1995 through 2006 related to \$4.8 billion in Medicare payments for 60 million DME items that contained diagnosis codes that were invalid, blank, or unprocessable. To analyze these claims, the Subcommittee conducted a detailed examination of a subset of 2,000 claim submissions. The Subcommittee could not verify more than 30 percent of the 2,000 claims as legitimate and found during the detailed review that other elements of the claim bore certain characteristics of fraudulent activity. Numerous claims, for instance, contained the identification number of a doctor who had died years before the service dates on the claims. For hundreds of other items, the doctors identified on the claims denied that they had prescribed those items, or even that they had treated those patients.

Notably, while not every instance of an invalid or questionable diagnosis code found during the Subcommittee’s review necessarily reflects an improper payment, and while the number of claims with invalid diagnosis codes decreased significantly after the implementation of HIPAA in 2003, Medicare’s history of weaknesses in its payment processes suggest that additional procedures are needed to ensure that payments are accurate and in compliance with program rules.⁹ The Subcommittee’s analysis suggests that incorporating system edits that would deny claims or flag them for medical review or follow-up, or otherwise performing analysis of diagnosis codes could be a useful tool in uncovering questionable DME claims, preventing fraud, waste, and abuse, and reducing improper payments. In fact, Congress contemplated the use of diagnosis codes for “prepayment screens” as far back as 1988.¹⁰ The Subcommittee’s findings propose that analyzing the diagnosis codes on claim submissions could be an effective control mechanism to assist Medicare’s efforts to reduce improper payments.

A. REPORT FINDINGS

Based on its investigation, the Subcommittee staff makes the following findings:

- 1. Rules Governing the Use of Diagnosis Codes on DME Claims from Suppliers Have Been Inconsistent.** Between 1991 and 2003, the laws and regulations governing the submission of diagnosis codes on claims from DME suppliers have been inconsistent and, in some cases, appear contradictory. Moreover, although diagnosis codes have been required since the implementation of HIPAA in 2003, CMS’s application of the diagnosis code requirement is inconsistent, potentially resulting in the payment of some items tied to invalid diagnosis codes and the rejection of claims that contain valid diagnosis codes.
- 2. Medicare Has Not Used Diagnosis Codes Effectively in the Claims Review Process.** Although diagnosis codes have been required for DME supplier claims since at least 2003, Medicare generally does not use the codes to assist in determining the validity or medical necessity of the claims. In paying the claims, CMS’s utilization of the codes is largely limited to verifying the presence of a valid code.

⁹ The Subcommittee’s review of the claims data revealed that Medicare continued to pay DME suppliers for claims that contained invalid diagnosis codes after the 2003 implementation of HIPAA. However, the volume and amount of these claims decreased after 2003, with Subcommittee analysis showing that Medicare paid more than \$23 million for DME claims that contained invalid diagnosis codes.

¹⁰ See 54 FR 30558, Medicare Program; Diagnosis Codes on Physician Bills (July 21, 1989).

- 3. Some Data Related to Millions of Claims Was Incorrect and Outdated.** Over the course of its investigation, the Subcommittee learned that some claims records contained incorrect and outdated information. Although the source of the flawed data is unclear, that data caused certain diagnosis codes to be described as invalid, when in fact, they were valid. This caused an overstatement of claims with invalid diagnosis codes of more than \$1.4 billion.

In its communications with the Subcommittee, CMS officials stated that CMS is currently undergoing substantial changes in the way Medicare claims are processed. According to the officials, many changes that directly affect Medicare claims are in progress, such as changes to physician and DME supplier identification numbers.¹¹ The officials assert that these modifications will make the claims process more standardized among the claims processing contractors.¹²

B. REPORT RECOMMENDATIONS

Based upon the Subcommittee's investigation and the ongoing reform of the Medicare claims review processes, the Subcommittee minority staff makes the following recommendations:

- 1. Strengthen Claims Review Process.** CMS should consider strengthening the claims review process by more effectively utilizing all diagnosis codes submitted on claims. All diagnosis codes entered onto a claim should be valid and medically relate to the supplied DME items. Claims with any invalid or incorrect codes should be rejected and returned to the biller for correction.
- 2. Consider Developing Procedures to Link Diagnosis Codes with Medical Procedures.** CMS should consider developing processes that use the diagnosis codes to prevent, detect, and reject improper payments. This could include creating procedures to link ICD-9-CM diagnosis codes included on DME claims with authorized medical procedures (HCPCS), similar to what is already being performed by some contractors on select DME items.
- 3. Consider Developing Procedures to Link Claims for DME Items with a Corresponding Claim for Medical Treatment.** CMS should consider incorporating an edit into the claims processing system that would check a claim for a DME item against a claim for a doctor visit that would have resulted in an order or prescription for the item, similar to what is already being performed on DME claims for select items. Furthermore, for DME claims that do not have a corresponding medical treatment claims, CMS should consider performing additional procedures in order to ensure the medical necessity and integrity of the claims.
- 4. Strengthen Contractor Oversight.** CMS should consider strengthening its contractor oversight, including contractor penalties for making improper payments or maintaining unreliable data.

¹¹ See 45 CFR Part 162, Federal Register, Vol. 69, No. 15, January 23, 2004, at pg. 3434.

¹² Subcommittee interview of CMS officials, January 10, 2008.

III. BACKGROUND

This report examines certain aspects of the Medicare claims process in general and the durable medical equipment benefit in particular. In exploring these issues, several central concepts, terms, and entities warrant some background and context, which is presented below.

A. OVERVIEW OF MEDICARE AND CLAIMS FOR DURABLE MEDICAL EQUIPMENT UNDER PART B

1. Medicare and DME in General

Title XVIII of the Social Security Act (SSA), entitled “Health Insurance for the Aged and Disabled,” established the Medicare program in 1965.¹³ Medicare was created to provide health insurance for the aged, disabled, and persons with end-stage renal disease. The program is administered by the HHS through CMS.

Medicare is comprised of four parts. Part A, the Hospital Insurance Program, covers hospital services, post-hospital services, and hospice services. Part B, the Supplementary Medical Insurance Program, covers medical services including physician, laboratory, outpatient services, and DME. Part C covers managed care options for beneficiaries enrolled in Part A and Part B. Part D, created by the Medicare Prescription Drug Improvement and Modernization Act of 2003, covers outpatient prescription drug benefits as of January 1, 2006.¹⁴

Under Part B, the Medicare program will pay for certain DME for eligible Medicare beneficiaries under the DMEPOS benefit.¹⁵ The term DME refers to medical equipment and supplies that are used in the patient’s home (including an institution such as a nursing home in which the patient resides).¹⁶ Medicare regulations define DME as:

[E]quipment furnished by a supplier or a home health agency that:

- (1) Can withstand repeated use;
- (2) Is primarily and customarily used to serve a medical purpose;
- (3) Generally is not useful to an individual in the absence of an illness or injury; and
- (4) Is appropriate for use in the home.¹⁷

Examples of DME include wheelchairs, oxygen concentrators, nebulizers, canes, hospital beds, and diabetic equipment and supplies, such as blood glucose test strips.

2. DME Claims and Suppliers

The Medicare claims process for DME typically involves three parties: (1) the Medicare beneficiary, who is a patient eligible for Medicare that needs certain medical supplies or equipment; (2)

¹³ Title XVIII appears in the United States Code at 42 USC §§ 1395-1395(ccc).

¹⁴ Prior to this date, certain prescription drugs were covered under Medicare Part B.

¹⁵ See SSA §1833(a)(1)(I).

¹⁶ See SSA §1861(n).

¹⁷ See 42 CFR 414.202.

the medical practitioner, such as a physician, nurse practitioner, physician assistant, clinical social worker or psychologist, who is treating the beneficiary and prescribing the equipment; and (3) the DME supplier, a private entity authorized by CMS to provide DME items to Medicare beneficiaries and bill Medicare directly. The process of a DME claim generally starts with the Medicare beneficiary receiving treatment from a medical practitioner. If the physician writes an order or prescription for DME, the beneficiary can take the prescription to a DME supplier of his or her choosing and the DME supplier sells or rents the prescribed item to the beneficiary.¹⁸

In most circumstances, the DME supplier then submits a claim for payment to an entity authorized by CMS to receive, review, and process Medicare claims, Durable Medical Equipment Regional Carrier (DMERC) or other Medicare carrier.¹⁹ DMERCs were established to standardize the coverage and payment of DME claims and were designed to be the experts in the Medicare DME claims process. Their primary role was to accept and process Medicare Part B DME claims. In doing so, DMERCs were also expected to consolidate and focus efforts to combat fraud, waste, and abuse in the DME benefit program.²⁰

Physicians generally file claims to Medicare that deal with treatment, office visits, and other medical procedures, while DME claims are typically submitted by suppliers. As noted above, DME suppliers are entities that are enrolled in the Medicare program to sell or rent durable medical equipment to eligible beneficiaries and submit claims for payment directly to Medicare. DME suppliers typically include pharmacies or companies that specialize in DME such as wheelchairs, oxygen supplies, diabetic supplies and other supplies and equipment that are provided to Medicare beneficiaries, as well as other medical patients.

3. DME Must Be “Medically Necessary”

In creating Medicare, the Social Security Act provides that only items and services that are medically necessary will be covered. Section 1862 (a)(1)(A) of the Social Security Act states: “[N]o payment may be made under Part A or Part B for any expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”

CMS has referenced the medical necessity requirement frequently in its regulations, publications, and notices sent to DME suppliers and contractors. For instance, in a 2002 Program Memorandum sent to Medicare carriers, CMS stated, “Medicare pays for DMEPOS when it is medically necessary for use in a patient’s home.”²¹ Similarly, the Medicare Program General Information section of CMS’s website

¹⁸ For certain DME, including equipment that is expensive and prone to fraudulent activity, CMS regulations require the physician to provide a Certificate of Medical Necessity (CMN) in addition to a prescription. For instance, Medicare requires a CMN for oxygen or infusion pumps. A CMN is a form required to help document the medical necessity and other coverage criteria for selected DMEPOS. See Medicare Claims Processing Manual, Chapter 20, Section 100.2.

¹⁹ DME Medicare Administrative Contractors (DME MACs) replaced the DMERCs beginning in January 2006 to comply with Medicare Modernization Act of 2003, which amended 42 U.S.C. Section 1874A. The DME MACs are now responsible for administering the Medicare Part B DME Claims. DMERCs were the claims processing contractors for all claims reviewed for this report.

²⁰ Section 911 of the Medicare Modernization Act of 2003, known as the Medicare Contracting Reform provision, required CMS to compete all currently held contracts for administration of the Medicare fee-for service program. The new contractors selected through these competitions are called Medicare Administrative Contractors (MACs). DME MACs are the new contractors for DME services.

²¹ See CMS Program Memorandum - Carriers, Transmittal B-02-087, Change Request 2453, November 8, 2002.

emphasizes that Part B of Medicare (which includes DME claims) covers only medically necessary items and services: “Part B helps pay for these covered services and supplies when they are medically necessary.”²²

CMS also uses the term in its Medicare Claims Processing Manual. For instance, Chapter 20, Section 10.2 of the manual contains a table that delineates the conditions that must be met before a DME claim will be paid; the first requirement in the table is that the DME must be medically necessary.²³ Medicare carriers, the contractors retained by CMS to administer many functions of the program, have also emphasized the requirement that claims for DME be medically necessary in notices they have published for the providers within their jurisdictions.²⁴ More recently, the Chief Financial Officer of CMS testified before the House of Representatives Committee on the Budget in July 2007 and reiterated the medical necessity requirement established in the Social Security Act, stating “Medicare contractors review claims submitted by providers to ensure payment is made only for Medicare-covered items and services that are reasonable and necessary and furnished to eligible individuals.”²⁵

The failure to establish the medical necessity requirement has been a substantial problem in the Medicare program, according to previous annual reports issued by the HHS/OIG. The HHS/OIG analyzed Medicare claims filed over the four-year period between 1996 and 1999 and found that the failures to establish the medical necessity of the DME supplies and other errors “have been and continue to be pervasive problems.”²⁶ The OIG reported that documentation errors and the failure to establish medical necessity accounted for more than 70 percent of the total improper payments over the four-year timeframe.

The HHS/OIG’s analysis of claims filed in 1999 with respect to the medical necessity requirement is particularly noteworthy. The HHS/OIG conducted an in-depth audit of Medicare claims filed in 1999 in order to determine whether Medicare fee-for-service payments were made in accordance with the Social Security Act and implementing regulations, including the medical necessity requirement. In the report, the HHS/OIG concluded that Medicare made improper payments totaling

²² See <http://www.cms.hhs.gov/MedicareGenInfo/>; see also http://www.cms.hhs.gov/MedicareGenInfo/03_Part%20B.asp#TopOfPage.

²³ See Medicare Claims Processing Manual, Chapter 20, Section 10.2.

²⁴ See [http://www.palmettogba.com/palmetto/providers.nsf/\(Docs\)/296333A85C1581A2852573310065FDC7?OpenDocument](http://www.palmettogba.com/palmetto/providers.nsf/(Docs)/296333A85C1581A2852573310065FDC7?OpenDocument); http://www.cignagovernmentservices.com/jc/pubs/pdf/2007_winter/2007_winter_SM.pdf; https://www.noridianmedicare.com/dme/news/bulletins/dmercdialogue/winter_2005/winter05_dd.pdf.

²⁵ See Testimony of Timothy B. Hill, CFO, Centers for Medicare & Medicaid Services before the House Budget Committee, Medicare Health Care Fraud & Abuse Efforts, July 17, 2007, <https://www.hhs.gov/asl/testify/2007/07/t20070717b.html>. Federal courts have also noted that claims under Medicare Part B must be medically necessary. The U.S. Supreme Court in Schweiker v. McClure described the Medicare Part B claims review process as follows: “Once the carrier has been billed for a particular service, it decides initially whether the services were medically necessary, whether the charges are reasonable, and whether the claim is otherwise covered by Part B.” 456 U.S. 188, 191, 102 S. Ct. 1665, 1667 (1982) (citing the Social Security Act). Although the facts of Schweiker involved a claim under Part B for medical services, rather than the DME claims that are at issue in this report, the requirement of medical necessity is identical. Like the Supreme Court in Schweiker, the United States Court of Appeals for the Eleventh Circuit explained in Gulfcoast Medical Supply, Inc. v. Secretary, Department of Health and Human Services that Part B Medicare coverage “extends to only those medical services that are medically ‘reasonable and necessary’ for the beneficiary.” 468 F.3d 1347 (11th Cir. 2006).

²⁶ See HHS/OIG, *Improper Fiscal Year 1999 Medicare Fee-for-Service Payments*, Number A-17-99-01999.

\$13.5 billion in 1999 alone. Notably, the HHS/OIG found that more than 45 percent of the total improper payments in 1999 – meaning \$4.4 billion – were for claims that lacked proof of medical necessity.

4. International Classification of Diseases, Ninth Revision, with Clinical Modification (ICD-9-CM) Diagnosis Codes

Medicare regulations require that claims must contain certain information in order to qualify for payment. Claims must include valid identification numbers for the beneficiary, medical provider, and DME supplier.²⁷ Additionally, claims must contain certain codes or other information that describes the beneficiary's diagnosis.²⁸ For instance, if a beneficiary needs a DME item, such as a wheelchair, the claim must include a diagnosis from a medical professional of the physical condition that indicates the wheelchair is reasonable and necessary. Current CMS regulations mandate that claims that do not have valid information – including a medical diagnosis – must be returned to the supplier for correction.²⁹

Medicare regulations have required that certain claims must reflect the patient's diagnoses in a standardized numeric or alphanumeric code.³⁰ CMS has adopted the coding system called the International Classification of Diseases, Ninth Revision, with Clinical Modification, which is commonly referred to as the ICD-9-CM. CMS described and provided the history of the ICD-9-CM as follows:

The International Classification of Diseases, Ninth Revision (ICD-9) is a classification system developed by the World Health Organization for recording morbidity and mortality information for statistical purposes, for indexing hospital records by diseases, and for storing and retrieving data. The clinical modification to ICD-9 (that is, ICD-9-CM) is a coding system for reporting diagnostic information and procedures performed on a patient in hospitals or connected with other types of health care delivery systems.

ICD-9-CM was developed under the guidance of the National Center for Health Statistics (NCHS) to adapt the ICD-9 classification system to the needs of hospitals in the United States. The modifications were intended to provide a mechanism to present a clinical picture of the patient. Thus, ICD-9-CM codes are more precise than those included in ICD-9 since greater precision is needed to describe the clinical picture of a patient than for statistical groupings and trend analysis.

Effective January 1979, after nearly two years of development by numerous national experts on clinical technical matters, the ICD-9-CM became the single classification system intended for use by hospitals in the United States. This system replaced several earlier related but somewhat dissimilar classification systems. []

²⁷ See Medicare Claims Processing Manual, Chapter 1, Section 80.3.1 through 80.3.2.

²⁸ See, e.g., 42 C.F.R. 424.32 (requiring physicians to provide ICD-9-CM diagnosis code for all claims for services and items).

²⁹ See Medicare Claims Processing Manual, Chapter 1, Section 80.3.2. When a claim is valid, CMS regulations require that the claim be paid within thirty days. See Medicare Claims Processing Manual, Chapter 1, Section 80.2.1.1. Any claim that contains invalid data, however, is not considered received for purposes of the thirty-day prompt-payment rule. See Medicare Claims Processing Manual, Chapter 1, Section 80.3.2.

³⁰ See *id.*

The ICD-9-CM is a numeric and, in some circumstances, alphanumeric code that ranges from three to five digits and describes the clinical reason for a patient’s treatment. Examples of valid ICD-9-CM diagnosis codes are identified in Figure 1 below.

EXAMPLES OF VALID ICD-9-CM DIAGNOSIS CODES	
Medical Diagnosis	ICD-9-CM Diagnosis Code
Asthma	493
Diabetes	250.0
Chronic airway obstruction not elsewhere classified	496
Bubonic plague	020.0
Acute but ill-defined cerebrovascular disease	436
Cholera	001
Congestive heart failure unspecified	428.0
Motor vehicle traffic accident involving collision with other vehicle injuring other specified person	E813.8

Figure 1

B. LEGISLATION AND REGULATIONS GOVERNING DME CLAIMS UNDER MEDICARE PART B

Prior to 1989, only hospitals were required to include ICD-9-CM diagnosis codes in connection with Medicare claims. In 1989, HCFA implemented rules pursuant to the Medicare Catastrophic Coverage Act of 1988 (MCCA) that required that claims submitted by physicians for items or services contain a valid diagnosis code.³¹ In the conference report that accompanied the MCCA, the conferees explained their reasoning for requiring diagnostic coding for physician services under Part B as follows: “This information would be available for immediate use for utilization review of physician services (and could be used for prepayment screens) [].”³² In keeping with the use of ICD-9-CM codes for hospital claims, CMS determined that the appropriate codes for physician claims would be the ICD-9-CM as well.³³ Although DME claims submitted by hospitals and physicians were required to contain diagnosis

³¹ See PL 100-360, Section 202(g)(p)(1) (amending Social Security Act, 42 USC 1395u), July 1, 1988. A Senate version of the MCCA would have required that all prescriptions from physicians contain a valid diagnosis code, but the Conference Committee determined that requirement would be too burdensome on physicians. As a result, the Conference Committee agreed that only claims for services from physicians required a diagnosis code. See CR 100-661. The final language of the MCCA, however, still included the term “items”: “Each request for payment, or bill submitted, for an item or service furnished by a physician for which payment may be made under this part shall include the appropriate diagnosis code (or codes) as established by the Secretary for such item or service.”

³² H.R. Rep. No. 661, 100th Cong., 2nd Sess. 191 (1988).

³³ See 54 FR 30558.

codes, it is unclear when DME claims submitted by suppliers were required to include diagnosis codes. Below is a review of relevant laws and regulations that address the use of diagnosis codes for DME claims from suppliers.

1. The 1991 Notice

On November 29, 1991, HCFA published 56 FR 61023, a notice entitled “Medicare Program: Standard Claim Forms for Part B Claims Completed and Submitted by Physicians, Suppliers and Other Persons” (the 1991 Notice). Before the promulgation of this notice, DME suppliers had been allowed to attach supporting documents to their claims that contained relevant diagnosis information, such as medical records, narratives, or Certificates of Medical Necessity. The 1991 Notice forbade the attachment of supplemental materials and required all claims to be uniform. The notice announced that, effective April 1, 1992, Medicare would no longer accept so-called non-standard claims. The notice defined non-standard claims as claims accompanied by attachments in lieu of the biller entering the required information in the designated blocks of the prescribed claim forms. Additionally, the rule mandated that physician and supplies must submit claims on a specified form, the HCFA Form 1500.³⁴

Effective April 1, 1992, Medicare carriers will no longer accept claim attachments for information that physicians and suppliers may enter in designated blocks of prescribed claim forms. Incomplete claim forms will be returned to the billing individual or entity for proper completion and resubmission. The claim submission requirement in section 1848(g)(4)(A) of the Act is not satisfied until a standard, prescribed claim form is properly completed and submitted by the physician, supplier or authorized billing entity and received for processing by the servicing carrier.³⁵

CMS explained in the notice that the change was necessary to eliminate costly and inefficient claim processing practices that were resulting from processing claims with attachments. CMS also justified the rule change by stating that non-standard claims (i) create additional administrative burdens on the carriers that process the claims, (ii) generate additional cost per claim, and (iii) slow the claim process down 30 to 50 percent. CMS also explained that each of the carriers handled claims differently.³⁶

Currently, we allow carriers to determine whether they will accept non-standard claims for processing. Some carriers accept only standard claims. Some accept non-standard claims, but may restrict which information is allowed to be included. Others accept non-standard claims without restrictions.

The notice instructed physicians, suppliers, and other persons to stop submitting claims for DME with attachments when the information contained in the attachments could be entered into the appropriate blocks of the HCFA Form 1500. Notably, the HCFA Form 1500 contains blocks for up to four diagnosis codes.

³⁴ The HCFA Form 1500 is the standard claim form used by physicians and suppliers to file claims for treatment and equipment provided to Medicare beneficiaries.

³⁵ See 56 FR 61023.

³⁶ See *id.*

2. 1994 Final Rule from MCCA

Roughly two years later, on March 4, 1994, HCFA published a rule that affected the submission of diagnosis claims in DME claims from suppliers.³⁷ This rule, which was adopted pursuant to the MCCA, amended the relevant Medicare regulations to require that all claims for items and services from physicians contain a valid ICD-9-CM diagnosis code. However, in promulgating the final rule, HCFA stated, “the proposed rule did not apply to suppliers or other providers whose services are covered under Part B.”³⁸ HCFA also responded to a comment submitted during the comment period on the proposed rule concerning the diagnosis code requirement. The commenter asserted that, even though most DME suppliers were already providing diagnosis codes with their claims, there should be no requirement for DME suppliers to provide diagnosis codes. Notably, despite the language of the 1991 Notice that required suppliers to use the Form 1500 and complete the field for diagnosis codes on that form, HCFA responded that it had never required DME suppliers to provide diagnosis codes.³⁹ Figure 2 below presents the relevant section of the final rule.

Comment: One commenter stated that suppliers cannot be required to include diagnostic coding on Part B bills even though they often provide the diagnostic codes identified by the physician on bills for equipment and supplies.

Response: We have never required suppliers to include diagnostic coding on their Part B bills. Section 1842(p)(1) of the Act requires physicians, as defined in section 1861(r) of the Act, and subject to limitations concerning the scope of practice by each State and other provisions of title XVIII of the Act, to furnish diagnostic coding. That is, only doctors of medicine or osteopathy, dental surgery or dental medicine, podiatry, optometry, or chiropractic must furnish diagnostic coding. Durable medical equipment suppliers are not included in this requirement.

Figure 2

3. 1996 Bulletin

In February 1996, HCFA issued a bulletin to all of its providers – including DME suppliers – that articulated new rules regarding invalid and incomplete claims. Section 5.0 of the Provider Bulletin, entitled “Return/Reject Claims,” stated:

The Health Care Financing Administration (HCFA) is continuing efforts to reduce costs and administrative waste. As of April 1, 1996, a new editing process will be implemented for assigned claims which will save the Medicare Trust Fund millions of dollars. For some time, the denial of claims with incomplete or invalid information has resulted in claims surfacing inappropriately into the appeals process. This practice has not only been costly, it has resulted in an inappropriate use of the appeals system.

This new editing process will return paper or electronic claims to you as unprocessable if the claim contains certain incomplete or invalid information.

³⁷ See 59 FR 10290, March 4, 1994, Medicare Program: Diagnosis Codes on Physician Bills.

³⁸ See *id.*, Section III. Provisions of the Proposed Rule.

³⁹ See *id.* at 10291.

No appeal rights will be afforded to these claims, or portion of these claims, because the ‘initial determination’ can not be made; rendering the claim unprocessable.

The bulletin contains a matrix that instructs providers on how to handle certain issues. The matrix states that claims will be returned as unprocessable if the information supplied for certain sections of the claim form (the HCFA Form 1500) is incomplete or invalid. The matrix indicates that Medicare will reject claims if the information regarding diagnosis codes is incomplete or invalid.⁴⁰

4. The Health Insurance Portability and Accountability Act of 1996 (HIPAA)

The landscape concerning the use of diagnosis codes changed once again with the enactment of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) on August 21, 1996. HIPAA amended various statutes including the Internal Revenue Code of 1986 and the Social Security Act. Title II of HIPAA, entitled “Preventing Health Care Fraud and Abuse; Administrative Simplification; Medical Liability Reform,” mandated certain requirements for Medicare claims. In particular, Section 1173(c) mandated that the program establish standardized codes for the data required for Medicare claims. As part of that requirement, HIPAA required HHS to establish a standardized set of codes, including diagnosis codes, for all Medicare claims.⁴¹ [As noted above, Medicare regulations already required hospitals and physicians to use ICD-9-CM for diagnoses in connection with the submission of DME claims.]

5. The Balanced Budget Act of 1997

Section 4317 of the Balanced Budget Act of 1997 expanded the requirement for medical professionals to provide diagnostic information for Medicare claims. The Act added additional medical professionals to the definition of “practitioner” in 42 U.S.C. 1395(u) such as a physician assistant, nurse practitioner or certified nurse anesthetist. This Act also stated that, when an item or service ordered by a practitioner is provided by “another entity” (including a DME supplier) and Medicare requires that entity to provide diagnostic information, the practitioner must provide the diagnostic information at the time the item or service is ordered.

6. Implementation of HIPAA in 2003

Pursuant to the requirements set forth in HIPAA, CMS published a bulletin on June 13, 2003, entitled “Establishing New Requirements for ICD-9-CM Coding on Claims Submitted to Medicare Carriers – Increased Role for Physicians/Practitioners.” The bulletin stated that, pursuant to the requirements established by HIPAA, for claims with dates of service on or after October 1, 2003:

ICD-9-CM diagnosis codes must be included on all Medicare electronic and paper claims billed to Part B carriers, with the exception of ambulance claims. Providers and suppliers rely on physicians to provide a diagnosis code or narrative diagnostic statement on orders/referrals. This guidance serves as a reminder that physician/practitioners must provide a diagnosis on all orders and referrals.

⁴⁰ See February 1996 HCFA Provider Bulletin, Section 5.0.

⁴¹ See Section 1173 (a) (1), Public Law 104-191, August 21, 1996.

The bulletin states under the heading, “New Policy,” that any claim (other than ambulance services) submitted for payment that does not contain a valid diagnosis code will be returned as unprocessable:

Effective for dates of service on or after October 1, 2003, all paper and electronic claims submitted to carriers must contain a valid diagnosis code with the exception of claims submitted by ambulance suppliers []. Carriers will return as unprocessable paper and electronic claims that do not contain a valid diagnosis code with the exception of claims submitted by ambulance suppliers [] Therefore, the diagnosis code must be entered on the claim by the submitter.

This bulletin, like the 1996 HCFA bulletin, made clear that all claims must contain the complete and valid diagnosis code in order to be accepted for processing.

Following the implementation of the HIPAA regulations in 2003, CMS repeatedly emphasized to DME suppliers that they must provide valid diagnosis codes in their claims. For instance, in February 2004, CMS issued a bulletin instructing its claims processing contractors to strengthen the review of claims to ensure that claims containing invalid diagnosis codes, among other errors, would be rejected. This bulletin, which is reproduced in Figure 3 below, required CMS’s contractors to reject all inbound electronic claims that contained an invalid diagnosis code. This change was effective as of July 1, 2004. Notably, under the headings “Provider Action Needed” and “Caution – What You Need to Know,” the bulletin stated that Medicare providers – such as DME suppliers and physicians – should note that Medicare systems are strengthening system edits to ensure that submitted claims are HIPAA compliant, including containing diagnosis codes.

Medicare Learning Network
MLN Matters CMS
 Information for Medicare Fee-for-Service Health Care Professionals

Related Change Request (CR) #: 3050 MLN Matters Number: MM3050
 Related CR Release Date: February 6, 2004
 Related CR Transmittal #: R86CP
 Effective Date: July 1, 2004
 Implementation Date: July 6, 2004

Health Insurance Portability and Accountability Act (HIPAA) X12N 837 Professional Health Care Claim Implementation Guide (IG) Editing

Note: This article was revised to contain Web addresses that conform to the new CMS web site and to show they are now MLN Matters articles. All other information remains the same.

Provider Types Affected
 Physicians, practitioners, suppliers, and providers who bill Medicare carriers, including Durable Medical Equipment Carriers (DMERCs).

Provider Action Needed

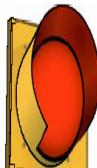
 **STOP – Impact to You**
 Affected providers should stop submitting electronic claims with diagnosis codes, zip codes, or telephone numbers that are not HIPAA compliant.

 **CAUTION – What You Need to Know**
 Providers should note that Medicare systems are strengthening their system edits to assure receipt of HIPAA compliant claims. Effective July 1, 2004, Medicare will reject electronic claims that have diagnosis codes, zip codes, or telephone numbers that are not HIPAA compliant.

 **GO – What You Need to Do**
 Be sure your billing systems are modified to generate electronic claims that will pass Medicare's HIPAA compliancy edits for diagnosis codes, zip codes, and telephone numbers.

Background
 The Health Insurance Portability and Accountability Act (HIPAA) directed the Secretary of the Department of Health and Human Services (HHS) to adopt standards for transactions to enable health information to be exchanged electronically. In addition, one of the HIPAA provisions requires standard formats to be used for electronically submitted health care transactions.

Provider Action Needed

 **STOP – Impact to You**
 Affected providers should stop submitting electronic claims with diagnosis codes, zip codes, or telephone numbers that are not HIPAA compliant.

 **CAUTION – What You Need to Know**
 Providers should note that Medicare systems are strengthening their system edits to assure receipt of HIPAA compliant claims. Effective July 1, 2004, Medicare will reject electronic claims that have diagnosis codes, zip codes, or telephone numbers that are not HIPAA compliant.

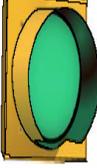
 **GO – What You Need to Do**
 Be sure your billing systems are modified to generate electronic claims that will pass Medicare's HIPAA compliancy edits for diagnosis codes, zip codes, and telephone numbers.

Figure 3

In 2007, CMS issued another bulletin to Medicare providers further confirming that valid diagnosis codes must be included in all DME claims. CMS published the Medicare B News bulletin, entitled *Common Billing Errors to Avoid When Billing Medicare Carriers*, which discussed frequent billing problems in Medicare claims.⁴² One of the common billing errors listed involved diagnosis codes, stating:

Diagnosis codes being used are either invalid or truncated. Diagnosis codes are considered invalid usually because an extra digit is being added to make it 5 digits. Please remember not all diagnosis codes are 5 digits. Please check your ICD-9-CM coding book for the correct diagnosis code.⁴³

These bulletins illustrate that, at least since the implementation of HIPAA in 2003, DME suppliers have been required to provide valid ICD-9-CM diagnosis codes. Despite the requirement to include diagnosis codes, however, it is clear based on comments made by CMS officials and the results of the Subcommittee's review that the codes are not used effectively to help ensure payments are made on claims that are medically necessary or utilized as a mechanism to prevent fraud, waste, and abuse.

⁴² See Medicare B News, Issue 236, April 17, 2006, MLN Matters Number: SE0712.

⁴³ See *id.*

IV. ANALYSIS

The Subcommittee's investigation has focused on fraud, waste, and abuse in claims submitted by DME suppliers and the efficacy of oversight by CMS and its contractors designed to prevent such abuses.⁴⁴ The Subcommittee's review reveals that the laws governing the use of diagnosis codes in DME claims have been inconsistent and, even after CMS required the submission of valid diagnosis codes for all DME supplier claims, Medicare does not fully utilize the submitted diagnosis codes to prevent fraud, waste, and abuse. For instance, Medicare has required hospitals and physicians to provide diagnosis codes on DME claims for decades; in contrast, the rules governing the use of such codes in claims from DME suppliers have been inconsistent. Moreover, even after Congress expressly required DME suppliers to provide such codes, the Medicare program does not use the codes for any significant purpose. In fact, CMS officials have emphasized to the Subcommittee that CMS requires DME claims to have diagnosis codes only to comply with HIPAA and, in the vast majority of cases, does not use them in its determination of whether a claim is valid or compliant with program requirements.⁴⁵ The Subcommittee examined several issues concerning the requirement for and use of diagnosis codes and its findings are presented below.

A. LAWS AND REGULATIONS GOVERNING THE USE OF DIAGNOSIS CODES ON CLAIMS FROM DME SUPPLIERS HAVE BEEN INCONSISTENT

1. From 1991 to 2003, Rules Governing the Submission of Diagnosis Code for DME Supplier Claims Were Unclear and Contradictory

The laws and regulations described above illustrate the inconsistent history of the requirement for diagnosis codes on DME supplier claims. Current law, established by HIPAA in 1996 and implemented by CMS regulations in 2003, requires that DME claims submitted by suppliers must include valid ICD-9-CM diagnosis codes or else those claims will be rejected and returned to the supplier for correction.⁴⁶ Before HIPAA required the inclusion of such codes, however, the requirements regarding diagnosis codes on supplier submitted DME claims appear to shift from 1991 through 2003. Figure 4 delineates how those rules appeared to change over time.

⁴⁴ The Subcommittee's review of the database revealed that it included only claims submitted from DME suppliers and did not include claims from physicians or hospitals.

⁴⁵ Subcommittee interview with CMS officials, May 10, 2008; *see also* CMS Response, Appendix, at pgs. 2-3 and CMS Response, Appendix, Addendum A, at pgs. 1-2.

⁴⁶ *See* CMS Program Memorandum-Carriers, Transmittal B-03-046, Change request 2784, June 10, 2003.

HISTORY OF MEDICARE RULES GOVERNING THE USE OF DIAGNOSIS CODES FOR DME SUPPLIER CLAIMS

Year	Action	Description of Rules	Diagnosis codes required for DME supplier claims?#
1991	CMS issues 1991 Notice	Standardizes claim submissions, including those from suppliers, and requires completion of HCFA Form 1500, which contained blocks to enter diagnosis codes.	Yes
1994	CMS implements final rule pursuant to MCCA	Requires valid diagnosis codes for DME claims submitted only by physicians. CMS stated in Section III and in reference to comments made on the proposed rule that DME suppliers are not required to provide diagnosis codes.	No
1996	CMS issues a bulletin to all providers	States that claims submitted by providers, including DME suppliers, would be returned as unprocessable if the claim contained incomplete or invalid information. Included is a matrix that indicated Medicare would reject claims if information regarding diagnosis codes was incomplete or invalid.	Yes
2003	CMS begins implementation of HIPAA rules	Requires all providers, including suppliers, to use valid ICD-9-CM diagnosis codes on all electronic and paper claims, except ambulance claims.	Yes

Figure 4

In 1991, CMS issued the 1991 Notice, which mandated that all Medicare providers – including DME suppliers – must submit claims on a completed HCFA Form 1500. Considering that the Form 1500 requires the submission of diagnosis codes and CMS emphasized that incomplete claim forms would be rejected, the 1991 Notice appears to have required DME suppliers to include diagnosis codes when submitting claims. Nevertheless, a few years later, CMS promulgated a rule in 1994 pursuant to the MCCA that required physicians to provide diagnosis codes on DME claims, but in the Provisions of the Proposed Rule section and in response to a comment, expressly excluded DME suppliers from this requirement. CMS could not have been clearer in its statement: “Durable medical equipment suppliers are not included in this requirement.”⁴⁷

Although DME suppliers were excluded from the diagnosis code requirement in the 1994 rule, the February 1996 Provider Bulletin, which was issued to DME suppliers as well as physicians and other providers, lists diagnosis codes as required data for the submission of DME claims. HCFA appears to state in the 1996 bulletin that DME claims – including claims submitted by suppliers – that did not contain valid diagnosis codes would be returned and rejected. However, in its comments to the Subcommittee, CMS stated that prior to HIPAA implementation, “the DME claim processing system did not check a claim’s primary diagnosis code upon submission to determine whether the code was recognized and in the appropriate format as defined by the ICD-9-CM Manual.”⁴⁸ CMS goes on to

Based on Subcommittee analysis.

⁴⁷ See *id.* at 102941.

⁴⁸ See CMS Response, Appendix, at pg. 2.

comment that “one may very well find paid DME claims with invalid or illegitimate ICD-9 codes.”⁴⁹ Arguably, diagnosis codes were required on claims as early as 1991, years earlier than HIPAA implementation in 2003, as CMS has suggested.

2. Since Implementation of HIPAA in 2003, Application of Diagnosis Code Requirement Has Been Inconsistent

Even after implementation of the HIPAA requirement for claims to contain diagnosis codes, CMS’s application of the diagnosis code requirement is inconsistent. As described below, the manner in which the Medicare claims review process examines diagnosis codes can result in the payment of some items tied to invalid diagnosis codes and the rejection of claims that contain valid diagnosis codes.

CMS regulations require that all DME claims must use the CMS Form 1500. That claim form permits DME suppliers to enter up to six items on one form; each individual item is listed on a separate “claim line.” Each claim line is essentially equivalent to a separate DME claim, and for efficiency purposes, CMS permits up to six different claim lines on a single Form 1500. Because each item may relate to a different diagnosis, the Form 1500 contains spaces for up to four diagnosis codes. The claims form instructs the DME supplier to indicate which diagnosis relates to the individual DME items. The pertinent section of the claim form (Form 1500) is reproduced in Figure 5 below. The spaces for the four diagnosis codes appear in Section 21; the codes for the DME items appear in Section 24. The form directs the supplier to link the applicable diagnosis code to the associated item through the “pointer” on the right of the DME item.

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate Items 1, 2, 3 or 4 to item 24E by Line)										22. MEDICAL CODE	23. PRIORITY
1.											
2.											
3.											
4.											
24. A. DATE(S) OF SERVICE		B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances)			E. DIAGNOSIS POINTER		\$ CHARGE		
From	To			CPT/HCPCS	MODIFIER						
MM DD YY	MM DD YY										
1											
3											
4											
5											
6											
25. FEDERAL TAX I.D. NUMBER			SSN EIN	26. PATIENT'S ACCOUNT NO.			27. ACCEPT ASSIGNMENT? (For gov. claims, see back)		28. TOTAL \$		
			<input type="checkbox"/> <input type="checkbox"/>				<input type="checkbox"/> YES <input type="checkbox"/> NO				
31. SIGNATURE OF PHYSICIAN OR SUPPLIER				32. SERVICE FACILITY LOCATION INFORMATION							

Figure 5

⁴⁹ *Id.*

Even though the Form 1500 can include multiple items involving up to four different diagnoses, CMS informed the Subcommittee that the Medicare claims review system checks only whether the first diagnosis code – called the “primary” code – is valid and does not determine whether other diagnosis codes, if any, are valid:

For claims that were processed after the installation of edits required by HIPAA began, the DME core claim system and front end started to check a claim’s primary diagnosis code against the current ICD-9-CM Manual list, which is updated October 1 of every year. This means that at present—assuming all other minimum claim information is valid—a claim with a valid primary diagnosis code will pass into the claim processing system. Conversely, if a claim contains an invalid primary diagnosis code, the claim is rejected and returned to the submitting supplier as opposed to being processed and denied.⁵⁰

According to CMS, the Medicare claims review process will examine only the first diagnosis code on each claim, even if a claim contains more than one diagnosis code.⁵¹

CMS’s statement identifies a potential inconsistency with respect to applying the diagnosis code requirement. By checking only the primary diagnosis code on a given claim and ignoring any other

diagnosis codes, the current claims review process could lead to illogical results. As illustrated in Figure 6, CMS could be paying claims that contain invalid codes and rejecting claims that contain valid diagnosis codes.⁵² Specifically, if Medicare reviews only the primary code for validity, then claim lines relating to the non-primary invalid codes could be paid; as a result, a claim containing a valid primary code but three invalid non-primary codes would not be rejected and Medicare would pay for the items tied to the invalid diagnosis codes.

Primary Diagnosis Code	Secondary/Tertiary Diagnosis Codes	Result
Valid	Valid	Paid
Valid	Invalid	Paid (Claims with Invalid Diagnoses Paid)
Invalid	Valid	Not Paid (Claims with Valid Diagnoses Not Paid)
Invalid	Invalid	Not paid

Figure 6

Conversely, if a claim contained a primary diagnosis code that was invalid, but the diagnosis codes for other claim lines were valid, the entire claim would be rejected. Thus, Medicare would be rejected ostensibly valid claims simply because the first diagnosis code on the claim form was not valid. Therefore, CMS’s implementation of the diagnosis code requirement appears both over-inclusive and under-inclusive at the same time.

⁵⁰ See *id.* at pg. 2.

⁵¹ See CMS Response, Appendix, at pg. 3; also Subcommittee interview of CMS officials, February 12, 2008.

⁵² Figure 6 assumes that all other information on the claims form is correct and valid.

B. MEDICARE DOES NOT EFFECTIVELY UTILIZE DIAGNOSIS CODES ON DME SUPPLIER CLAIMS

The Subcommittee's investigation has established that the Medicare claims review process does not utilize diagnosis codes effectively. CMS emphasized that the Medicare claims review processes checked that the diagnosis codes submitted with suppliers' claims complied with HIPAA and CMS regulations, but in general, did not use the codes to validate the integrity of the claim.⁵³ In other words, the claims review process verifies whether a valid diagnosis code is present (as required by HIPAA and CMS regulations), and whether the code meets the required format (the appropriate numbers and letters), but does not use the code to determine whether the diagnosis relates to the DME item purchased. In response to the Subcommittee's initial conclusions concerning the use of diagnosis codes, CMS argued that ICD-9-CM diagnosis codes were not required for suppliers' DME claims until the implementation of HIPAA in 2003 and only for the purpose of meeting HIPAA requirements: "[HIPAA] does not require that [Medicare claims review contractors] actually use any particular data element, including diagnosis codes, in its internal claims processes after it receives the claim."⁵⁴

CMS further commented that, for select DME items, it has instituted additional precautions that include the use of a claim's diagnosis code.⁵⁵ In particular, for select claims subject to Local Coverage Determinations (LCDs),⁵⁶ edits are placed in the DME claim processing system to match a particular DME item (referred to as a HCPCS or procedure code) against a specific list of ICD-9-CM Manual codes that are identified in the LCD policy.⁵⁷ Although an exception exists for a limited number of DME items, CMS stated that "in many other instances, however, a claim's ICD-9 code is not used to determine whether a claim should process for payment."⁵⁸

The Subcommittee examined data related to millions of DME claims in order to determine the impact of not effectively utilizing diagnosis codes in the claims review process. In particular, the Subcommittee examined claims in two categories of diagnosis codes: (i) claims that contained diagnosis codes with valid ICD-9-CM designations, and (ii) claims that contained diagnosis codes that were invalid, blank, or unprocessable. The Subcommittee's analysis of these claims suggests that examining the diagnosis codes on DME claims could be a valuable tool to uncover fraudulent or abusive claims.

1. DME Claims With Valid but Questionable ICD-9-CM Diagnosis Codes

The Subcommittee found a significant volume of claims that contained valid ICD-9-CM diagnosis codes, but the diagnosis appeared to raise serious questions about the legitimacy of the claim. For instance, the Subcommittee found claims in which the purported diagnosis appeared unrelated to the

⁵³ Subcommittee interview with CMS officials, May 10, 2008; *see also* CMS Response, Appendix, at pg. 2.

⁵⁴ *See* CMS Response, Appendix, Addendum A at pg. 1; *see also id.* at pg. 1 ("[F]or the sole purpose of achieving compliance with new healthcare industry-wide electronic claims transaction standards (mandated by HIPAA), CMS did begin to require DME suppliers to include diagnosis codes on their claims in recent years") and at pg. 2 ("The new computer processes put in place by CMS during 2003 and 2004 only check the ICD-9-CM codes on the claim for HIPAA compliance").

⁵⁵ According to CMS, the type of select items include blood glucose monitors, ankle and foot orthoses, refractive lenses, and oral anti-cancer drugs. *See* CMS Response, Appendix, at pg. 2.

⁵⁶ According to CMS, LCDs are policies and coverage guidelines that are promulgated by the DME MAC Medical Directors.

⁵⁷ *See* CMS Response, Appendix, at pg. 2.

⁵⁸ *Id.*

purchased DME supplies. The Subcommittee reviewed claims data from January 2001 to December 2006 for 18 DME items that had been identified by law enforcement and Medicare oversight agencies as particularly susceptible to fraudulent claims or overpayments.⁵⁹ The Subcommittee's examination of the claims for those 18 items found payments totaling more than \$1 billion in which the purported diagnosis was questionable.⁶⁰

Claims for blood glucose test strips provide an illustrative example of the disconnect surrounding the use of diagnosis codes.⁶¹ Numerous experts interviewed by the Subcommittee have confirmed that blood glucose test strips are used almost exclusively for patients with diabetes.⁶² According to experts at a prominent manufacturer that researches, develops, and markets diabetic supplies, blood glucose test strips are used for the "quantitative measurement of blood glucose."⁶³ For various reasons, these products are highly susceptible to fraud and abuse. For instance, a June 2000 report from HHS/OIG noted that Medicare paid more than \$79 million for test strips without proper documentation and that the cost to Medicare for this item had increased sharply between 1994 and 1997.⁶⁴

As a result, Medicare implemented several additional restrictions on claims for those items. The June 2000 HHS/OIG report observed that, unlike most DME items, only beneficiaries with diabetes would be covered for blood glucose test strips: "prior to July 1, 1998, Medicare coverage for home blood glucose monitors and test strips was restricted to beneficiaries with Type 1, or insulin-treated diabetes. Medicare expanded coverage on that date to beneficiaries with Type 2, or non-insulin treated diabetes."⁶⁵ In addition, suppliers that submit claims for blood glucose test strips must have documentation from the ordering physician that verifies that the beneficiary needs the diabetic testing supplies.⁶⁶ CMS stated that, because of the high incidence of abuse related to these products, blood glucose test strips "are governed

⁵⁹ The law enforcement and oversight agencies included the HHS/OIG, GAO, and the Health Care Fraud Unit of the U.S. Department of Justice. The 18 items were: (1) blood glucose test strips, (2) standard weight power wheelchair with control, (3) high strength lightweight wheelchair, (4) lightweight wheelchair, (5) standard wheelchair, (6) albuteral compound solution, (7) negative pressure wound therapy pump, (8) oxygen concentrator, (9) power operated vehicle, (10) continuous airway pressure device, (11) nebulizer with compression, (12) walker – folding wheeled, (13) enteral feed supply pump per day, (14) nasal application device, (15) collagen based wound filler, (16) diabetic custom molded shoe, (17) diabetic shoe for density insert, and (18) wheelchair seat pad.

⁶⁰ The Subcommittee's review of the diagnosis codes was not a medical or scientific review but based on a reasonableness review of the data, identifying only those diagnoses as questionable that did not appear to correlate with the medical device or equipment being prescribed.

⁶¹ According to an HHS/OIG report, "Diabetics are taught to use special devices called blood glucose monitors or meters to test their blood sugar levels. Typically, patients place a tiny amount of fingertip blood on a test or reagent strip which produces a numeric read-out when inserted into the monitor. Depending on the results of the read-out, patients can adjust their insulin dosages or contact their physicians for further instructions. Patients usually test their glucose levels in this manner one or more times a day." See HHS/OIG, *Blood Glucose Test Strips: Inappropriate Medicare Payments*, June 2000, OEI-03-98-00230, (the HHS/OIG Blood Glucose Test Strips Report) at pg. 5.

⁶² Subcommittee interviews of experts at a prominent medical school and manufacturing company of diabetic supplies.

⁶³ Subcommittee interview of manufacturing company officials, May 26, 2008.

⁶⁴ See HHS/OIG, *Blood Glucose Test Strips: Inappropriate Medicare Payments*, June 2000, OEI-03-98-00230.

⁶⁵ *Id.*

⁶⁶ See http://www.cms.hhs.gov/DiabetesSelfManagement/02_ProvResources.asp.

by specific [] policies; therefore, their diagnosis codes do edit against a defined list of ICD-9 codes as the claim is processed to pay or deny.”⁶⁷

Although blood glucose test strips have been associated with fraudulent activity and claims for those items must contain specific diagnosis codes related to diabetes, the Subcommittee found numerous instances in which claims for blood glucose test strips were paid, even though the submitted diagnosis codes were quite different from diabetes, such as typhoid and paratyphoid fevers, cholera, and scabies. In total, Medicare made payments for claims for blood glucose test strips containing 2,699 different ICD-9-CM diagnosis codes. The Subcommittee’s review of claims for blood glucose test strips revealed that the most frequent non-diabetes related diagnosis code for every year from 2001 through 2006 was chronic airway obstruction. Other questionable diagnosis codes for blood glucose test strips, which are presented in Figure 7, included leprosy, and psychosexual dysfunction, as well as respiratory, coronary, mental health and cancer conditions. Another questionable diagnosis code contained in several claims for blood glucose test strips was the bubonic plague.

EXAMPLES OF PURPORTED DIAGNOSES FOR BLOOD GLUCOSE STRIPS PAID BY MEDICARE	
TYPHOID AND PARATYPHOID FEVERS	LEUKEMIA OF UNSPECIFIED CELL TYPE
SALMONELLA GASTROENTERITIS	BENIGN NEOPLASM OF PROSTATE
OTHER FOOD POISONING (BACTERIAL)	DELAY IN SEXUAL DEVELOPMENT AND PUBERTY, NOT ELSEWHERE
PRIMARY TUBERCULOUS COMPLEX	PSYCHOSEXUAL DYSFUNCTION
BUBONIC PLAGUE	ACUTE BRONCHITIS
LEPROSY, UNSPECIFIED	CONTUSION OF ELBOW
ARTHRITIS DUE TO RUBELLA	DENTAL EXAMINATION
INFECTIOUS MONONUCLEOSIS	PREGNANT STATE, INCIDENTAL
CHOLERA	SCABIES

Figure 7

Experts interviewed by the Subcommittee, including officials from the Centers for Disease Control and Prevention (CDC), a prominent medical school and a manufacturer of diabetic supplies, confirmed that none of the diagnoses in Figure 7 would justify the use of blood glucose test strips.⁶⁸ The medical school experts stated, “In general, the use of glucose test strips is justified by a diagnosis in the codes that relate to diabetes,” and that if the listed diagnosis codes were used for the diagnoses listed in Figure 7, they could have been used mistakenly.⁶⁹ CDC experts confirmed that such items would not be appropriate treatment for the bubonic plague.⁷⁰ Furthermore, officials at the stated, “CDC is not aware of glucose strips being used to treat any of the conditions listed [in Figure 7] nor do the use of the strips diagnose infectious diseases [noted in Figure 7].”⁷¹

The Subcommittee’s review of the remaining 17 items revealed similar instances in which the reported diagnosis codes do not appear to justify the purchase of the DME item or appear medically

⁶⁷ See CMS Response, Appendix, at pg. 2.

⁶⁸ Subcommittee interviews of officials at CDC, experts at a prominent medical school, and diabetic supplies manufacturer.

⁶⁹ Subcommittee interview of experts at a prominent medical school, April 29, 2008.

⁷⁰ Subcommittee interview of CDC officials, May 23, 2008.

⁷¹ *Id.*

improbable. Figure 8 below presents examples of claims that contained diagnosis codes that appear improper.

EXAMPLES OF QUESTIONABLE DIAGNOSES FOR SELECTED ITEMS	
Purchased Item	Stated/Purported Diagnosis
Diabetic Shoes	Traumatic Amputation of Leg(s)
Diabetic Shoe Density Insert	Precocious Sexual Development and Puberty, Not Elsewhere Defined
Walker	Sinus Congestion
Wheelchair pad	Acquired Deformity of Nose
Blood Glucose Strips	Impotence of Organic Origin
Power Wheelchair	Sprained Wrist
Walker	Paraplegia

Figure 8

2. DME Claims with Invalid Diagnosis Codes Contain Potential Instances of Fraud, Waste, and Abuse

In addition to examining claims with valid, but questionable, diagnosis codes, the Subcommittee analyzed Medicare payment data for DME claims submitted by suppliers from 1995 through 2006 that contained blank, invalid, or unprocessable diagnosis codes. The Subcommittee’s analysis revealed that Medicare spent billions of dollars on claims from DME suppliers that contained one or more invalid diagnosis codes, although the volume of such payments decreased dramatically after the implementation of HIPAA in 2003.

As noted above, a valid ICD-9-CM code is a numeric and, in some circumstances, alphanumeric code that ranges from three to five digits. Examples of valid diagnosis codes include 496 (chronic airway obstruction), E813.8 (motor vehicle traffic accident involving collision with other vehicle injuring other specified person), and 428.0 (congestive heart failure unspecified). In contrast, the data examined by the Subcommittee included codes that were obviously invalid, such as unusual combinations of letters and numbers, as well as non-alphanumeric characters such as slashes, dashes and other “special characters.” For instance, the Subcommittee observed claims in which the purported diagnosis codes were “////” “?” “@” “----” and “zzzzz.”

EXAMPLES OF VALID ICD-9-CM DIAGNOSIS CODES	SUBMITTED DIAGNOSIS CODES
493 (Asthma)	!
250.0 (Diabetes)	'
020.0 (Bubonic Plague)	///
001 (Cholera)	G
428.0 (Congestive heart failure unspecified)	---

Figure 9

To determine the magnitude of the payments for claims with blank, invalid, or unprocessable diagnosis codes, the Subcommittee examined claims data, identified invalid codes, and selected the 198 invalid diagnosis codes that had the highest total of payments in dollar amounts from 1995 to 2006.⁷² The Subcommittee’s analysis revealed that, from 1995 through 2006, Medicare paid almost \$5 billion for more than 60 million DME items on claims that contained one or more of those 198 invalid diagnosis codes.⁷³ Figure 10 provides illustrations of invalid diagnosis codes, with the total volume of claims submitted with those codes and the amounts paid in connection with those claims.

⁷² The Subcommittee initially examined the claims data associated with the 300 codes that had the highest total payments from 1995 through 2006 and whose codes were described in Medicare claims data as “Invalid Diagnosis Code.” CMS and its data contractor, called SADMERC, informed the Subcommittee that SADMERC data regarding the descriptions of diagnosis codes was inaccurate and out-of-date. As a result, the Subcommittee examined the actual ICD-9-CM codes for these entries; in doing so, the Subcommittee determined that 102 were valid codes that had been incorrectly described as invalid by the SADMERC. [The fact that the SADMERC, CMS’s data contractor, had inaccurate data concerning millions of claims is addressed in Section IV.C below.] Of the remaining 198 codes, the Subcommittee found that 143 codes have never been valid ICD-9-CM codes and 55 of the codes were invalid at some point from 1995 through 2006. For the diagnosis codes that had become valid at some point from 1995 to 2006, the Subcommittee included only those claims that were submitted using a diagnosis code before the code became valid.

⁷³ This finding does not include the \$720,788,318 paid for 8,206,776 DME items on claims from 1995 through 2002 in which the associated invalid diagnosis code was “XX000.” As described in Section V.B below, CMS officials contend that the code XX000 was a “fictitious” code created by CMS and its contractors for use in certain narrow circumstances to comply with requirements imposed by MCCA.

Examples of Invalid Diagnosis Codes and Payments Made for Associated Claims		
INVALID DIAGNOSIS CODE	TOTAL NUMBER OF CLAIMS SUBMITTED USING THIS CODE	TOTAL AMOUNT PAID
Y0000	433,201	\$19,558,552
G	95,905	\$3,798,484
78720	7,436	\$2,360,420
00000	21,832	\$1, 127, 099

Figure 10

The Subcommittee found that the overwhelming majority of these claims – more than 56 million DME items on claims totaling more than \$4 billion in payments – contained the word “NULL” in the diagnosis code field. CMS and its data contractor, commonly called the Statistical Analysis DME Regional Carrier or SADMERC,⁷⁴ informed the Subcommittee that, when a claim contained an unprocessable diagnosis code or the relevant field was blank, the SADMERC would enter “NULL” into the relevant block in order to facilitate the storage and retrieval of that claim data.⁷⁵ Unprocessable entries, according to SADMERC, included diagnosis codes that had (i) symbols, such as a tilde (~), (ii) non-printable entries including a carriage return, a tab, or a space, or (iii) icons, such as a smiley face.⁷⁶ Such unprocessable entries or a blank field, according to SADMERC, would cause the relevant claims to be omitted from certain data analysis functions. In order to prevent the deletion or omission of these claims, SADMERC would enter the NULL value into the related claims data after a claim had already been paid or denied and the claim had been transferred to SADMERC for claims analysis. Thus, the claims with a NULL value in the diagnosis field do not reflect that the claim was submitted with “NULL” as the diagnosis code; to the contrary, the NULL designation identifies claims that were paid when the diagnosis code was unprocessable or blank.

To determine the accuracy and legitimacy of claims with invalid codes, the Subcommittee obtained full claims data concerning approximately 650,000 of the 60 million DME item claims that contained invalid diagnosis codes. The Subcommittee arbitrarily selected a subset of 2,000 claims from the 650,000 claims for further investigation.⁷⁷ For each of these claims, the Subcommittee contacted the doctors whose Unique Physician Identification Number (UPIN) was associated with the claims to verify the accuracy of the submitted information. The Subcommittee determined that more than 30 percent of

⁷⁴ SADMERC is the CMS contractor responsible for collecting and analyzing data regarding Medicare DME claims. As of August 2008, CMS has transitioned to a new data contractor.

⁷⁵ Subcommittee interview of SADMERC officials, February 28, 2008; *see also* CMS Response, Appendix, at pp. 6-7. SADMERC, which is an acronym of the Statistical Analysis DME Regional Carrier, is discussed in greater detail in Section IV.C below.

⁷⁶ Subcommittee communication with SADMERC officials, February 28, 2008.

⁷⁷ The Subcommittee obtained the information used in this study from claims data that had been previously provided by SADMERC and that contained complete claims information including the physician, beneficiary and supplier names and address as well as the treatment and diagnosis. The Subcommittee selected a group of claims from this data based on the diagnosis description being “invalid diagnosis code.” The data was not selected based on a purely random formula and could not be described as random for statistical analysis purposes. Therefore, the results are limited to the specific claims reviewed and the Subcommittee did not extrapolate these findings to the entire universe of relevant claims.

the 2,000 claims could not be verified as legitimate and bore characteristics of fraudulent activity. Some of these suspicious claims involved the following:

- For 101 claims that were filed after 2001, the doctor who allegedly prescribed the DME items had died in 2004 and, according to a family member interviewed by the Subcommittee, had not practiced medicine since the early 1990s.
- For 213 claims that were submitted after 2001, the identified doctor had retired from the practice of medicine in the late 1990s, and the address listed as the place of business for the doctor was never occupied by that doctor.
- A physician that purportedly prescribed items associated with 182 claims told the Subcommittee that he had never treated the patients involved.
- For 345 claims, the doctor involved verified that he had not treated nor prescribed the DME items involved in 39 claims, which is more than 12 percent of the claims filed using his UPIN and containing invalid diagnosis codes.
- A doctor reviewed 96 claims that contained his UPIN and said that 15 claims were from patients whom he had never treated. He also said that 13 claims were monthly payments for a hospital bed for a patient who died one month after receiving the bed. The supplier continued to bill Medicare and was paid for the bed for 12 months after the patient's death.
- The Subcommittee identified 36 claims for DME that were allegedly prescribed by a pediatrician where the claims were for elderly patients.

As discussed in detail in Section V.A below, CMS has asserted that Medicare rules did not require DME suppliers to provide valid diagnosis codes on their claims until the implementation of HIPAA in 2003. The Subcommittee's review of the claims data, however, revealed that Medicare continued to pay DME suppliers for claims that contained invalid diagnosis codes after the 2003 implementation of HIPAA. The volume and amount of these claims decreased precipitously since 2003, but the data indicated that Medicare paid more than \$23 million for DME claims from suppliers that contained invalid diagnosis codes after HIPAA regulations were implemented.

In 2004, Medicare paid \$10,746,665 for claims with invalid diagnosis codes included in the top 198 invalid diagnosis codes list. In 2005 and 2006, the amounts paid for supplier claims with invalid diagnosis codes were roughly \$1,447,997 and \$10,991,268 respectively. These figures likely understate the volume of claims paid with invalid diagnosis codes because the Subcommittee's analysis was limited to the 198 invalid codes with the highest total payments during the period reviewed.⁷⁸ In sum, the lower volume of payments from 2004 through 2006 indicate that Medicare has made great strides in ensuring that only claims with valid diagnosis codes are accepted, although the amounts also indicate that an unknown number of claims with invalid diagnosis codes continued to pass through the system undetected after 2003.

⁷⁸ The Subcommittee noted that there were more than 39,000 different codes used on claims from 1995 through 2007, while the 2006 version of the ICD-9-CM listing only contained 13,549 diagnosis codes.

C. CLAIMS DATA MAINTAINED BY CMS'S DATA CONTRACTOR WAS INCORRECT AND NOT UPDATED IN A TIMELY MANNER

The Subcommittee's investigation uncovered a problem related to a large subset of DME claims data. As noted above, the Subcommittee's investigation included a detailed review of data concerning Medicare claims from DME suppliers submitted between 1995 and 2006. The Subcommittee obtained the relevant claims data from SADMERC.⁷⁹ SADMERC is the CMS contractor responsible for collecting and analyzing data regarding Medicare DME claims. SADMERC described its responsibilities as (i) providing data analysis support to the DME Program Safeguard Contractors; (ii) offering guidance to manufacturers and suppliers on the proper use of the Healthcare Common Procedure Coding System (HCPCS) and is the means by which DME services are identified for Medicare billing; (iii) performing a variety of national pricing functions for DME services; (iv) assisting CMS with the DME Fee Schedules; and (v) analyzing DME fees to identify unreasonable or excessive reimbursement amounts.⁸⁰

One of SADMERC's primary roles in fighting against fraud, waste, and abuse is its analyses of claims data and supplier billing patterns. In fact, CMS underscored the importance of SADMERC's role in the Medicare program and emphasized its role in combating fraud, waste, and abuse in Medicare:

The SADMERC's data is used by many to develop policies, facilitate program integrity activities, and to support special initiatives. Further, federal and state law enforcement agencies, including the Department of Justice and the Office of the Inspector General, have utilized the SADMERC's data and reports in both civil and criminal cases, without question.⁸¹

The claims data that the Subcommittee received from SADMERC contained a category of information – called the Diagnosis Description field – that described the diagnosis code associated with each individual claim. As previously explained, for the review of invalid codes, the Subcommittee initially reviewed the top 300 codes described as invalid based on the amount paid from 1995 through 2006. That analysis indicated that claims totaling more than \$6.3 billion were paid in which the Diagnosis Description field stated “Invalid Diagnosis Code.” After discussions with CMS and SADMERC officials, the Subcommittee examined the codes and found that 102 of the 300 purportedly invalid codes were in fact valid. This reduced the scope of review to the remaining 198 codes. Of those 198 codes, 143 codes had never been valid and 55 codes became valid at some point during the relevant timeframe. In total, the Subcommittee's analysis of the 198 diagnosis codes revealed that the amount paid for claims with invalid diagnosis codes from 1995 to 2006 was \$4.8 billion. Thus, SADMERC data field of Diagnosis Descriptions overstated the amount of claims with actual invalid diagnosis codes by more than \$1.4 billion. Notably, the Subcommittee's initial analysis was limited to the top 300 codes, and therefore, the extent of the overstatement related to the SADMERC Diagnosis Description field could be materially larger.

To its credit, CMS discovered that SADMERC data describing diagnosis codes was defective and informed the Subcommittee. CMS assessed the data and determined that the Diagnosis Descriptions for the entire batch of claims data was flawed: “The apparent disconnect between the SADMERC ICD-9

⁷⁹ During the relevant timeframe, SADMERC was the CMS contractor responsible for collecting and analyzing data regarding Medicare DME claims.

⁸⁰ See <http://www.palmettogba.com/palmetto/Other.nsf/Home/Other+Medicare+Partners+SADMERC+Home?OpenDocument> (accessed May 7, 2008).

⁸¹ See CMS Response, Appendix, at pg. 9.

code description and the current ICD-9-CM Manual indicates to us that the SADMERC description field is not reliable.” CMS provided a detailed explanation of the errors as follows:

Following our meeting with the PSI staff on February 12, CMS approached its contractor, the SADMERC, to discuss the reports it had provided to the PSI staff, with a focus upon the ICD-9 description field contained in the reports. In response, the SADMERC advised CMS that they had provided the requested files to the PSI staff at their request, with the clear indication both orally and via e-mail that the source table used to determine whether a diagnosis code was valid was not regularly updated, and was believed to have last been updated in August 2003. Since this initial response, the SADMERC has now informed us that they cannot confirm the last time the file was actually updated, nor can it document the source of the ICD-9 table that it conveyed to the PSI staff. After independently reviewing the ICD-9 codes and sample claims from the SADMERC reports against actual claims history, CMS is not at all confident that the field in the SADMERC reports describing the validity of a particular ICD-9 code can be relied upon conclusively for any period of time.⁸²

Thus, it appears that some data maintained by CMS’s data contractor was (a) incorrect, (b) supplied by an unidentified source, and (c) outdated by at least four years and possibly longer. It is unclear at this stage whether the data originated with SADMERC, CMS, one or more of the Medicare carriers, or an unrelated third-party; accordingly, it would be premature to hold SADMERC or any other party responsible for that incorrect data and this report makes no finding in that regard. Nevertheless, the revelation of a large amount of flawed, unsourced, and outdated data maintained by SADMERC – Medicare’s data contractor – raises concerns about both the validity of other data maintained by SADMERC and the level of oversight performed by CMS on one of the Medicare program’s most important contractors. As noted above, SADMERC plays a crucial role in the prevention of fraud, waste, and abuse in the Medicare program by maintaining, examining, and reporting various analyses on the voluminous claims data. Its ability to identify abusive practices and trends is dependent on accurate claims data. While it is clear that the descriptions of diagnosis codes are not the most important data maintained by SADMERC, it is also clear that there was a breakdown of some variety in the Medicare data maintenance processes.

For the purposes of the Subcommittee’s investigation, the incorrect data in the Diagnosis Descriptions field had no impact on the findings in this report, including the analysis of more than \$4.8 billion in payments from 1995 to 2006 for DME supplier claims that contained invalid diagnosis codes. The analysis in this report did not rely on the Diagnosis Description field; in contrast, the relevant findings were based on a review of the actual diagnosis codes submitted with the claims, rather than the flawed description of those codes in SADMERC data fields.

V. CMS COMMENTS

Over the course of its investigation, the Subcommittee has had extensive interaction, including numerous interviews and briefings, with officials from CMS and its contractors. In February 2008, the Subcommittee presented to CMS its preliminary findings concerning the prevalence of invalid diagnosis codes in DME supplier claims and provided supporting analysis containing examples of the claims at

⁸² See CMS Response, Appendix, at pg. 7 (emphasis in original).

issue. The Subcommittee invited CMS and its contractors to comment on the Subcommittee's initial conclusions.

CMS provided substantial comments to the Subcommittee's preliminary findings and conclusions and its complete response is attached to this report in Appendix. While most of CMS's responses have been incorporated in this report, several issues warrant further discussion and are examined below.

A. CMS ASSERTION THAT DIAGNOSIS CODES WERE NOT REQUIRED FOR DME SUPPLIER CLAIMS UNTIL IMPLEMENTATION OF HIPAA IN 2003

In response to the Subcommittee's initial conclusions concerning the use of diagnosis codes, CMS argued that ICD-9-CM diagnosis codes were not required for suppliers' DME claims until the implementation of HIPAA in 2003. According to their comments:

Historically, CMS did not generally require DME suppliers to include ICD-9-CM codes with their claims. CMS now requires DME suppliers to include diagnosis codes with their claims, and requires its DME claims processing contractors to check these codes, but this Medicare requirement is a relatively new one that was put in place during 2003 and 2004 for the sole purpose of achieving compliance with new healthcare *industry-wide* electronic claims transaction standards (mandated by the Health Insurance Portability and Accountability Act). Accordingly, depending on the date a DME claim was processed, the claim may, in fact, have been paid without a valid ICD-9 code as defined by the ICD-9-CM Manual and, regardless of the ICD-9 code's validity, it does not necessarily mean that the claim was paid inappropriately or that it was processed incorrectly[.]⁸³

As a threshold matter, over the course of its inquiry, the Subcommittee conducted numerous interviews concerning the requirements surrounding diagnosis codes, including frequent communications with officials from CMS, SADMERC, DME carriers, and DME suppliers. The Subcommittee repeatedly confirmed with those officials that diagnosis codes were required for DME supplier claims and confirmed that the requirement had been in place for many years. In fact, one CMS official stated that the requirement for diagnosis codes for DME claims from suppliers had been in effect "since the Program began."⁸⁴ Other officials stated that they believed that Medicare required diagnosis codes on supplier claims for DME have "always" been required.⁸⁵ In fact, a representative of one large DME supplier stated that Medicare required valid diagnosis codes for their claims since 1993.⁸⁶ These comments and the fact that significant claims data stretching back to 1995 included diagnosis codes further support the Subcommittee's finding that the laws and regulations governing diagnosis codes were unclear prior to 2003 and the use of the codes was inconsistent. Moreover, when the Subcommittee briefed CMS and its contractors on its initial findings in February – a meeting that included numerous officials from CMS and its contractors – not a single representative from CMS or its contractors indicated that diagnosis codes were not required for suppliers' claims until 2003. Roughly one month later, however, CMS submitted its

⁸³ See CMS response, Appendix, at pg. 1.

⁸⁴ Subcommittee interview of CMS officials and contractors, January 10, 2008.

⁸⁵ Subcommittee interview of CMS officials and contractors, December 19, 2007.

⁸⁶ Subcommittee interviews of DME supply company representatives, March 2008.

official response and asserted – for the first time – its position that Medicare rules did not require diagnosis codes for DME claims from suppliers until the implementation of HIPAA in 2003.

Putting aside the fact that CMS’s official written response to the Subcommittee’s report appears to conflict with earlier statements from its officials, contractors, and others, the assertion that diagnosis codes were not required for supplier claims until 2003 is also arguably inconsistent with its own regulations. As described above, the 1991 Notice and the bulletin issued to all providers in 1996 arguably require the use of valid diagnosis codes on all DME claims – including those submitted by suppliers. It would therefore be reasonable to conclude that any payments for claims with invalid or incorrect diagnosis codes after those bulletins were improper.

Regardless of any potential inconsistencies between CMS’s official written response, prior oral statements made by CMS officials, and the governing Medicare regulations, the Subcommittee staff has accepted CMS’s assertion that diagnosis codes were generally not required for DME claims submitted by suppliers until the implementation of HIPAA in 2003. Accordingly, this report does not find that the payments made for the DME supplier claims with invalid diagnosis codes were *per se* improper. To the contrary, the relevant findings in this report are limited: Based on the data obtained from SADMERC, the Subcommittee found payments totaling more than \$4.8 billion for the DME claims submitted by suppliers that contained invalid diagnosis codes; a review of 2,000 sample claims that contained invalid codes indicated that roughly 30 percent of those claims could not be verified as legitimate.

While CMS’s assertion that DME suppliers were first required to submit diagnosis codes in 2003 may impact the analysis related to claims with invalid codes, it has little impact on the analysis of claims with questionable diagnoses. To the contrary, the Subcommittee’s review revealed that claims with questionable diagnosis codes continued long after Medicare required ICD-9-CM diagnosis codes.

Claims for blood glucose test strips once again provide a telling example. In 2001, Medicare paid \$526,059 for claims for blood glucose strips with a diagnosis of chronic airway obstruction; Medicare paid roughly the same amount – \$535,032 – for the same product with the same questionable diagnosis code in 2006. In fact, as noted above, chronic airway obstruction was the single most frequent diagnosis code for blood glucose test strips for each year from 2001 through 2006, and the amount of claims paid over those years fluctuated little from the time before diagnosis codes were required (2001-2003) through the following three years (2004-2006).

Figure 11 below presents the most frequent non-diabetes diagnosis codes for blood glucose test strips and illustrates that the use of these questionable codes did not decrease – and, in some cases, increased substantially – after diagnosis codes were required in 2003. The amount paid for blood glucose test strips for one questionable diagnosis code – urinary incontinence – more than doubled in just a few years following the requirement of valid diagnosis codes on supplier claims (2003-2006). Therefore, the analysis of claims data for these 18 prominent DME items suggests that, even after valid diagnosis codes became a required element of supplier claims in 2003, the claims review process conducted by Medicare carriers did not examine whether the diagnosis codes related to the purchased supplies.

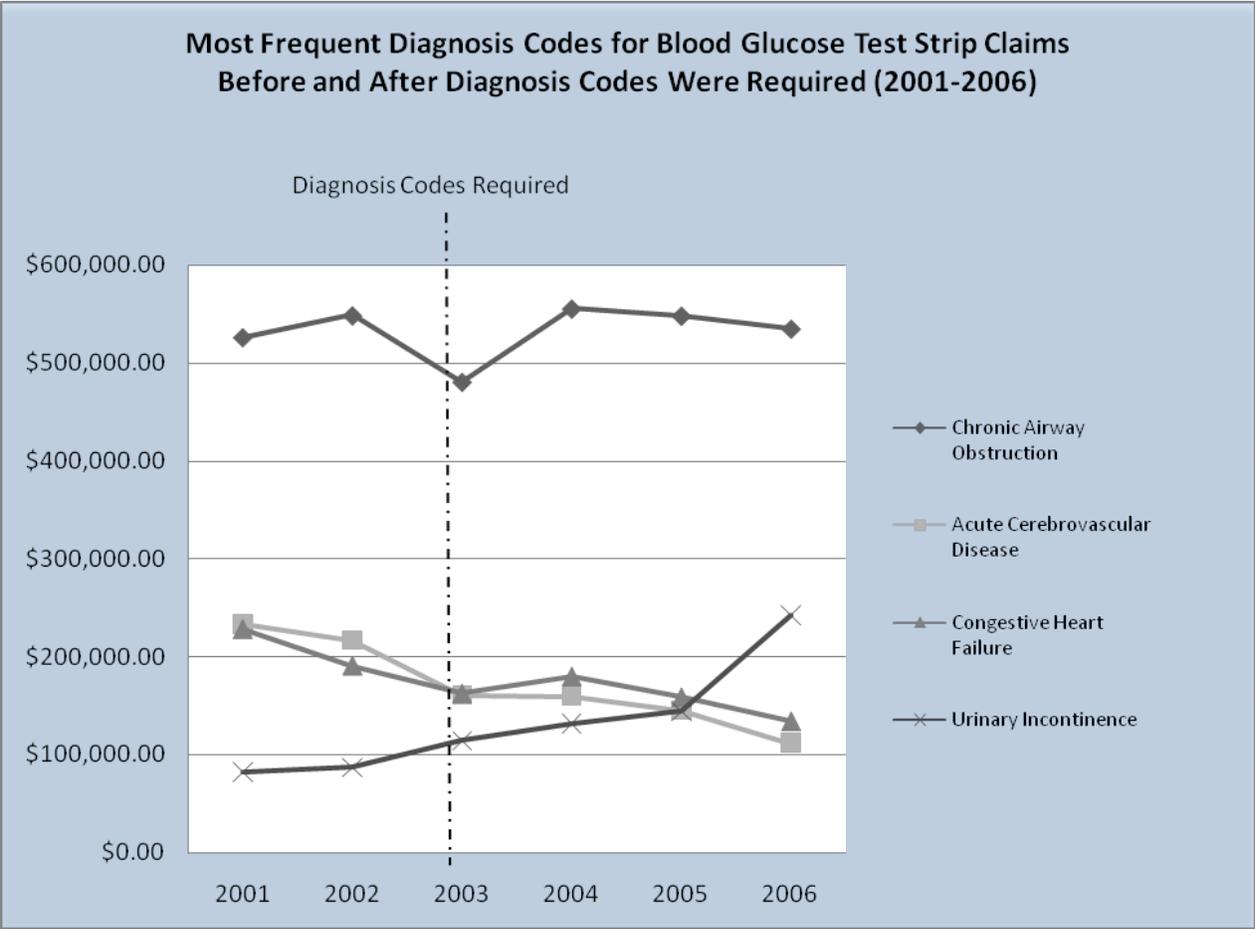


Figure 11

B. “XX000,” A PROMINENT INVALID CODE, WAS CREATED BY CMS

As part of its preliminary findings, the Subcommittee identified 8,206,776 claims amounting to \$720,788,318 in payments from 1995 through 2002 in which the associated diagnosis code read “XX000.” XX000 is not on the ICD-9-CM list of diagnosis codes, and therefore, the Subcommittee initially considered it an invalid code. CMS has asserted that the code XX000 should not be considered invalid because it was a “fictitious” code created by CMS and its contractors to comply with requirements imposed by MCCA.

As noted above, MCCA, enacted in 1988, required that all claims for services or items submitted by physicians contain a valid diagnosis code. In requiring the inclusion of diagnosis codes, the MCCA drew a distinction between two categories of Medicare claims – “assigned” and “unassigned” claims. In general, assigned claims are those in which the physician has accepted the claim on assignment from the beneficiary and agreed with Medicare to accept the Medicare fee schedule. Unassigned claims are those in which the physician has not agreed to accept assignment of the claim or to abide by the Medicare fee schedule. [A detailed description of assigned and unassigned claims is set forth in Figure 12 on this page.]

With respect to assigned claims, the MCCA required that Medicare deny payment to claims that did not contain the proper diagnosis code. For unassigned claims, the MCCA authorized the Secretary to institute civil fines and penalties against physicians who refuse to provide valid diagnosis codes.⁸⁷

Assigned vs. Unassigned Claims

Assigned claims are those in which the physician has entered into an agreement with Medicare to participate in the Medicare program. As part of the agreement, the physician agrees to accept assignment of claims from Medicare beneficiaries and agrees to accept the fee set by Medicare for the service or item provided. The physician cannot require the beneficiary to pay any amount other than the deductible set by the Medicare fee schedule.

Unassigned claims are those in which the physician has not agreed to participate in the Medicare program or accept the fees established by the Medicare fee schedule. Beneficiaries may still choose to receive treatment from a physician on an unassigned basis, but the beneficiary will be responsible for paying for the treatment out-of-pocket and file their own claim with Medicare. In that case, Medicare will reimburse the beneficiary based on the fee schedule, regardless what the beneficiary actually paid the physician.

Figure 12

To comply with the requirements of the MCCA, in April 1989, CMS published a revision to the Medicare Carriers Manual, Part 3, the guidance provided to Medicare DME carriers that instructed them on how to process Medicare claims. The April 1989 revision directed carriers how to process claims under the new diagnosis code requirement for physicians. The new rule also instructed carriers to deny any assigned claim submitted by a physician without a valid ICD-9-CM diagnosis code after June 1, 1989; in doing so, the rule also established a grace period until June 1989 to allow physicians to comply with the new diagnosis code rules before denying the claim.⁸⁸

As part of the grace period, CMS established the use of the fictitious diagnosis code, XX000, which was supposed to be entered into the relevant diagnosis field when the block was improperly left blank.⁸⁹ Importantly, according to the Medicare Carriers Manual revision, this fictitious code was supposed to be used only in connection with assigned claims submitted by physicians during the grace period – i.e., up to June 1, 1989 – but not after that date.⁹⁰ Carriers could, however, continue to use the fictitious code after that grace period, in instances where a physician failed to provide a valid diagnosis code on unassigned claims. According to the Carrier Manual revision, the purpose of the fictitious XX000 code was to identify those physicians that did not comply with the rules by providing the valid diagnosis codes. The revisions stated, “The fictitious code will identify claims adjudicated without an actual ICD-9-CM code from the physician. Unassigned claims submitted without the ICD-9-CM code must be recorded on an individual physician basis. These records will be used to monitor compliance in accordance with §§7600-7604.”

⁸⁷ MCCA did not allow unassigned claims to be denied because it was desirable to reimburse the beneficiary. Once the physician was contacted regarding the failure to provide a valid diagnosis code, however, they were subject to the fines and civil penalties if they did not promptly provide them.

⁸⁸ See Medicare Carriers Manual Part 3 – Claims Process, No. 1298, April 1989.

⁸⁹ See *id.*

⁹⁰ See *id.* at 4-20.1.

Section 7600 referred to that section of the Carriers Manual that directed monitoring the use of diagnosis codes on unassigned claims. Section 7601 (A) required carriers to produce a monthly report of physicians who did not furnish diagnosis codes on bills submitted with unassigned claims. The guidance indicated that, if a physician failed to provide diagnosis codes on more than 10 claims during a single month, the carrier was to contact the physician and explain the law and the physician's requirement to provide the diagnosis code.

It is clear that the fictitious code of XX000 was initially introduced as a temporary measure to comply with the requirements of MCCA. Indeed, it was initially used only for a small subset of DME claims from physicians and was intended to keep track of which physicians were failing to comply with the new diagnosis code requirements. Since physicians who did not provide a valid ICD-9-CM diagnosis code on unassigned claims were subject to fines under the MCCA, the Subcommittee asked CMS for any records of how many fines were levied annually since 1995.⁹¹ CMS advised the Subcommittee that there have been no fines levied as there have been no reports from the carriers that physicians are refusing to provide diagnosis codes.⁹²

At some point, the fictitious XX000 code was introduced for claims coming from DME suppliers as well as physicians. The data received by the Subcommittee from SADMERC indicates the XX000 code has been used on supplier claims since at least 1995, the first year of data reviewed. Because this code was designed to be used to monitor physician compliance with the requirement to provide diagnosis codes, any use of the code by non-physicians or on non-physician related claims, such as claims from DME suppliers, would appear to hamper any efforts to identify physicians who were not providing diagnosis codes. Because this code was used on more than eight million claims submitted by DME suppliers, it is impossible to determine which of these claims did not contain a diagnosis code because the physician neglected to provide one to the supplier. Therefore, the use of XX000 for claims submitted by DME suppliers would appear to undermine the central purpose behind the creation of the XX000 code.

Nevertheless, the Subcommittee staff has accepted CMS's assertion with respect to the XX000 code. Accordingly, the claims that contain that code – which amount to more than eight million claims totaling more than \$720 million in payments – were not included in the Subcommittee's analysis of claims with invalid diagnosis codes. Further, the Subcommittee staff noted that the volume of claims using the code XX000 diagnosis code decreased dramatically following the implementation of HIPAA requirements in 2003. Consequently, that code does not represent a significant vulnerability for fraud, waste, and abuse going forward.

C. “MEDICAL NECESSITY” IS DETERMINED THROUGH OTHER RECORDS, NOT DIAGNOSIS CODES

As noted in Section III.A.3 above, the Social Security Act and Medicare regulations require that Medicare cannot pay for any DME claim unless the item is medically necessary. CMS officials stated that the claims review process does not normally examine a claim's diagnosis code to determine whether the DME item is medically necessary, instead it relies on suppliers to furnish a CMN signed by the physician or other records to document medical necessity and on the pre- and post-payment review processes.

There are several weaknesses with this practice. CMNs are not required for all DME items. CMNs are only required for select DME items, such as oxygen or infusion pumps. Further, CMNs are not

⁹¹ Subcommittee interview of CMS officials, April 10, 2008.

⁹² Subcommittee interview of CMS officials, April 14, 2008.

routinely submitted with the Medicare claims. Instead, suppliers are required to maintain CMNs in their files and provide them during pre- and post-payment reviews. Therefore, Medicare claims are paid under the assumption that the item or items claimed are medically necessary and that the suppliers have the CMNs or other necessary supporting documentation to prove it.

According to CMS officials, medical necessity is reviewed during the pre- and post-payment review process, and that approximately three percent of paid claims are reviewed.⁹³ Because CMS processes billions of Medicare claims annually, this means that only a fraction of claims are reviewed for medical necessity and in some instances, only after payment has been made. As previously mentioned, past HHS/OIG reports have illustrated that providers have failed to establish the medical necessity requirement. Further, the limited number of post-payment reviews performed would be ineffective for identifying those suppliers that establish fraudulent companies.

Preventing claims from being paid in the first place would be more efficient and effective than attempting to recover improperly paid amounts after the fact. While checking that the diagnosis code correlates with the DME item claimed does not prove medical necessity, some diagnosis code and DME item combinations discovered by the Subcommittee raise the questions as to the medical necessity of the items.

VI. CONCLUSION AND RECOMMENDATIONS

Considering the fact that diagnosis codes are required to be submitted on claims, they should be used in a meaningful manner. Based on the Subcommittee's analysis, billions of DME claims have been paid where the purported diagnosis is questionable and does not appear related to the purchased equipment. CMS's failure to effectively utilize diagnosis codes have resulted in questionable payments and may have left billions of taxpayer's money susceptible to fraud, waste, and abuse. The Subcommittee believes that ensuring that diagnosis codes included on claims are both valid and consistent with the DME item supplied could be a more effective utilization of the codes by reducing costs for claims processing and review, helping ensure the medical necessity of the claim, and preventing and identifying fraud, waste, and abuse. CMS should do more to more to ensure integrity in the Medicare program. Strengthening internal controls on the front-end is more beneficial than attempting to recover improperly paid amounts after the fact. It is for these reasons that the Subcommittee minority staff makes the following recommendations:

- 1. Strengthen Claims Review Process.** CMS should consider strengthening the claims review process by more effectively utilizing all diagnosis codes submitted on claims. All diagnosis codes entered onto a claim should be valid and medically relate to the supplied DME items. Claims with any invalid or incorrect codes should be rejected and returned to the biller for correction.
- 2. Consider Developing Procedures to Link Diagnosis Codes with Medical Procedures.** CMS should consider developing processes that use the diagnosis codes to prevent, detect, and reject improper payments. This could include creating procedures to link ICD-9-CM diagnosis codes included on DME claims with authorized medical procedures (HCPCS), similar to what is already being performed by some contractors on select DME items.

⁹³ According to CMS officials, this percent includes claims for both Part A (hospital insurance) and Part B. CMS officials stated that it spent \$160 million in fiscal year 2007 to conduct pre- and post-payments reviews.

3. **Consider Developing Procedures to Link Claims for DME Items with a Corresponding Claim for Medical Treatment.** CMS should consider incorporating an edit into the claims processing system that would check a claim for a DME item against a claim for a doctor visit that would have resulted in an order or prescription for the item, similar to what is already being performed on DME claims for select items. Furthermore, for DME claims that do not have a corresponding medical treatment claims, CMS should consider performing additional procedures in order to ensure the medical necessity and integrity of the claims.
4. **Strengthen Contractor Oversight.** CMS should consider strengthening its contractor oversight, including contractor penalties for making improper payments or maintaining unreliable data.



APPENDIX

Comments and Documents
Submitted to the
Permanent Subcommittee on Investigations
by CMS

**Senate Homeland Security and Governmental Affairs Committee (HSGAC) Permanent
Subcommittee on Investigations (PSI)
Preliminary Conclusions Surrounding DME Payments for Invalid Diagnosis Codes:
CMS Response – March 7, 2008**

On February 12, 2008, in a meeting between staff from the Centers for Medicare & Medicaid Services (CMS) and PSI staff investigators, PSI staff surfaced serious concerns about potential findings of incorrect claims payments as a result of an extensive review of reports shared by the Statistical Analysis Durable Medical Equipment Carrier (SADMERC), which focused on the validity of ICD-9 or diagnosis codes on durable medical equipment (DME) claims. PSI staff provided examples from the SADMERC reports which identified several thousand claims that had apparently been paid since 2001, but contained a description indicator noting that the diagnosis code was invalid. Flowing from these examples, PSI staff asked CMS to explain how a DME claim with an invalid diagnosis code could be paid, and what safeguards were in place to ensure that only claims with valid diagnosis codes are accepted to process.

Since the meeting, CMS has reviewed the SADMERC reports and claim reference examples provided by the Subcommittee on February 12 and subsequently on February 19. CMS also reviewed the diagnosis codes in the report, selected a sample of the claims listed for review by the current DME MACs, and consulted with SADMERC staff on their report to the PSI staff. Based on our review and analysis, we have come to the following conclusions:

- Historically, CMS did not generally require DME suppliers to include ICD-9-CM codes with their claims. CMS now requires DME suppliers to include diagnosis codes with their claims, and requires its DME claims processing contractors to check these codes, but this Medicare requirement is a relatively new one that was put in place during 2003 and 2004 for the sole purpose of achieving compliance with new healthcare *industry-wide* electronic claims transaction standards (mandated by the Health Insurance Portability and Accountability Act). Accordingly, depending on the date a DME claim was processed, the claim may, in fact, have been paid without a valid ICD-9 code as defined by the ICD-9-CM Manual and, regardless of the ICD-9 code's validity, it does not necessarily mean that the claim was paid inappropriately or that it was processed incorrectly;
- Based on a claim file review of a sample of the claim lines provided by the PSI staff, it appears that most of the claims listed on the SADMERC reports were processed appropriately; and
- The diagnosis description field in the SADMERC reports provided to the PSI staff is not accurate or reliable; therefore, it should not be used to conclude whether a claim was paid with an invalid diagnosis code.

The basis for these conclusions stems from several different findings, including the DME claim processing controls that have evolved over time since 2003, a review of sample claim lines presented on the SADMERC reports, the validity of the ICD-9 code descriptors presented in the SADMERC reports, and the descriptions from SADMERC staff about the contents of the data they provided the PSI staff. We outline our supporting rationale for each finding below.

I. Evolution of the DME Claims Process and Editing for ICD-9-CM Codes

Historically, CMS did not generally require DME suppliers to include ICD-9-CM codes with their claims. Instead, DME suppliers were and continue to be required to maintain a doctor's order in their files for each and every billing. Moreover, for some DME items, suppliers are expected to furnish Medicare a certificate of medical necessity signed by the physician to document medical necessity. CMS does now require DME suppliers to include diagnosis codes with their claims, and CMS requires its DME claims processing contractors to check these codes. However, this Medicare requirement is a relatively new one that was put in place during 2003 and 2004 for the sole purpose of achieving compliance with new healthcare *industry-wide* electronic claims transaction standards (mandated by the Health Insurance Portability and Accountability Act (HIPAA)). For more information on this issue, please see Addendum A.

More specifically, prior to HIPAA requirements that were implemented beginning in May 2003, DME claims were not edited in the core DME claim processing system or at the front end of the automated adjudication process to determine whether a claim contained a valid ICD-9-CM Manual code. In other words, the DME claim processing system did not check a claim's primary diagnosis code upon submission to determine whether the code was recognized and in the appropriate format as defined by the ICD-9-CM Manual. This effectively means that for claims adjudicated prior to the implementation of the HIPAA-mandated claims processing edits, one may very well find paid DME claims with invalid or illegitimate ICD-9 codes. For claims that processed after the installation of edits required by HIPAA began, the DME core claim system and front end started to check a claim's primary diagnosis code against the current ICD-9-CM Manual list, which is updated October 1 of every year. This means that at present—assuming all other minimum claim information is valid—a claim with a valid primary diagnosis code will pass into the claim processing system. Conversely, if a claim contains an invalid primary diagnosis code, the claim is rejected and returned to the submitting supplier as opposed to being processed and denied.

It is important to note that when a paid DME claim with an invalid ICD-9 code is identified, it would be incorrect to conclude that the claim was processed inappropriately or paid incorrectly. A DME claim's ICD-9 code is not always used to assess whether a particular service or supply meets medical necessity or coverage criteria. In some cases, some DMEPOS supplies are covered by Medicare only if they meet the parameters outlined by Local Coverage Determination (LCDs) policies and coverage guidelines promulgated by the DME MAC Medical Directors. To implement these coverage policies, edits are placed in the DME claim processing system that check a particular HCPCS code (i.e., procedure code) or range of HCPCS codes against a specific list of covered ICD-9-CM Manual codes identified in the LCD policy. Claims for supplies such as blood glucose monitors, ankle and foot orthoses, refractive lenses, and oral anti-cancer drugs, for example, are governed by specific LCD policies; therefore, their diagnosis codes do edit against a defined list of ICD-9 codes as the claim is processed to pay or deny.

In many other instances, however, a claim's ICD-9 code is not used to determine whether a claim should process for payment. Rather, the claim is paid based upon whether an appropriate certificate of medical necessity (CMN) has been submitted or is on-file for the particular claim in question, or whether an appropriate modifier code has been submitted on the claim to denote

compliance with required documentation criteria (claims for power wheel-chairs and oxygen are common examples of supplies that fall under this umbrella). Practically speaking, this means that before HIPAA implementation changes began in May 2003, it would not be uncommon to find DME claims that processed and paid with an invalid or illegitimate diagnosis code, but which were nevertheless processed and paid appropriately. The diagnosis code, whether valid or not, had no bearing on whether the claim was processed appropriately or paid. Following the implementation of HIPAA implementation edits, we would expect claims history to contain only valid primary ICD-9-CM Manual codes on processed claims, but whether the code was used to determine payment would still depend upon the type of supply or service on the claim (i.e., whether the supply or service on the claim required compliance with an LCD versus a CMN or other claim modifier to process).

For precision, we would note that installation of claim submission and system changes to implement HIPAA began in May 2003 and were phased in over time. Claim submission requirements and some system edits on primary diagnosis codes for electronic claims to determine their validity began to be installed in May 2003. Other system changes to edit on electronic and paper claims were installed progressively in October 2003 and into July 2004, while additional system edits on secondary and tertiary diagnosis codes on paper claims are not scheduled to be completed until July 2008. The phased installation of HIPAA edits on different claim types and different levels of diagnosis codes on a claim means that while we would expect the number of DME claims submitted with truly invalid diagnosis codes to greatly diminish after May 2003, some paper claim lines that were relying upon secondary or tertiary diagnosis codes listed on a claim still are not edited for validity; as a result, a few DME claim lines with truly invalid ICD-9-CM Manual codes can still enter the claim processing system rather than reject.

II. ICD-9 Code Review

CMS reviewed the claim examples provided by the PSI staff during our February 12 meeting. Apart from some entries that were obviously not valid (i.e., NULL and XX000), we identified 53 distinct and separate ICD-9 diagnosis codes listed on the claims. While the diagnosis code descriptor on the SADMERC reports indicated that all these codes were invalid, our review against the ICD-9-CM Manual compiled by the National Center for Health Statistics and CMS, which contains all coding changes issued through October 1, 2007, indicates that all but three—**3515, 7155, and 7156**—are truly valid ICD-9 codes (see table below). In other words, only three codes are not and have not been listed as legitimate, defined codes in the ICD-9-CM Manual. Two additional codes identified as invalid may simply reflect an input error as similar, valid codes do exist.

ICD-9 Code Number	Code Description	Effective date of code
3515	Not a valid code	
4940	Bronchiecstasis without acute exacerbation	10/01/2000
4941	Bronchiecstasis with acute exacerbation	10/01/2000
4969	Invalid code (but 496 is Chronic Obstructive Pulmonary Disease, NEC)	
5859	Chronic kidney disease, unspecified	10/01/2005
7155	Not a valid code	
7156	Not a valid code	

7837	Adult failure to thrive	10/01/2000
27702	Cystic fibrosus with pulmonary manifestation	10/01/2002
29410	Dementia in conditions classified elsewhere w/o behavioral disturbance	10/01/2000
32721	Primary central sleep apnea	10/01/2005
32723	Obstructive sleep apnea	10/01/2005
34831	Metabolic encephalopathy	10/01/2003
35800	Myasthenia gravis without (acute) exacerbation	10/01/2003
42820	Systolic heart failure, unspecified	10/01/2002
43884	Late effect of cerebrovascular disease, Ataxia	10/01/2002
45912	Postphlebitic syndrome with inflammation	10/01/2002
45930	Chronic venous hypertension w/o complications	10/01/2002
45933	Chronic venous hypertension w ulcer and inflammation	10/01/2002
49392	Asthma w/ (acute) exacerbation	10/01/2002
51883	Chronic respiratory failure	10/01/1998
51884	Acute and chronic respiratory failure	10/01/1998
56962	Mechanical complication of colostomy and enterostomy	10/01/1998
70700	Decubitus ulcer, unspecified site	10/01/2004
70701	Decubitus ulcer, elbow	10/01/2004
70702	Decubitus ulcer, upper back	10/01/2004
70703	Decubitus ulcer, lower back	10/01/2004
70705	Decubitus ulcer, buttock	10/01/2004
70707	Decubitus ulcer, heel	10/01/2004
70709	Decubitus ulcer, other site	10/01/2004
70710	Ulcer of lower limbs, except decubitus, ulcer of lower limb, unspecified	10/01/2000
70713	Ulcer of lower limbs, except decubitus, ulcer of ankle	10/01/2000
70715	Ulcer of lower limbs, except decubitus, ulcer of other part of foot	10/01/2000
71502	Osteoarthritis, generalized, upper arm	Not Available
71506	Osteoarthritis, generalized, lower leg	Not Available
71507	Osteoarthritis, generalized, ankle and foot	Not Available
71508	Osteoarthritis, generalized, other specified sites	Not Available
71599	Osteoarthrosis, unspecified whether generalized or localized, mult. sites	Not Available
72100	Invalid code (but 7210 is Cervical spondylosis without myelopathy)	Not Available
72887	Muscle weakness (generalized)	10/01/2003
72888	Rhabdomyolysis	10/01/2003
78079	Other malaise and fatigue	10/01/1998
78099	Other general symptoms	10/01/2002
78192	Abnormal posture	10/01/2000
78340	Lack of normal physiological development, unspecified	10/01/2000
78603	Apnea	10/01/1998
78604	Cheyne-Stokes respiration	10/01/1998
78605	Shortness of breath	10/01/1998
79901	Asphyxia	10/01/2005
79902	Hypoxemia	10/01/2005
E8880	Fall resulting in striking against sharp object	10/01/2001
E8889	Unspecified fall	10/01/2001
V5873	Aftercare following surgery of the circulatory system, NEC	10/01/2002

The apparent disconnect between the SADMERC ICD-9 code description and the current ICD-9-CM Manual indicates to us that the SADMERC description field is not reliable. We will discuss this further in section V of this summary.

III. Sample Claim Review

From the claim examples provided by the PSI staff on February 19 that contained HICNs (Health Insurance Claim Numbers) as well as CCNs (Claim Control Numbers), CMS selected a random sample of 11 claims with dates of service (DOS) ranging from January 2001 to November 2006 that were processed by the Region C DME carrier or DMERC. We then provided the CCN and HICN to the current Jurisdiction C DME MAC, Cigna Government Services (CGS), requesting that they obtain a copy of the original claim to determine whether the claim submitted contained a valid diagnosis code and whether the claim was processed correctly.

The DME MAC advised that they could retrieve eight of the 11 claims we provided them from their available on-line history. Of these, all eight contained valid ICD-9 codes at the time they were processed. Seven of the eight claims were processed and paid appropriately as they contained the appropriate supporting Certificate of Medical Necessity (CMN) information or claim modifiers. The remaining claim available on-line was denied because the amount of supplies being claimed was not supported by the claim information. (See table below for specific claim samples reviewed).

CLAIM CCN	HCPCS CODE	HCPCS DESC	DX CODE	SADMERC Report DX DESC	DX DESC Per CGS & CMS Review	Date of Service	Paid Amount	Found on Purged History Report?	CMN or Modifier Needed to Pay Regardless of ICD-9 Code?
01019833146000	L1845	Ko w/ adj flex/ext rotat cus	71506	INVALID DIAG CODE	Valid DX	05-Jan-01	\$578.52	No	Yes
06264854453000	E0562	Humidifier heated used w PAP	78603	INVALID DIAG CODE	Valid DX	20-Jul-06	\$0.00	Available Online	Yes
06241925709000	J7639	Dornase alpha inhal sol u d	27702	INVALID DIAG CODE	Valid DX	14-Aug-06	\$1,125.42	Available Online	Yes
02157150873000	K0014	Other power whlchr base	3515	INVALID DIAG CODE	Invalid DX	30-Oct-01	\$0.00	No	Yes
05075765369000	E0180	Press pad alternating w pump	70710	INVALID DIAG CODE	Valid DX	22-Jan-05	\$15.91	Available Online	Yes
06195789521000	E0143	Walker folding wheeled w/o s	29410	INVALID DIAG CODE	Valid DX	11-Jun-05	\$81.38	Available Online	Yes
06053746209000	E0431	Portable gaseous O2	79902	INVALID DIAG CODE	Valid DX	20-Feb-06	\$25.66	Available Online	Yes
06171705235000	E0439	Stationary liquid O2	79901	INVALID DIAG CODE	Valid DX	16-Jun-06	\$160.31	Available Online	Yes

CLAIM CCN	HCPCS CODE	HCPCS DESC	DX CODE	SADMERC Report DX DESC	DX DESC Per CGS & CMS Review	Date of Service	Paid Amount	Found on Purged History Report?	CMN or Modifier Needed to Pay Regardless of ICD-9 Code?
05089844582000	E0431	Portable gaseous 02	51883	INVALID DIAG CODE	Valid DX	25-Mar-05	\$28.78	Available Online	Yes
06310829635000	E0431	Portable gaseous 02	51883	INVALID DIAG CODE	Valid DX	02-Nov-06	\$25.66	Available Online	Yes
02325150030000	E1031	Rollabout chair with casters	7156	INVALID DIAG CODE	Invalid DX	04-Oct-02	\$0.00	No	Yes

The three claims out of the 11 sampled that the current DME MAC was unable to view from their on-line history were the oldest claims in the sample dating back to 2001 and 2002, respectively. Purged history reports were ordered for these claims, but either no report was available or the report that returned did not contain a CCN, date of service (DOS), and procedure code that corresponded to the information listed on the SADMERC report provided by the PSI staff. The DME MAC did note that based on the SADMERC report, two of these three claims contained truly invalid ICD-9 codes (**7156 and 3515**) and were denied. The exact reason for denial is unknown, however, and we continue to work to determine whether these claims are retrievable and if they were processed correctly.

In addition to reviewing a general sample of claims, CMS also provided the current DME MAC with the CCN and HICN information for the claims on the February 19 report provided by the PSI staff that contained what we believe to be truly invalid diagnosis codes: **3515, 7155, 7156, NULL and XX000**. All tallied, this amounted to 51 different claims with multiple claim lines on many of the claims with process dates in 2001, 2002, and 2003 respectively, with just two claims having processed after August 2003. As of this writing, the DME MAC was unable to obtain purged history reports that identify the bulk of these claims, but we continue work to determine if all the claims—including those with XX000 and NULL in the diagnosis field—are retrievable and if they were processed correctly.

IV. Report Values

Given the importance placed on code validity throughout the Medicare claims adjudication process, CMS investigated how and why NULL and XX000 appear as diagnosis codes in the SADMERC reports. Typically, values in data fields are read and loaded as received on the claims records from the Common Working File (CWF). There are exceptions, however, that require manual editing to facilitate data load:

- If special reserved characters in the database or other programs would cause the data to not load correctly, those fields are changed to blank spaces. The following field values are replaced with blanks:

- Pipe sign (|)
 - Tilde (~)
 - Carriage return
 - End of file marker
- Any HCPCS or diagnosis field that is empty (does not contain a value) is replaced with a token value of NULL. In this instance, NULL was a value plugged into the field by the SADMERC as it loaded processed claim data from the CWF.

With respect to XX000 appearing in a diagnosis field, prior to the implementation of HIPAA edits discussed earlier, DME claims processing contractors inserted XX000 into the diagnosis field on claims that contained no diagnosis. This was necessary in order to allow the claim to enter the CWF record, which was designed to look for alpha-numeric values in the diagnosis field before allowing a claim to enter and complete processing. Since prior to HIPAA editing DME claims did not require an ICD-9 code in order to enter the claim adjudication process, the XX000 was simply used as a filler code to allow a claim entry into the CWF, but it had no bearing on whether the claim processed correctly. Contractors were instructed to cease using filler codes in this manner as part of the HIPAA implementation instructions implemented October 1, 2003. We would note that of the claim lines we reviewed that contain an XX000 in the diagnosis field, all appear to have been processed prior to October 1, 2003.

V. SADMERC Reports

Following our meeting with the PSI staff on February 12, CMS approached its contractor, the SADMERC, to discuss the reports it had provided to the PSI staff, with a focus upon the ICD-9 description field contained in the reports. In response, the SADMERC advised CMS that they had provided the requested files to the PSI staff at their request, with the clear indication both orally and via e-mail that the source table used to determine whether a diagnosis code was valid was not regularly updated, and was believed to have last been updated in August 2003. Since this initial response, the SADMERC has now informed us that they cannot confirm the last time the file was actually updated, nor can it document the source of the ICD-9 table that it conveyed to the PSI staff. After independently reviewing the ICD-9 codes and sample claims from the SADMERC reports against actual claims history, CMS is not at all confident that the field in the SADMERC reports describing the validity of a particular ICD-9 code can be relied upon conclusively for any period of time.

CMS sincerely regrets the confusion that the SADMERC's descriptor field has generated in this instance. It is not unusual for the SADMERC to use certain files it obtains from other CMS sources or CMS contractors to fulfill requests for ad-hoc reports or for various research articles. For example, such information may include provider files from the National Supplier Clearinghouse which contain provider names and addresses, or a list of eligible Medicare beneficiaries provided by CMS. CMS has learned that in its desire to be responsive and comprehensive in the ad-hoc analysis reports and information it provides, the SADMERC has occasionally utilized information files from external sources (i.e., outside CMS or CMS contractors) to complete some specific ad-hoc reports. Prior to this event, CMS was neither aware of nor condoned the use of information from external sources.

VI. CMS Corrective Action

As a result of our analysis and findings, we have directed the SADMERC to immediately cease the practice of using externally sourced data files. The SADMERC has been directed to provide a list of any outside sources it utilizes in completing ad-hoc requests and is required to seek approval from CMS prior to utilizing data from outside sources. The SADMERC and their parent company's senior management at Palmetto Government Benefits Administrators (PGBA) have been made acutely aware of the significant ramifications of using outdated data and the serious nature of the conclusions by the PSI staff in this instance. CMS has received a complete and detailed report of the SADMERC's actions related to its use of the outdated diagnosis code/description file. The following is a summary report from the SADMERC on the subject:

"The SADMERC receives its claims data from CWF on a nightly basis. There is not an indicator on the claim itself regarding the validity of the diagnosis code. Apparently, Mr. Stoddard identified what he assumed were claims paid without a diagnosis code and/or with an invalid diagnosis code. He then requested the SADMERC to run a report identifying all claims paid from January 1, 1995 to January 31, 2008 with either an invalid diagnosis code or those claims that did not have a diagnosis code.

In order to obtain this information, the SADMERC ran all claims paid for the time period against its diagnosis code file, which is only current as of August 2003. Claims containing diagnosis codes that were either not on the August 2003 diagnosis code file or where the diagnosis code descriptions had changed were identified. A report of those claims was then developed for Mr. Stoddard. The report identified those claims as either "invalid diagnosis code" or "missing diagnosis code," which indicates that the diagnosis code was either NOT on the August 2003 file or the diagnosis code did not match the August 2003 description for that code. In its cover letter to Mr. Stoddard, the SADMERC statistician advised Mr. Stoddard "Note that since the SADMERC has diagnosis code descriptions current as of August 2003, it is possible that diagnosis codes contained in your data may be currently valid." The "your data" refers to the report developed by the SADMERC. The intent of this note was to make Mr. Stoddard aware that the report is basically not reliable since it may contain claims data where the diagnosis code is now valid or where the diagnosis code did not appear on the August 2003 diagnosis description file (obviously outdated). Further, the statistician clearly explained to Mr. Stoddard by phone and the cover letter that the diagnosis description file is outdated and the SADMERC does not maintain a current diagnosis description file."

Despite our critical view of the SADMERC's use of unauthorized external data sources in this incident, we would like to point out that producing ad-hoc reports of the kind at issue in this instance represents a very small portion of the SADMERC's role in supporting payment integrity. Since 1992, the SADMERC's operations have supported the DME Medicare Administrative Carriers (MACs) and their predecessors, DME Program Safeguard Contractors (PSCs), CMS, federal law enforcement agencies, and the National Supplier Clearinghouse (NSC) by performing the following critical functions:

- HCPCS Coding Process for DMEPOS
- Provide Medicare Coding Advice and Guidance
- Establish and Distribute Pricing Files for Certain Drugs and DMEPOS
- Statistical Analysis and Reporting

We have no reason to believe that the SADMERC has erred in fulfilling any of these primary roles as a result of this incident. The SADMERC's data is used by many to develop policies, facilitate program integrity activities, and to support special initiatives. Further, federal and state law enforcement agencies, including the Department of Justice and the Office of the Inspector General, have utilized the SADMERC's data and reports in both civil and criminal cases, without question. The SADMERC is recognized both within CMS and by the DME industry as an expert in its analytical and medical coding capabilities. CMS has confidence in the data produced by the SADMERC and its staff, and we have no reason to believe the SADMERC has compromised any of its day to day operations or work products.

VII. Conclusion

CMS thanks the HSGAC PSI staff for their interest in the Medicare program and maintaining its integrity. Further, we appreciate the opportunity to provide this feedback on the Subcommittee's preliminary findings. As discussed in this report, based on our review and analysis, we have come to the following conclusions:

- Historically, CMS did not generally require DME suppliers to include ICD-9-CM codes with their claims. CMS now requires DME suppliers to include diagnosis codes with their claims, and requires its DME claims processing contractors to check these codes, but this Medicare requirement is a relatively new one that was put in place during 2003 and 2004 for the sole purpose of achieving compliance with new healthcare *industry-wide* electronic claims transaction standards (mandated by the Health Insurance Portability and Accountability Act). Accordingly, depending on the date a DME claim was processed, the claim may, in fact, have been paid without a valid ICD-9 code as defined by the ICD-9-CM Manual and, regardless of the ICD-9 code's validity, it does not necessarily mean that the claim was paid inappropriately or that it was processed incorrectly;
- Based on a claim file review of a sample of the claim lines provided by the PSI staff, it appears that most of the claims listed on the SADMERC reports were processed appropriately; and
- The diagnosis description field in the SADMERC reports provided to the PSI staff is not accurate or reliable; therefore, it should not be used to conclude whether a claim was paid with an invalid diagnosis code.

Regardless of the ultimate conclusions drawn from the SADMERC data reports under scrutiny, CMS welcomes the external interest of the Subcommittee as a means to ensure that our programs operate as efficiently as possible and with the highest level of integrity.

ADDENDUM A

Issue: Are DME suppliers required to include ICD-9-CM diagnosis codes on electronic and paper claims? If so, when did CMS promulgate this requirement to its claims processors and to DME suppliers? For what purpose did CMS promulgate the requirement?

CMS Response

Historically, CMS did not generally require DME suppliers to include ICD-9-CM codes with their claims. Instead, DME suppliers were and continue to be required to maintain a doctor's order in their files for each and every billing. Moreover, for some DME items, suppliers are expected to furnish Medicare a certificate of medical necessity signed by the physician to document medical necessity.

There are several reasons why Medicare did not require DME suppliers to submit diagnosis data with their claims. First, DME suppliers do not hold clinical licenses, are not qualified to exercise clinical judgment, and sometimes have problems obtaining clinical information from the patient's physician. In addition, a physician might order the same kind of DME – e.g., a wheelchair – for many different kinds of underlying conditions, and (in these cases) it is not effective or cost-effective to try and match the diagnosis to the DME item within the claims process. Moreover, the patient's diagnosis does not affect Medicare's payment calculation for DME. For all of these reasons, Medicare did not and does not generally need these codes on DME claims to meet its own internal coverage and payment policy needs.

CMS now requires DME suppliers to include diagnosis codes with their claims, and requires its DME claims processing contractors to check these codes, but this Medicare requirement is a relatively new one that was put in place during 2003 and 2004. More specifically, for the sole purpose of achieving compliance with new healthcare *industry-wide* electronic claims transaction standards (mandated by HIPAA), CMS *did* begin to require DME suppliers to include diagnosis codes on their claims in recent years. In May 2003, CMS directed DME suppliers to begin including these codes on their electronic claims. In October 2003, this mandate was extended to DME claims billed on paper. However, due to the newness of this activity, CMS did not effectuate rigorous computer systems logic to enforce "valid" ICD-9-CM codes on DME claims until June 2004.

CMS promulgated these mandates in keeping with its understanding of the HIPAA requirements. The "implementation guide" governing HIPAA-compliant electronic health transactions seems to require that at least one current ICD-9-CM code be entered on all electronic health claims, and that all codes that are included be compliant with the current codebook.

It is important to note, however, that the HIPAA "implementation guide" does not require that a health payer actually use any particular required data element, including diagnosis codes, in its internal claims processes after it receives the claim. Moreover, the guide does not require that a payer analyze, for instance, whether a specific diagnosis code is medically consistent with a specific procedure code – this decision is left to the payer. So, the fact that a particular ICD-9-CM code is deemed "valid" for HIPAA compliance purposes does not imply that the code is the

best code, or the only code, that could be used to describe the patient's condition. HIPAA compliance does not automatically confer medical accuracy, and is not equivalent to clinical judgment.

The new computer processes put in place by CMS during 2003 and 2004 only check the ICD-9-CM codes on the claim for HIPAA compliance. The DME claims processing contractors review the medical necessity of DME items, as well as complete their other claims processing tasks, through other processes within their overall claims operation. This includes the review of certificates of medical necessity for some DME. Certificates of medical necessity do include patient diagnosis codes, but – by Medicare law – only the physician is allowed to enter this data on the certificates.

For a few specific DME items, CMS's DME claims processing contractors have developed specific medical policies to adjudicate these kinds of claims. Some of these medical policies do require the presence of specific diagnosis codes on the claim or certificate of medical necessity. In these cases, the DME claims processing contractors have checked and continue to check that the required diagnosis code(s) is/are reported.

It may seem odd, at first blush, that CMS extended the HIPAA requirement to paper claims, which are not governed by the HIPAA electronic claims implementation guide. However, Medicare does transfer many claims to other payers – for secondary payment – in electronic format after Medicare has finished processing the claim. The HIPAA-compliant electronic “coordination of benefits” transaction also requires the presence of at least one “valid” diagnosis code. Since, in effect, Medicare's claims process converts a paper claim into electronic format for transfer to such other payers, CMS ultimately determined that Medicare needed to require that even paper claims have a HIPAA-complaint diagnosis code on them.

A listing of the medical policies that require specific diagnosis/diagnoses codes is enclosed. Also enclosed are copies of the 2003 CMS transmittals that required implementation of ICD-9-CM coding for (1) electronic and (2) paper DME claims. The CMS transmittal explaining the mid 2004 upgrades to Medicare's computer systems to better validate the HIPAA compliance of ICD-9-CM codes billed on DME claims is also enclosed.

ENCLOSURES

- (1) Chronology relating to diagnosis codes, HIPAA, and DME claims.
- (2) List of DME claims processing contractor medical policies, with policies requiring specific diagnosis/diagnoses codes annotated.
- (3) **CMS Transmittal B-03-028** (Issued April 18, 2003, for May 1, 2003 implementation). Requires DME suppliers to include a valid ICD-9-CM code on electronic claims. Note the DME supplier is given various options, including exercising its own judgment relative to the codebook, in determining the appropriate code in the event that the DME supplier cannot get this information from the physician.
- (4) **CMS Transmittal B-03-045** (Issued June 6, 2003, for October 1, 2003 implementation). Implements the same ICD-9-CM coding requirement for most billers of Part B claims for electronic claims and for paper claims.
- (5) **CMS Change Request 2956** (Issued December 19, 2003, for January 20, 2004, implementation). Further implements item #3 above.
- (6) **CMS Change Request 3050** (Issued February 6, 2004, for July 6, 2004, implementation). Directs the maintainer of CMS's computer systems for processing DME claims to implement more rigorous computer logic to block claims with diagnoses codes that are not compliant with ICD-9-CM from processing.
- (7) **CMS Change Request 3303** (Issued June 18, 2004, for October 4, 2004, implementation). Directs Medicare contractors to no longer allow providers and suppliers to implement ICD-9-CM coding updates as they occur.

CHRONOLOGY DIAGNOSIS CODES, HIPAA, and DME CLAIMS

- 1979** Hospitals and other institutional providers are required to report ICD-9-CM codes on the CMS-1450 claims form. These codes are not yet required on Medicare Part B claims (including DME claims).
- 04/1989** Use of ICD-9-CM codes becomes mandatory for physicians' services - but not DME claims - submitted on the CMS-1500 claims form. (42 CFR 424.32).
- 08/1996** The Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Public Law 104-91) is enacted. Subtitle F of HIPAA requires the HHS Secretary to establish a number of standards for electronic data interchange in the healthcare sector, including standards for electronic health claims transactions and medical code sets.
- 08/2000** HHS announces that ICD-9-CM codes will serve as the mandatory code set for reporting patient diagnosis data within electronic health care transactions. Standards for electronic health claims transactions (ANSI X12 837) are also established. (45 CFR 162). The effective date of the regulation is October 16, 2000, with an *initial* 2-year compliance deadline (payers and providers would face penalties if they did not comply by October 16, 2002).
- 01/2001** The Administrative Simplification Compliance Act (ASCA) gives health payers and health care providers one additional year to comply with the HIPAA-mandated electronic claims transaction and code set standards, so long as these entities file a plan for achieving compliance with HHS. Hence, ASCA sets a de-facto industry compliance deadline of October 16, 2003.
- 2002-3** Medicare begins to tighten computer systems editing to validate ICD-9-CM codes against dates of service, if and when these codes are submitted by DME suppliers.
- 05/2003** Medicare begins requiring DME suppliers to include at least one "valid" ICD-9-CM codes on electronic claims. This requirement does not extend to paper claims. (PM-B-03-028).
- 10/2003** Medicare achieves HIPAA-compliance and requires the ICD-9-CM code on all electronic claims, except ambulance claims. Medicare adopts a "contingency plan" that allows a few submitters to temporarily continue using pre-HIPAA electronic formats.
- 10/2003** Most providers and suppliers (including DME suppliers) are required to submit electronic claims to Medicare. However, in accordance with ASCA, small DME suppliers (and some others) are allowed to continue paper billing.
- 10/2003** CMS announces a requirement that contractors reject paper claims that fail to include valid ICD-9-CM codes. This requirement apparently extends to DME suppliers (but excludes ambulance suppliers). The purpose of the requirement is to ensure that Medicare's "coordination of benefits" transactions meet HIPAA standards. However,

Medicare's computer systems enforce the requirement only for primary diagnosis codes, and other diagnosis codes that are referenced in claims line item detail. (PM-B-03045).

- 07/2004** Medicare implements upgraded “front-end” computer systems logic to reject inbound *electronic* claims, including DME claims, that contain any “invalid” diagnosis codes. Systems edits now ensure that electronic DME claims will only process if all diagnosis codes on the claim are “valid” – the codes exist in the Codebook and reflect the highest level of specificity. These edits do not, of themselves, implement a medical policy – that is, the front-end edits do not check for clinical consistency between the diagnosis code(s) and the DME supplies billed on the claim. (CMS change request #3050). DME suppliers (and other billers) continue to get a 90-day “grace period” in using new diagnoses codes as annual coding updates are made.
- 07/2004** As of this date, Medicare's computer systems are rejecting “invalid” diagnosis codes (whether reported in the primary position or otherwise) on *electronic* DME claims. Moreover, the DME claims processing system also validates the primary diagnosis billed on paper DME claims, as well as other diagnoses referenced in the line item detail of paper DME claims.
- 10/2004** CMS stops allowing providers and suppliers a 90-day “grace period” in implementing each year's coding updates. (CMS change request #3303).
- 10/2005** Medicare terminates its “contingency plan” for electronic health claims transactions – only HIPAA-compliant electronic claims are accepted.

MEMORANDUM

To: David Barnett
From: Adrian M. Oleck, M.D.
Date: March 5, 2008
Subject: DME MAC Medical Policies with ICD-9 Codes

Attached is the list of DMEPOS policies that identify specific ICD-9 codes that are linked to coverage. It should be noted that:

- In some policies the ICD-9 diagnosis codes relate to all HCPCS codes addressed by the policy. In other policies, the ICD-9 codes relate to only some of the HCPCS codes in the policy.
- In some policies, the ICD-9 codes are found in the Local Coverage Determination (LCD). In other policies, the ICD-9 codes are found in the related Policy Article.

Policy	ICD-9 Codes Specified
Ankle-Foot and Knee-Ankle-Foot Orthoses	X
Automatic External Defibrillators	X
Canes and Crutches	
Cervical Traction Devices	
Cold Therapy	
Commodes	
Continuous Positive Airway Pressure (CPAP) Systems	
Enteral Nutrition	
Epoetin	
External Breast Prostheses	X
External Infusion Pumps	X
Eye Prostheses	
Facial Prostheses	
Glucose Monitors	X
High Frequency Chest Wall Oscillation Devices	X
Home Dialysis Supplies and Equipment	
Hospital Beds and Accessories	
Immunosuppressive Drugs	X
Infrared Heating Pad Systems	
Intrapulmonary Percussive Ventilation System	
Lower Limb Prostheses	
Manual Wheelchair Bases	
Mechanical In-Exsufflation Devices	X
Nebulizers	X
Negative Pressure Wound Therapy Pumps	
Oral Anticancer Drugs	X
Oral Antiemetic Drugs (Replacement for Intravenous Antiemetics)	X
Orthopedic Footwear	X
Osteogenesis Stimulators	X
Ostomy Supplies	X
Oxygen and Oxygen Equipment	
Parenteral Nutrition	
Patient Lifts	
Pneumatic Compression Devices (for Lymphedema)	
Power Mobility Devices	
Pressure Reducing Support Surfaces, Group 1	
Pressure Reducing Support Surfaces, Group 2	X
Pressure Reducing Support Surfaces, Group 3	
Refractive Lenses	X
Respiratory Assist Devices	
Seat Lift Mechanisms	
Speech Generating Devices	
Spinal Orthoses: TLSO and LSO	
Suction Pumps	
Surgical Dressings	
Therapeutic Shoes for Diabetics	X
Tracheostomy Supplies	X
Transcutaneous Electrical Nerve Stimulators (TENS)	
Urological Supplies	
Walkers	
Wheelchair Options and Accessories	
Wheelchair Seating	X

Program Memorandum

Carriers

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal B-03-028

DATE: APRIL 18, 2003

SUBJECT: Durable Medical Equipment Regional Carriers (DMERC) – ICD-9-CM Coding

Background

The Centers for Medicare & Medicaid Services (CMS) has issued several instructions on the implementation of the 2003 Update to the International Classification of Diseases, 9th Edition, Clinical Modification (ICD-9-CM) diagnosis codes. The ICD-9-CM diagnosis codes were adopted under the Health Insurance Portability and Accountability Act (HIPAA) as the medical code set to be used for reporting diagnosis in the HIPAA X12N 837 Health Care Claim Transaction. The X12N 837 (version 4010A1) requires a diagnosis on all claims unless there are no diagnoses (i.e., taxi claims). Since current CMS policy does not always require a diagnosis on the claim for certain services, this Program Memorandum (PM) provides additional guidance to DMERCs in implementing the HIPAA X12N 837 requirement for reporting diagnosis codes. Instructions that will address reporting the ICD-9-CM on other carrier claims will be forthcoming.

Policy

The physician should code the ICD-9-CM code that provides the highest degree of accuracy and completeness. In the past, there has been some confusion about the meaning of “highest degree of specificity,” and in “reporting the correct number of digits”. In the context of ICD-9-CM coding, the “highest degree of specificity” refers to assigning the most precise ICD-9-CM code that most fully explains the narrative description of the symptom or diagnosis. Concerning level of specificity, ICD-9-CM codes contain either 3, 4, or 5-digits. If a 3-digit code has 4-digit codes which further describe it, then the 3-digit code is not acceptable for claim submission. If a 4-digit code has 5-digit codes which further describe it, then the 4-digit code is not acceptable for claim submission.

For electronically submitted claims for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), a valid diagnosis code, which most fully explains the patient’s diagnosis, is required. CMS understands that physicians may not always provide suppliers of DMEPOS with the most specific diagnosis code, and may provide only a narrative description. In those cases, suppliers may choose to utilize a variety of sources to determine the most specific diagnosis code to include on the individual line items of the **claim**. (Suppliers are precluded from including diagnostic information on a certificate of medical necessity per §1842(j)(2)(a) of the Social Security Act.) These sources may include, but are not limited to: coding books and resources, contact with physicians or other health professionals, documentation contained in the patient’s medical record, or verbally from the patient’s physician or other healthcare professional.

Listed below is specific information about claims submission:

- a) All electronic claims submitted to the DMERC must contain a valid diagnosis code for each line item on the claim.

- b) Electronic claims (assigned or unassigned) **without** an ICD-9-CM code(s) shall be returned as front end rejects to the supplier. These claims do not get in the front door.
- c) For all claims with an ICD-9-CM code, a valid ICD-9-CM code (the code that provides the highest level of specificity for the date the service was provided) must be used.

CMS-Pub. 60B

2

- d) Assigned claims with an **invalid** ICD-9-CM code shall be returned as unprocessable and unassigned claims shall be denied for incorrect coding. (**NOTE:** If DMERCs are currently developing these unassigned claims prior to denial, they may continue to do so.)
- e) Paper claims require an ICD-9-CM code if specified (e.g., required by a local medical review policy (LMRP)). However, if an ICD-9-CM code is required, the code will go through the same accuracy edits as electronic claims.

The DMERCs shall not deny claims where the diagnosis code on a claim does not match the diagnosis on the order or a certificate of medical necessity (CMN), so long as: 1) There is sufficient evidence in the patient's medical record to justify the use of the diagnosis code, 2) The diagnosis on the claim justifies coverage for the item or service, and 3) The diagnosis code on the claim is valid and to the highest level of specificity.

In addition, DMERCs shall not require suppliers to obtain new orders or CMNs in those cases where ICD-9-CM codes were updated unless normal business practices would require a new order or CMN. For instance, suppliers are required to obtain new orders and/or CMNs when the patient's medical condition changes. If an ICD-9-CM code is updated, and the patient's medical condition has not changed, there is no requirement for the supplier to obtain a new order and/or CMN.

Provider Education:

Educate suppliers on the above instructions on your Web sites, next regularly scheduled bulletin, training sessions, and listservs.

The *effective date* for this PM is May 1, 2003.

The *implementation date* for this PM is May 1, 2003.

These instructions should be implemented within your current operating budget.

This PM may be discarded after April 1, 2004.

If you have any questions, contact your Regional Office.

Program Memorandum Carriers

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal B-03-045

Date: JUNE 6, 2003

CHANGE REQUEST 2725

SUBJECT: ICD-9-CM Coding Requirements for Claims Submitted
to Medicare Carriers

I. GENERAL INFORMATION

A. Background:

This Program Memorandum (PM) implements a new policy to require an ICD-9-CM diagnosis code on all paper and electronic claims billed to carriers with the exception of ambulance claims (specialty type 59).

In accordance with the Health Insurance Portability and Accountability Act (HIPAA), a final rule published in the **Federal Register** on August 17, 2000 established new standards, requirements, and implementation specifications for health plans, health care clearing houses, and health care providers who transmit any health information in an electronic form. The applicable electronic format for transmitting Medicare claims information is the ASC X12N 837. The implementation specifications define the new requirements for these formats. The ASC X12N 837 Professional Implementation Guide (version 4010A.1) requires a diagnosis(es) on “all claims/encounters except claims for which there are no diagnoses (e.g., taxi claims).”

This PM clarifies that based upon the implementation specifications for HIPAA, an ICD-9-CM code is not required for all ambulance supplier claims, but is required for all other professional claims e.g., physicians, non-physician practitioners, independent clinical diagnostic laboratories, occupational and physical therapists, independent diagnostic testing facilities, audiologist, and ASCs. Although the HIPAA requirements do not apply to paper claims, you are to implement the ICD-9-CM requirement for paper claims as well as all electronic claims, regardless of the version of the electronic claim format.

Emergency medical technicians (EMTs) and paramedics use a trip sheet to document the condition of the beneficiary, including the patient’s chief complaints, at the time that the beneficiary is loaded onto the ambulance. This documentation may later be requested by the intermediary/carrier during medical review of the claim for use in determining whether the ambulance transport and services provided were medically necessary.

However, EMTs and paramedics do not have the training necessary to make a diagnosis. Thus, no diagnosis is available at the time of transport. Moreover, it is the condition of the beneficiary at the time of transport, rather than the beneficiary’s diagnosis, that determines whether the transport and services provided are payable under the Medicare ambulance benefit.

B. Policy:

A diagnosis code must be included on all Medicare claims (electronic and paper) submitted to Part B carriers, except those claims submitted by ambulance suppliers. Professional suppliers of service include: physicians, non-physician practitioners, independent clinical diagnostic laboratories, occupational and physical therapists, independent diagnostic testing facilities, audiologist, and ASCs.

The claim should contain the ICD-9-CM code that provides the highest degree of accuracy and completeness. In the past, there has been some confusion about the meaning of “highest degree of specificity,” and in “reporting the correct number of digits”. In the context of ICD-9-CM coding, the “highest degree of specificity” refers to assigning the most precise ICD-9-CM code that most fully explains the narrative description of the symptom or diagnosis. Concerning level of specificity, ICD-9-CM codes contain either 3, 4, or 5-digits. If a 3-digit code has 4-digit codes which further describe it, then the 3-digit code is not acceptable for claim submission. If a 4-digit code has 5-digit codes which further describe it, then the 4-digit code is not acceptable for claim submission.

C. Implementation:

Editing of Claims Submitted to Carriers for the Presence of a Diagnosis Code

Effective for dates of service on or after October 1, 2003, all paper and electronic claims submitted to carriers must contain a valid diagnosis code with the exception of claims submitted by ambulance suppliers (specialty type 59). Carriers must return as unprocessable, paper and electronic claims that do not contain a valid diagnosis code with the exception of claims submitted by ambulance suppliers (specialty type 59).

Program Memorandum B-03-028, Change Request 2672, implemented requirements for submittal of a diagnosis for electronic claims processed by durable medical equipment regional carriers. This PM expands the requirements for submittal of the diagnosis required in PM B-03-028 to include paper claims.

If any carriers are currently placing invalid or valid diagnosis codes on any claims prior to sending the claim to CWF and their coordination-of-benefits trading partners, they must discontinue this practice.

Carriers and CWF must not reject an ambulance claim on the basis that it does not contain a diagnosis code.

Physicians Reporting Diagnosis Codes When A Diagnostic Test Is Ordered

Section 4317 of the Balanced Budget Act of 1997 provides, with respect to diagnostic laboratory and certain other services, that “if the Secretary (or fiscal agent of the Secretary) requires the entity furnishing the services to provide diagnostic or other medical information to the entity, the physician or practitioner ordering the service shall provide that information to the entity at the time the service is ordered by the physician or practitioner.” A laboratory or other provider must report on a claim for Medicare payment the diagnostic code(s) furnished by the ordering physician. In the absence of such coding information, the laboratory or other provider may determine the appropriate diagnostic code based on the ordering physician’s narrative diagnostic statement or seek diagnostic information from the ordering physician/practitioner. However, a laboratory or other provider may not report on a claim for Medicare payment a diagnosis code in the absence of physician-supplied diagnostic information supporting such code.

Provider Education

Carriers must notify suppliers of these changes through your Web sites within two weeks of receipt and publish the information in your next regularly scheduled bulletin. In addition, if you have a listserv that targets the affected provider communities, you shall use it to notify subscribers that important information about “ICD-9-CM Coding Requirements” is available on your Web site. The CMS will publish a national provider education article shortly that addresses these guidelines.

II. BUSINESS REQUIREMENTS

Requirement #	Requirements	Responsibility
1.1	Carriers must return paper and electronic claims as unprocessable from all specialty types except “59” that does not have a diagnosis code(s) on the claim.	Carriers
1.2	Carriers may not return as unprocessable a paper or electronic claim for an ambulance service (specialty type 59) because the claim has no diagnosis code.	Carriers
1.3	CWF may not reject an ambulance service claim (specialty type 59) because the claim has no diagnosis code.	Common Working File
1.4	Carriers must not enter a diagnosis code (valid or invalid) on any claim type.	Carriers

III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions:

X-Ref Requirement #	Instructions

B. Design Considerations:

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces:

D. Contractor Financial Reporting/Workload Impact:

E. Dependencies:

F. Testing Considerations:

IV. ATTACHMENT(S)

<p>Version:</p> <p>Implementation Date: October 1, 2003</p> <p>Discard Date: October 1, 2004</p> <p>Post-Implementation Contact: regional offices</p>	<p>Effective Date: October 1, 2003</p> <p>Funding: These instructions should be implemented within your current operating budget.</p> <p>Pre-Implementation Contact: If you have any questions, contact your regional office.</p>
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CMS Manual System

Pub. 100-04 Medicare Claims Processing

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 47

Date: DECEMBER 19, 2003

CHANGE REQUEST 2956

I. SUMMARY OF CHANGES: This instruction manualizes the return as unprocessable requirements concerning ICD-9-CM diagnosis coding for Medicare Part B claims previously released in Program Memorandum Transmittal B-03-045, Change Request (CR) 2725, dated June 6, 2003. Chapter 1, section 80.3.2.1.1 is revised to include a sentence stating that the requirements are in addition to requirements established under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Chapter 1, section 80.3.2.1.3 subparagraph p. is deleted and following subparagraphs redesignated accordingly.

NOTE: Chapter 26, Completing and Processing Form CMS-1500 Data Set, of the Medicare Claims Processing Manual will further incorporate the provisions of CR 2725 when that chapter is next revised.

NEW/REVISED MATERIAL-EFFECTIVE DATE: October 1, 2003

IMPLEMENTATION DATE: January 20, 2004

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged.

II. CHANGES IN MANUAL INSTRUCTIONS: (R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	1/80.3.2.1.1/Carrier Data Element Requirements
R	1/80.3.2.1.3/Carrier Specific Requirements for Certain Specialties/Services

III. FUNDING: Medicare contractors only:

These instructions should be implemented within your current operating budget.

IV. ATTACHMENTS:

X	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification

Business Requirements

Pub. 100-04	Transmittal: 47	Date: December 19, 2003	Change Request 2956
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I. GENERAL INFORMATION

A. Background: The Medicare Carriers Manual return as unprocessable instructions had provided in two subparagraphs that claims for physician and nonphysician specialty claims, and for other services where required, must submit diagnosis code(s) in item 21 of the CMS-1500 claim form or electronic equivalent. If the code(s) was missing, incorrect, or truncated, the claim was to be returned by the carrier as unprocessable. Change Request (CR) 2725, Transmittal B-03-045, June 6, 2003 requires that valid diagnosis code(s) must be submitted for all claims with the exception of claims submitted by ambulance suppliers. Thus, CR 2725 had expanded the types of services where valid diagnosis codes were required on claims.

B. Policy: Effective for claims with dates of service on or after October 1, 2003, carriers must return Form CMS-1500 paper claims or electronic equivalent claims as unprocessable where a claim is required to have ICD-9-CM diagnosis code(s) on the claim but required diagnosis code(s) are not entered on the claim. This policy was set forth in CR 2725.

C. Provider Education: None

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement

"Should" denotes an optional requirement

Requirement #	Requirements	Responsibility
1	Carriers shall return paper and electronic claims with dates of service on or after October 1, 2003 as unprocessable for all specialty types that require diagnosis code(s) on the claim where the claim does not have valid diagnosis code(s). All specialty types except 59, ambulance, require diagnosis code(s) on the claim.	Carrier

III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

IV. OTHER CHANGES: N/A

Citation	Change

V. SCHEDULE, CONTACTS, AND FUNDING

<p>Effective Date: October 1, 2003</p> <p>Implementation Date: January 20, 2004</p> <p>Pre-Implementation Contact(s): appropriate CMS regional office</p> <p>Post-Implementation Contact(s): Appropriate regional office</p>	<p>These instructions should be implemented within your current operating budget</p>
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80.3.2.1.1 - Carrier Data Element Requirements

(Rev. 47, 12-19-03)

B3-3005.4

A - Required Data Element Requirements

1 - Paper Claims

The following instruction describes certain data element formatting requirements to be followed when reporting the calendar year date for the identified items on the Form CMS-1500:

- If birth dates are furnished in the items stipulated below, then these items must contain 8-digit birth dates (MMDDCCYY). This includes 2-digit months (MM) and days (DD), and 4-digit years (CCYY).

Form CMS-1500 Items Affected by These Reporting Requirements:

Item 3 - Patient's Birth Date

Item 9b - Other Insured's Date of Birth

Item 11a - Insured's Date of Birth

Note that 8-digit birth dates, when provided, must be reported with a space between month, day, and year (i.e., MM_DD_CCYY). On the Form CMS-1500, the space between month, day, and year is delineated by a dotted, vertical line.

If a birth date is provided in items 3, 9b, or 11a, and is not in 8-digit format, carriers must return the claim as unprocessable. They use remark code MA 52 on the remittance advice. For formats other than the remittance, use code(s)/messages that are consistent with the above remark codes.

If carriers do not currently edit for birth date items because they obtain the information from other sources, they are not required to return these claims if a birth date is reported in items 3, 9b, or 11a. and the birth date is not in 8-digit format. However, if carriers use date of birth information on the incoming claim for processing, they must edit and return claims that contain birth date(s) in any of these items that are not in 8-digit format.

For certain other Form CMS-1500 conditional or required date items (items 11b, 14, 16, 18, 19, or 24a), when dates are provided, either a 6-digit date or 8-digit date may be provided.

If 8-digit dates are furnished for any of items 11b, 14, 16, 18, 19, or 24a (excluding items 12 and 31), carriers must note the following:

- All completed date items, except item 24a, must be reported with a space between month, day, and year (i.e., MM_DD_CCYY). On the Form CMS-1500, the space between month, day, and year is delineated by a dotted, vertical line;
- Item 24a must be reported as one continuous number (i.e., MMDDCCYY), without any spaces between month, day, and year. By entering a continuous number, the date(s) in item 24a will penetrate the dotted, vertical lines used to separate month, day, and year. Carrier claims processing systems will be able to process the claim if the date penetrates these vertical lines. However, all 8-digit dates reported must stay within the confines of item 24a;
- Do not compress or change the font of the "year" item in item 24a to keep the date within the confines of item 24a. If a continuous number is furnished in item 24a with no spaces between month, day, and year, you will not need to compress the "year" item to remain within the confines of item 24a;
- The "from" date in item 24a must not run into the "to" date item, and the "to" date must not run into item 24b;

- Dates reported in item 24a must not be reported with a slash between month, day, and year; and
- If the provider of service or supplier decides to enter 8-digit dates for any of items 11b, 14, 16, 18, 19, or 24a (excluding items 12 and 31), an 8-digit date must be furnished for all completed items. For instance, you cannot enter 8-digit dates for items 11b, 14, 16, 18, 19 (excluding items 12 or 31), and a 6-digit date for item 24a. The same applies to those who wish to submit 6-digit dates for any of these items.

Carriers must return claims as unprocessable if they do not adhere to these requirements.

2 - Electronic Claims

Carriers must return all electronic claims that do not include an 8-digit date (CCYYMMDD) when a date is reported. They use remark code MA52 on the remittance advice. For formats other than the remittance, carriers use code(s)/message(s) that are consistent with the above remark codes.

If carriers do not currently edit for birth date items because they obtain the information from other sources, they are not required to return these claims if a birth date is reported in items 3, 9b, or 11a and the birth date is not in 8-digit format. However, if carriers do use date of birth information on the incoming claim for processing, they must edit and return claims that contain birth date(s) in any of these items that are not in 8-digit format.

B - Required Data Element Requirements

The following Medicare-specific, return as unprocessable requirements in this section and the following two sections are in addition to requirements established under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Carriers must return a claim as unprocessable to a provider of service or supplier and use the indicated remark codes if the claim is returned through the remittance advice or notice process. In most cases, reason code 16, Claim/service lacks information that is needed for adjudication, will be used in tandem with the appropriate remark code that specifies the missing information. Carriers use the following:

1. If a claim lacks a valid Medicare Health Insurance Claim Number (HICN) in item 1A or contains an invalid HICN in item 1A. (Remark code MA61.)
2. If a claim lacks a valid patient's last and first name as seen on the patient's Medicare card or contains an invalid patient's last and first name as seen on the patient's Medicare card. (Remark code MA36.)
3. If a claim does not indicate in item 11 whether or not a primary insurer to Medicare exists. (Remark code MA83 or MA92.)
4. If a claim lacks a valid patient or authorized person's signature in item 12 or contains an invalid patient or authorized person's signature in item 12. (See "Exceptions," bullet number one. Remark code MA75.)
5. If a claim lacks a valid "from" date of service in item 24A or contains an invalid "from" date of service in item 24A. (Remark code M52.)
6. If a claim lacks a valid place of service (POS) code in item 24b, or contains an invalid POS in item 24b, return the claim as unprocessable to the provider or supplier, using RA remark code M77. Effective for claims received on or after April 1, 2004, on the Form CMS-1500, if a claim contains more than one POS (other than Home – 12), for services paid under the MPFS and anesthesia services.
7. If a claim lacks a valid procedure or HCPCS code (including Levels 1-3, "unlisted procedure codes," and "not otherwise classified" codes) in item 24D or contains an invalid or obsolete

procedure or HCPCS code (including Levels 1-3, “unlisted procedure codes,” and “not otherwise classified” codes) in item 24D. (Remark code M20 if the HCPCS is missing, or M51 for an invalid/obsolete HCPCS.)

Note: Level 3 HCPCS will be going away with HIPAA.

8. If a claim lacks a charge for each listed service. (Remark code M79.)
9. If a claim does not indicate at least one day or unit in item 24G (Note: To avoid returning the claim as “unprocessable” when the information in this item is missing, the FI must program the system to automatically default to “1” unit).
10. If a claim lacks a signature from a provider of service or supplier, or their representative. (See “Exceptions,” bullet number one; Remark code MA70 for a missing provider representative signature, or code MA81 for a missing physician/supplier/practitioner signature.)
11. If a claim does not contain in item 33:
 - a. A billing name, address, ZIP code, and telephone number of a provider of service or supplier. (Remark code MA82.)

AND EITHER
 - b. A valid PIN (or NPI when effective) number or, for DMERC claims, a valid National Supplier Clearinghouse number for the performing provider of service or supplier who is not a member of a group practice. (Remark code MA82 or M57 if another provider is involved.)

OR
 - c. A valid group PIN (or NPI when effective) number or, for DMERC claims, a valid National Supplier Clearinghouse number for performing providers of service or suppliers who are members of a group practice. (Remark code MA112.)

80.3.2.1.3 - Carrier Specific Requirements for Certain Specialties/Services

(Rev.47, 12-19-03)

Carriers must return the following claim as unprocessable to the provider of service/supplier:

- a. For chiropractor claims:
 1. If the x-ray date is not entered in item 19 for claims with dates of service prior to January 1, 2000. Entry of an x-ray date is not required for claims with dates of service on or after January 1, 2000.
 2. If the initial date “actual” treatment occurred is not entered in item 14. (Remark code MA122 is used.)
- b. For certified registered nurse anesthetist (CRNA) and anesthesia assistant (AA) claims, if the CRNA or AA is employed by a group (such as a hospital, physician, or ASC) and the group’s name, address, ZIP code, and PIN (or NPI when effective) number is not entered in item 33 or their personal PIN (or NPI number when effective) is not entered in item 24K. (Remark code MA112 is used.)
- c. For durable medical, orthotic, and prosthetic claims, if the name, address, and ZIP code of the location where the order was accepted were not entered in item 32. (Remark code MA 114 is used.)
- d. For physicians who maintain dialysis patients and receive a monthly capitation payment:
 1. If the physician is a member of a professional corporation, similar group, or clinic, and the attending physician’s PIN (or NPI when effective) is not entered in item 24K. (Remark code MA112 is used.)
 2. If the name, address, and ZIP code of the facility other than the patient’s home or physician’s office involved with the patient’s maintenance of care and training is not entered in item 32. (Remark code MA114 is used.) Effective for claims received on or after April 1, 2004, the name, address, and ZIP code of the service location for all services other than those furnished in place of service home – 12 must be entered.
- e. For routine foot care claims, if the date the patient was last seen and the attending physician’s PIN (or NPI when effective) is not present in item 19. (Remark code MA104 is used.)
- f. For immunosuppressive drug claims, if a referring/ordering physician, physician’s assistant, nurse practitioner, clinical nurse specialist was used and their name and/or UPIN (or NPI when effective) is not present in items 17 or 17A. (Remark code M33 or MA102 is used.)
- g. For all laboratory services, if the services of a referring/ordering physician, physician’s assistant, nurse practitioner, clinical nurse specialist are used and his or her name and/or UPIN (or NPI when effective) is not present in items 17 or 17A. (Remark code M33 or MA102 is used.)
- h. For laboratory services performed by a participating hospital-leased laboratory or independent laboratory in a hospital, clinic, laboratory, or facility other the patient’s home or physician’s office (including services to a patient in an institution), if the name, address, and ZIP code of the location where services were performed is not entered in item 32. (Remark code MA114 is used.) Effective for claims received on or after April 1, 2004, the name, address, and ZIP code of the service location for all services other than those furnished in place of service home – 12 must be entered.
- i. For independent laboratory claims:
 1. Involving EKG tracing and the procurement of specimen(s) from a patient at home or in an institution, if the claim does not contain a validation from the prescribing physician that any laboratory service(s) performed were conducted at home or in an

- institution by entering the appropriate annotation in item 19 (i.e., “Homebound”). (Remark code MA116 is used.)
2. If the name, address, and ZIP code where the test was performed is not entered in item 32, if the services were performed in a location other than the patient’s home or physician’s office. (Remark code MA114 is used.) Effective for claims received on or after April 1, 2004, the name, address, and ZIP code of the service location for all services other than those furnished in place of service home – 12 must be entered.
- j. For mammography “diagnostic” and “screening” claims, if a qualified screening center does not accurately enter their 6-digit, FDA-approved certification number in item 32 when billing the technical or global component. (Remark code MA128 is used.)
 - k. For parenteral and enteral nutrition claims, if the services of an ordering/referring physician, physician assistant, nurse practitioner, clinical nurse specialist are used and their name and/or UPIN (or NPI when effective) is not present in items 17 or 17A. (Remark code MA102 is used.)
 - l. For portable x-ray services claims, if the ordering physician, physician assistant, nurse practitioner, clinical nurse specialist’s name, and/or UPIN (or NPI when effective) are not entered in items 17 or 17A. (Remark code MA102 is used.)
 - m. For radiology and pathology claims for hospital inpatients, if the referring/ordering physician, physician assistant, nurse practitioner, clinical nurse specialist’s name, and/or UPIN (or NPI when effective) if appropriate are not entered in items 17 or 17A. (Remark code MA102 is used.)
 - n. For outpatient services provided by a qualified, independent physical, or occupational therapist:
 1. If the UPIN (or NPI when effective) of the attending physician is not present in item 19. (Remark code MA104 is used.)
 2. If the 6-digit (MM | DD | YY) or 8-digit (MM | DD | CCYY) date patient was last seen by the attending physician is not present in item 19. (Remark code MA104 is used.)
 - o. For all laboratory work performed outside a physician’s office, if the claim does not contain a name, address, and ZIP code, and PIN (or NPI when effective) where the laboratory services were performed in item 32, if the services were performed at a location other than the place of service home – 12. (Use Remark code MA114.)
 - p. For all physician office laboratory claims, if a 10-digit CLIA laboratory identification number is not present in item 23. This requirement applies to claims for services performed on or after January 1, 1998. (Remark code MA51 is used.)
 - q. *For investigational devices billed in an FDA-approved clinical trial if an Investigational Device Exemption (IDE) number is not present in item 23. (Remark code MA50 is used.)*
 - r. For physicians performing care plan oversight services if the 6-digit Medicare provider number of the home health agency (HHA) or hospice is not present in item 23. (Remark code MA49 is used.)

40.7.2 – X12N 837 Professional Implementation Guide (IG) Edits

(Rev. 86, 02-06-04)

The Part B Carriers and Durable Medical Equipment Regional Carriers (DMERCs) must reject inbound electronic claims that contain invalid diagnosis codes whether pointed to a specific detail line or not.

The Part B Carriers and Durable Medical Equipment Regional Carriers shall reject inbound electronic claims that contain a space, dash, special character, or 1 byte numeric in any zip code.

The Part B Carriers and Durable Medical Equipment Regional Carriers (DMERCs) must reject inbound electronic claims that contain a space, dash, special character, or parentheses in any telephone number.

Related Change Request (CR) #: 3050

MLN Matters Number: MVB050

Related CR Release Date: February 6, 2004

Related CR Transmittal #: R86CP

Effective Date: July 1, 2004

Implementation Date: July 6, 2004

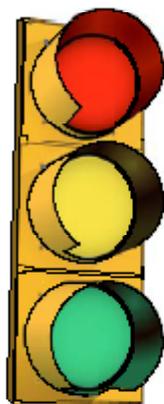
Health Insurance Portability and Accountability Act (HIPAA) X12N 837 Professional Health Care Claim Implementation Guide (IG) Editing

Note: This article was revised to contain Web addresses that conform to the new CMS web site and to show they are now MLN Matters articles. All other information remains the same.

Provider Types Affected

Physicians, practitioners, suppliers, and providers who bill Medicare carriers, including Durable Medical Equipment Carriers (DMERCs).

Provider Action Needed



STOP – Impact to You

Affected providers should stop submitting electronic claims with diagnosis codes, zip codes, or telephone numbers that are not HIPAA compliant.

CAUTION – What You Need to Know

Providers should note that Medicare systems are strengthening their system edits to assure receipt of HIPAA compliant claims. Effective July 1, 2004, Medicare will reject electronic claims that have diagnosis codes, zip codes, or telephone numbers that are not HIPAA compliant.

GO – What You Need to Do

Be sure your billing systems are modified to generate electronic claims that will pass Medicare's HIPAA compliancy edits for diagnosis codes, zip codes, and telephone numbers.

Background

The Health Insurance Portability and Accountability Act (HIPAA) directed the Secretary of the Department of Health and Human Services (HHS) to adopt standards for transactions to enable health information to be exchanged electronically. In addition, one of the HIPAA provisions requires standard formats to be used for electronically submitted health care transactions.

Disclaimer

This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written laws or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents.

CMS is committed to implementing the §37 COB transaction set per the HIPAA implementation guide (IG), and it recognizes that a change in its systems is needed to:

- 1) Comply with the §37 Professional IG; and
- 2) To allow the creation of compliant coordination of benefits (COB) claim files.

To accomplish this, Medicare systems will be changed to include edits that reject electronic claims that contain:

- Invalid diagnosis codes;
- A dash, a space, or special character in any zip code field; and
- A dash, space, special character, or a parenthesis in telephone numbers.

Implementation

July 6, 2004.

Related Instructions

The ANSI X12N §37 implementation guides are the standards of compliance for claim transactions and are available electronically at http://www.wvpc-edi.com/hipaa/HIPAA_40.asp on the CMS web site.

The *Medicare Claims Processing Manual, Chapter 24* has been updated to include the new *Section 40.7.2, Professional Implementation Guide (IG) Edits*. This new section is included below:

40.7.2 – X12N §37 Professional Implementation Guide (IG) Edits

The Part B Carriers and Durable Medical Equipment Regional Contractors (DMERCs) must reject inbound electronic claims that contain invalid diagnosis codes whether pointed to or not.

The Part B Carriers and Durable Medical Equipment Regional Contractors (DMERCs) must reject inbound electronic claims that contain a dash, space, or special character in any zip code.

The Part B Carriers and Durable Medical Equipment Regional Contractors (DMERCs) must reject inbound electronic claims that contain dashes, spaces, special characters or parentheses in any telephone number.

Disclaimer

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CMS Manual System

Pub. 100-04 Medicare Claims Processing

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 210

Date: JUNE 18, 2004

CHANGE REQUEST 3303

I. SUMMARY OF CHANGES: This instruction is CMS' annual reminder to the contractors of the ICD-9-CM update that is effective for the dates of service on and after October 1, 2004, as well as discharges on or after October 1, 2004 for institutional providers.

NEW/REVISED MATERIAL - EFFECTIVE DATE: October 1, 2004

***IMPLEMENTATION DATE: October 4, 2004**

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS:

(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	23/10.2 Relationship of ICD-9-CM Codes and Date of Service

*III. FUNDING:

These instructions shall be implemented within your current operating budget.

IV. ATTACHMENTS:

X	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

*Medicare contractors only

Attachment – Business Requirements

Pub. 100-04	Transmittal: 210	Date: June 18, 2004	Change Request 3303
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SUBJECT: Medicare Contractor Annual Update of the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)

I. GENERAL INFORMATION

A. Background: In 1979, use of ICD-9-CM codes became mandatory for reporting provider services on Form CMS-1450. On April 1, 1989, use of ICD-9-CM codes became mandatory for all physician services submitted on Form CMS-1500. Effective October 1, 2003 (refer to Transmittal B-03-045, dated June 6, 2003) an ICD-9-CM code is required on all paper and electronic claims billed to Medicare carriers with the exception of ambulance claims (specialty type 59).

Effective for dates of service on and after October 1, 2004, CMS will no longer provide a 90-day grace period for providers (billing carriers/DMERCs) to use in billing discontinued ICD-9-CM diagnosis codes on Medicare claims. Institutional providers did not have a grace period, they were always required to bill the new ICD-9-CM codes for discharges on or after October 1.

The ICD-9-CM codes are updated annually. The CMS sends the ICD-9-CM Addendum out to the regional offices and Medicare contractors annually.

B. Policy: This instruction serves as a reminder to contractors regarding the annual ICD-9-CM coding update to be effective for dates of service on or after October 1, 2004 (effective for discharges on or after October 1, 2004 for institutional providers).

An ICD-9-CM code is required for all professional claims, e.g., physicians, non-physician practitioners, independent clinical diagnostic laboratories, occupational and physical therapists, independent diagnostic testing facilities, audiologist, ambulatory surgical centers (ASCs), and for all institutional claims. However, an ICD-9-CM code is not required for ambulance supplier claims.

The CMS posts the new, revised, and discontinued ICD-9-CM diagnosis codes on the CMS Web site at www.cms.hhs.gov/medlearn/icd9code.asp on an annual basis. The updated diagnosis codes are effective for dates of service on and after October 1. Providers can view the new updated codes at this site in June. Providers can also visit the National Center for Health Statistics (NCHS) Web site at www.cdc.gov/nchs/icd9.htm. The NCHS will post the new ICD-9-CM Addendum on their Web in June. Providers are also encouraged to purchase a new ICD-9-CM book or CD-ROM on an annual basis.

C. Provider Education: A provider education article related to this instruction will be available at <http://www.cms.hhs.gov/medlearn/matters> shortly after the CR is released. You will receive notification of the article release via the established "medlearn matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include

information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article must be included in your next regularly scheduled bulletin.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement

"Should" denotes an optional requirement

Requirement #	Requirements	Responsibility
3303.1	Carriers/DMERCs shall accept the new and revised 2004 ICD-9-CM update in order to process claims with dates of service on or after October 1, 2004. NOTE: Reminder Medicare carriers/DMERCs can no longer provide a 90-day grace period for providers to use in billing discontinued ICD-9-CM diagnosis codes.	Local Part B carrier and DMERCs
3303.2	FISS shall install and FIs shall accept the new and revised 2004 ICD-9-CM update in order to process claims with dates of service on or after October 1, 2004 for outpatient claims and for inpatient claims, with discharges on or after October 1, 2004.	FI, FISS
3303.3	Intermediaries shall encourage/remind hospitals to send a copy of the Addendum to the Director of Medical Records.	FI
3303.4	Intermediaries shall handle questions on the operation of GROUPER, MCE and OCE, in accordance with regular procedures.	FI

III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: Grouper v22.0, Medicare Code Editor v21.0, non-OPPS v20, and Outpatient Code Editor v5.3.

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: Two attachments: the table and the Addendum.

F. Testing Considerations: N/A

IV. SCHEDULE, CONTACTS, AND FUNDING

<p>Effective Date: October 1, 2004</p> <p>Implementation Date: October 4, 2004</p> <p>Pre-Implementation Contact(s): April Billingsley, abillingsley@cms.hhs.gov or 410-786-0140 (carriers), and Sarah Shirey, sshirey@cms.hhs.gov or 410-786-0187 (FIs)</p> <p>Post-Implementation Contact(s): Appropriate regional office</p>	<p>These instructions shall be implemented within your current operating budget.</p>
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Attachments