

**PNEUMONIA CODING:
INVESTIGATIONS, DEFENSES AND AFFIRMATIVE
COMPLIANCE MEASURES**

**A SPECIAL REPORT TO THE
AMERICAN HOSPITAL ASSOCIATION**

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INTRODUCTION

This white paper analyzes one of the federal government’s most active current enforcement initiatives against hospitals — the Pneumonia Coding Project. Through this project, the United States Department of Health and Human Services Office of Inspector General (“OIG”) and United States Attorneys Offices (“USAOs”) are investigating hospitals in all regions of the country for alleged False Claims Act (“FCA”) violations arising from the alleged “upcoding” of inpatient pneumonia cases.

While every hospital has unique facts and circumstances requiring specific consideration, there are common issues that American Hospital Association (“AHA”) members and their counsel should consider. This white paper provides a primer for AHA members regarding the Pneumonia Coding Project and offers possible actions and responses.

Section I, below, discusses the government’s concerns and inquiries. It summarizes the government’s allegations and provides background on the government’s enforcement initiative. Section II offers an analysis of the legal issues relating to the government’s FCA theories, relevant to those hospitals defending active pneumonia investigations. Section III analyzes affirmative compliance measures for hospitals to consider.

This white paper is not intended as legal advice. Hospitals should consult qualified counsel to obtain legal advice relevant to their particular facts and circumstances.

I. THE GOVERNMENT’S ALLEGATIONS AND ENFORCEMENT INITIATIVE

A. Summary of Government Contentions

The Pneumonia Coding Project is a joint effort by the OIG and the Department of Justice (“DOJ”) focused on claims submitted to Medicare for inpatient treatment of patients with pneumonia. Medicare pays for inpatient hospital treatment based upon the beneficiary’s

principal diagnosis at the time of admission. Hospitals assign ICD-9-CM¹ diagnostic codes corresponding to the patient's principal and secondary diagnoses. A diagnostic related group ("DRG") code is then assigned, based on the ICD-9-CM codes. Medicare payment for inpatient hospital services is a fixed amount per hospital, based on the DRG. Typically, and of particular importance in the context of pneumonia, a number of different ICD-9-CM codes feed into a designated DRG code. A principal diagnosis of pneumonia typically results in assignment of either DRG 79 or DRG 89, depending on the specific ICD-9-CM code selected.² Generally, DRG 89 relates to simple pneumonia and DRG 79 relates to more complex pneumonia. There is a \$2,000-\$2,500 per case difference in Medicare reimbursement between the lower-paying DRG 89 and higher-paying DRG 79.

The government's allegation underlying the pneumonia investigations is that hospitals unjustifiably used ICD-9-CM codes 482.83 (Pneumonia, Other Gram-Negative Pneumonia), 482.89 (Pneumonia, Other Specified Bacteria) and other ICD-9-CM codes that led to higher reimbursement at the DRG 79 level. According to the government's theory, in many such cases, hospitals should have used ICD-9-CM codes that resulted in lower reimbursement at the DRG 89 level.

B. Origins of Pneumonia Coding Project

The government's interest in pneumonia coding appears to have originated from a 1996 *qui tam* suit filed in the Eastern District of Pennsylvania by Health Outcomes Technology, a

¹ ICD-9-CM stands for International Classification of Diseases, Ninth Revision, Clinical Modification.

² If there are no complicating or comorbid conditions, DRG 80 or 90 may apply, instead of DRG 79 or 89.

Pennsylvania consulting firm.³ That suit, which remains partially sealed, accused over 100 hospital defendants of pneumonia “upcoding.” The *qui tam* allegations focused on the alleged excessive use by the defendant hospitals of a single ICD-9-CM code: 482.89 (Pneumonia, Other Specified Bacteria), which leads to DRG 79. The Complaint alleged that “ICD-9 code 482.89 is to be used by a Medicare provider only in circumstances where the patient suffers from a strain of bacterial pneumonia that has been specifically identified by a health care professional, but such strain does not have an individual corresponding ICD-9 diagnostic code.” (Exh. 1 at ¶ 126). The Complaint further asserted that “[b]ecause the most common types of bacterial pneumonia are enumerated in ICD-9 codes 480 through 487, it should be uncommon for a hospital to use ICD-9 code 482.89.” (Exh. 1 at ¶ 130).

The allegations in the *qui tam* Complaint were based on publicly available Medicare data from 1993 and 1994. Hospitals were named as defendants if, based on an analysis of claims data, their usage of ICD-9-CM code 482.89 exceeded the national average for frequency of ICD-9-CM codes by a certain threshold. According to the Complaint, ICD-9-CM code 482.89 is assigned to fewer than 4% of all Medicare pneumonia cases nationally. (Exh. 1 at ¶ 132). The Complaint contained no hospital-specific information beyond analysis of publicly available data, and it contained no information regarding the 100 defendant hospitals’ alleged intents to defraud.

C. Government Statements About The Pneumonia Coding Project

The OIG first publicly described the Pneumonia Coding Project in its Work Plan for fiscal year 1998, published in October, 1997, stating:

³ See *United States ex. rel. Health Outcomes Technologies v. [under seal]*, Civ. No. 96-1552 (E.D. Pa.) (redacted complaint attached, Exh. 1.)

The Pneumonia DRG Upcoding Project was initiated to identify hospitals that falsify the diagnosis and diagnosis related group on claims from viral to bacterial pneumonia. The Office of Investigations is currently working with the Department of Justice to initiate a nationwide project in this area.⁴

In its 1999 Work Plan, the OIG revised its description to note that the government is investigating pneumonia cases as both civil and criminal matters:

This cooperative effort with the Department of Justice focuses on information that hospitals have upcoded the diagnosis-related group for pneumonia claims from viral to bacterial pneumonia. By doing this, the hospitals obtained almost \$2,500 extra per claim in reimbursement. The OIG is looking at both civil and criminal implications.

This same description appears in the 2000 and 2001 Work Plans.

The OIG has also described this Project in its Semi-Annual Reports to Congress. The reports for October 1, 1997 through March 31, 1998 and April 1, 1998 through September 30, 1998 describe the Project in some detail:

The OIG and DOJ are investigating whether hospitals across the country have routinely assigned the incorrect diagnosis code to hospital admissions for bacterial pneumonia. Medicare pays for inpatient hospital services based on DRGs, which are assigned based on the diagnosis codes identifying the condition(s) treated during the hospital admission. One diagnosis code [482.89] is to be used for ‘bacterial pneumonia - other specified bacteria,’ *i.e.*, where a physician diagnoses the patient with a pneumonia caused by a specific bacteria and there is no other diagnosis code for that particular bacteria. This code should rarely be used since there are specific diagnosis codes for pneumonia caused by almost all known pneumonia-causing types of bacteria. Because cases that should properly be coded as ‘other specified bacteria’ are expected to be complex, such cases are generally assigned a higher-paying DRG than most pneumonia cases. The OIG believes that many hospitals have been using the ‘other specified bacteria’ diagnosis

⁴ The OIG Work Plans and Semi-Annual Reports to Congress, cited and quoted herein, are available on the OIG’s web page, <www.dhhs.gov/progorg/oig>.

code for hospital admissions where the physician has not diagnosed a specific bacteria as the cause of the pneumonia. In such cases, the hospital should use a different diagnosis code for 'bacterial pneumonia - unspecified,' which generally results in the case being assigned to a DRG which pays several thousand dollars less than the code for 'other specified bacteria.'

In its Semi-Annual Report for October 1, 1998 through March 31, 1999, the OIG made some minor revisions to its description to the Pneumonia Coding Project, indicating that it was looking beyond ICD-9-CM code 482.89:

Medicare inpatient hospital stays are reimbursed based on the diagnosis-related group (DRG) that is assigned to the patient's stay. The determination of the appropriate DRG for a particular case depends upon the hospital's assignment of diagnosis code(s) from the International Classification of Diseases, 9th Revision, Clinical Modification to the inpatient stay. Most pneumonia cases are grouped into one of four DRGs, one of which results in significantly higher payment to the hospital than do the others. Most pneumonia cases are grouped into the lower-paying DRGs. The OIG has found that a small percentage of hospitals across the country have assigned a disproportionate number of pneumonia cases diagnosis codes that result in an admission being assigned the higher paying DRG. Review of the medical records has demonstrated that most of the cases assigned these specific diagnosis codes at these hospitals should have been assigned a diagnosis code that would result in assignment of a lower-paying DRG.

This description has appeared in all subsequent Semi-Annual Reports. *See* OIG, Semi-annual Report for April 1, 1999 - September 30, 1999 at 10; OIG, Semi-Annual Report for October 1, 1999 - March 31, 2000 at 13; OIG, Semi-Annual Report for April 1, 2000 - September 30, 2000 at 11.

Aside from announcing specific settlements, the DOJ has not said a great deal about the Pneumonia Coding Project. In his February 1, 1999 address to the American Hospital Association, Deputy Attorney General Eric H. Holder, Jr. identified the Pneumonia Coding

Project as a basis for “the continuing need for aggressive enforcement efforts.” (Exh. 2.)

Mr. Holder also said that the Pneumonia Coding Project involved “illegal billing practices [that] violate clear and unambiguous Medicare rules.” *Id.* (Unfortunately, Mr. Holder did not identify these “clear and unambiguous” rules).

D. Nature Of Government’s Investigations

In some instances, the government’s pneumonia coding investigations have been triggered by the filing of other *qui tam* suits. In many other instances, OIG data analyses appear to have spurred the investigations. The OIG has conducted studies that compare a hospital’s frequency of ICD-9-CM codes 482.89 and 482.83, or overall DRG 79 frequency, to the hospital’s total number of pneumonia cases. Based upon such studies, the OIG has targeted certain hospitals for investigation. The OIG, however, has neither published the standards used to determine which hospitals should be contacted, nor advised the industry whether any standards exist. Because the OIG has never published the basis and parameters of its data analysis, it is difficult to determine the accuracy and reliability of these studies. Before accepting or relying on the OIG’s calculations for local and national utilization averages, hospitals should inquire about the basis of those averages and seek to independently verify them.

After a hospital is targeted for investigation, the OIG and DOJ contact the target hospital to seek additional information. The method of contacting the hospital varies from state to state. In some cases, the hospital is contacted by letter from the local U.S. Attorney’s Office requesting a voluntary production of medical records. The government has created a model “contact letter” to make the initial contact. (*See* Exh. 3). In other cases, the government has issued administrative subpoenas for medical records and other documents prior to any direct

communication with the target hospital. The OIG has created a model subpoena, which can be modified by each U.S. Attorney's Office. (*See* Exh. 4). The subpoenas and letters may request both medical records and other types of documents, such as personnel records for medical records personnel, coding guidelines or policies, contracts, reports and other documents relating to coding consultants.

The government is particularly interested in hospitals that used coding consultants. Although, as discussed below, reasonable reliance upon a qualified consultant should provide a good defense to an FCA allegation, the government generally seems to view the use of coding consultants with suspicion. Indeed, some coding consultants are currently the subjects of criminal and civil investigations.

After a hospital produces its medical records and other documents, the government typically turns the records over to a consultant retained by the government to review the coding. The medical records are usually reviewed by the consultant's nurse reviewer. Often, the government's consultant applies a very stringent coding standard, requiring a physician's express identification of the bacterial pathogen in the diagnostic statement in order to support ICD-9-CM codes 482.83 or 482.89. (Defenses based on technical coding issues are set forth below in Section II. C-G). Based on the consultant's report, the government develops an error rate and extrapolates that error rate to an alleged overpayment. Typically, the government will seek to settle the matter for two times the overpayment amount, and will demand that the settling hospital enter into a Corporate Integrity Agreement with the OIG.

If contacted by the DOJ or OIG, hospitals should prepare to respond to the government charges of FCA violations. Depending on the relevant facts and circumstances, hospitals should

prepare to proffer facts demonstrating the absence of any fraudulent intent on the part of the hospital. The hospital should also prepare to analyze critically the government's coding review. Examples of such defenses are provided in Section II, below.

According to the OIG's April 1 through September 30, 2000 Semi-Annual Report, 22 hospitals have settled pneumonia investigations for a total of over \$23.6 million. In addition, the \$840 million settlement reached by HCA-The Hospital Company included over \$403 million for inpatient DRG coding allegations, including pneumonia coding. An HCA subsidiary, Columbia Management Company, also pled guilty to Medicare fraud allegations based upon inpatient pneumonia coding.⁵ Moreover, following a self-disclosure to the OIG, Community Health Systems, Inc. paid \$31 million and entered into a Corporate Integrity Agreement to settle government claims concerning improper DRG coding, including pneumonia coding.⁶

II. LEGAL ISSUES AND DEFENSES RELEVANT TO PNEUMONIA CODING INVESTIGATIONS

A. Application of the False Claims Act and the Deputy Attorney General Guidelines

The fundamental premise in defending FCA investigations is that every inpatient coding error is not a violation of the FCA. Indeed, for a hospital to be liable under the FCA for pneumonia claims, the government must prove at trial that the hospital:

- (1) "knowingly;"
- (2) presented or caused to be submitted to a federal health program;
- (3) a false or fraudulent claim for payment.

⁵ Judith Thorn, AHCA Agrees to pay U.S. \$840 Million to Settle Criminal, Civil Allegations, *9 BNA's Health Law Reporter* 1879 (Dec. 21, 2000).

⁶ ACHS Settles >Upcoding= Charges, *9 BNA's Health Law Reporter* 737 (May 18, 2000).

31 U.S.C. § 3729(a)(1). Under the FCA, one has acted “knowingly” if one acted with “deliberate ignorance” or in “reckless disregard” of the truth or falsity of the claim submitted. 31 U.S.C. § 3729(b). Therefore, if a hospital has made a coding error due to an innocent mistake, as opposed to acting with deliberate ignorance or reckless disregard as to whether claims were accurate, the hospital should not be found liable under the FCA.⁷

The FCA is a powerful enforcement tool. It provides for treble damages and penalties of \$5,000-10,000 for each false claim. *See* 31 U.S.C. § 3729(a).⁸ Such penalties for each false claim are potentially ruinous for most hospitals. As a result, many hospitals have settled with the government on terms that are perhaps less favorable than the expected result at trial, because they are unwilling to risk possibly fatal liability.

Following criticism by AHA and others of “Project Bad Bundle,” the DOJ’s national lab unbundling enforcement initiative, Deputy Attorney General Eric Holder issued a memorandum on June 3, 1998 entitled “Guidance on the Use of the False Claims Act in Civil Health Care Matters” (“DOJ Guidelines”) (Exh. 5). The DOJ Guidelines acknowledge the potential for abuse of the FCA, and set forth standards for DOJ and USAO attorneys to follow before making

⁷ The elements of a criminal case will vary according to the charge, but will require a higher degree of intent than is required under the civil FCA. Conviction under the criminal FCA requires the government to prove that one presented a claim to the United States knowing such claim to be false, fictitious or fraudulent. 18 U.S.C. § 287. The government must prove the defendant actually knew that the claim submitted was false, fictitious or fraudulent. *See United States v. Barker*, 967 F.2d 1275, 1278 (9th Cir. 1992) (To be false, a claim must not only be inaccurate but consciously so). In addition, the government must prove its facts in a criminal case beyond a reasonable doubt, a higher standard than a civil FCA case. *See id.*

⁸ On August 30, 1999, the DOJ promulgated regulations increasing penalties to \$5,500-11,000 for each false claim, for claims submitted on or after September 29, 1999. 64 Fed. Reg. 47099, 47104 (Aug. 30, 1999).

allegations of FCA violations. Broadly speaking, the DOJ Guidelines require DOJ attorneys to be certain that there is a proper legal and factual foundation before they may allege violations by healthcare providers of the FCA. Specifically, DOJ attorneys are called upon to:

- Determine whether false claims were submitted. According to the DOJ Guidelines, this requires:
 - (i) an examination of relevant statutory and regulatory provisions and interpretive guidance;
 - (ii) the verification of the data and other evidence; and
 - (iii) conducting necessary investigative steps.
- Determine whether the provider knowingly submitted the false claims. According to the DOJ Guidelines, this requires DOJ attorneys to:
 - (iv) review notice given to the provider of the rule or policy upon which a potential case would be based;
 - (v) evaluate the clarity of the rule or policy allegedly breached;
 - (vi) consider the pervasiveness and magnitude of the false claims;
 - (vii) consider whether the hospital has a compliance plan or other steps to comply with billing rules;
 - (viii) consider past remedial efforts to identify and remedy the wrongful conduct under consideration;
 - (ix) assess whether the Health Care Financing Administration (“HCFA”), the fiscal intermediary (“FI”) or other government agents supplied guidance to the provider;
 - (x) consider whether the provider has previously been audited for the same matter; and
 - (xi) consider any other information that bears on the provider’s state of mind.

Although the DOJ maintains that the DOJ Guidelines are not privately enforceable, they at least set forth the standards to which the DOJ holds itself. The government must apply the

facts and circumstances of a hospital's pneumonia coding case to these guidelines before DOJ attorneys, under the DOJ's own standards, may properly accuse a hospital of FCA violations. Accordingly, a hospital's specific pneumonia coding circumstances must be evaluated under the rubric of the DOJ Guidelines. Hospitals and their counsel should be aware of the DOJ Guidelines and should remind government attorneys of their application.

In Sections II. C-G below, a number of technical coding and other considerations possibly relevant to a hospital's defense are set forth. Each of these considerations should be reviewed and applied against the standards of the FCA and the DOJ Guidelines. As noted above, coding errors do not necessarily equate to a violation of the FCA. Under the FCA, the government must establish more.

B. Regulatory Underpinnings For ICD-9-CM Coding And DRG-Based Reimbursement

Under the prospective payment system for hospital inpatient services, Medicare reimburses hospitals an amount based on the DRG for the particular discharge. *See* 42 U.S.C. § 1395ww(d). Congress directed the Secretary of Health and Human Services to "establish a classification of inpatient hospital discharges by diagnosis-related groups and a methodology for classifying specific hospital discharges within these groups." 42 U.S.C. § 1395ww(d)(4)(A).

Accordingly, HCFA regulations provide that each discharge is to be assigned a DRG related to the patient's principal diagnosis:

HCFA establishes a methodology for classifying specific hospital discharges within DRGs which ensures that each hospital discharge is appropriately assigned to a single DRG based on essential data abstracted from the inpatient bill for that discharge.

- (1) The classification of a particular discharge is based, as appropriate, on the patient's age, sex, principal diagnosis (that is, the diagnosis established after study to be chiefly responsible for causing the patient's admission to

the hospital), secondary diagnoses, procedures performed, and discharge status.

- (2) Each discharge is assigned to only one DRG (related . . . to the patient's principal diagnosis) regardless of the number of conditions treated or services furnished during the patient's stay....

42 C.F.R. § 412.60(c)(1)-(2).

As a condition of payment, HCFA regulations effectively require hospitals to include ICD-9-CM codes on inpatient bills, which are then used for DRG assignment. Since 1985, HCFA has required hospitals to use Form HCFA-1450 (also referred to as a "UB-92" or, formerly, as a "UB-82") as "the prescribed form[] for claims" submitted to Medicare for hospital inpatient services. *See* 42 C.F.R. § 424.32(b) (formerly designated at 42 C.F.R. § 1662). Form HCFA-1450 contains fields in which hospitals are to fill in the principal and secondary diagnoses using ICD-9-CM codes. Thus, HCFA's regulations indirectly require the use of ICD-9-CM codes through the requirement that hospitals submit claims using Form HCFA-1450.⁹

Currently, the federal government is responsible for maintaining and updating the ICD-9-CM codes.¹⁰

⁹ By contrast, HCFA regulations expressly require the inclusion of ICD-9-CM codes for claims for physician services. *See* 42 C.F.R. § 424.32(a)(2).

¹⁰ ICD-9-CM codes are derived from the World Health Organization's (WHO) International Classification of Diseases system (ICD). After World War II, the WHO created the ICD system for classifying morbidity and mortality information for statistical purposes, indexing medical records by disease and operations, and facilitating data storage and retrieval. In its original conception, the ICD system was expected to promote international comparability in the collection, processing and analysis of mortality statistics.

To streamline storage and retrieval of diagnostic data, the U.S. Public Health Service (PHS) and the Veterans Administration began testing the utility of ICD in the context of hospital coding in 1950. In 1956, the American Medical Association and the American Medical Record Association conducted a study of the relative merits of coding systems for diagnostic indexing. Following the study, the major users of ICD for hospital indices

C. Absent Legal or Regulatory Guidance, Hospitals Follow The Conventions Of Professional Coders When Preparing Medicare Claims.

Notwithstanding Deputy Attorney General Holder's assertions of "clear and unambiguous Medicare rules," coding standards have been imprecisely defined, recorded, and implemented. There are no federal statutes or regulations describing proper coding procedures or standards for pneumonia. Furthermore, as the OIG has long understood, selecting an ICD-9-CM code depends on industry conventions and the professional judgment and experience of trained coding personnel:

Processing a Medicare claim for payment commences with the patient's discharge from the hospital At the time of discharge, the attending physician (1) lists the principal diagnosis, secondary diagnoses and any inpatient procedures on the front of the chart; and (2) signs an attestation certifying the correctness of these statements.¹¹ The hospital then assigns ICD-9-CM codes to

(continued...)

consolidated their experiences and published their own adaptation of the ICD system in December 1959. In 1968, PHS published the Eighth Revision International Classification of Diseases, Adapted for Use in the United States. This publication eventually became commonly known as ICDA and was used to code diagnostic data for official morbidity and mortality statistics in the United States for a number of years.

In February 1977, the National Center for Health Statistics (ANCHS), a component of the Centers for Disease Control and part of HHS, convened a committee to provide guidance and counsel in the development of the ICDA. The committee included representatives of numerous organizations, including HCFA, WHO, AHA, the American Medical Record Association, the American Association of Health Data Systems and the American College of Physicians. The result of these efforts was ICD-9-CM, a clinical modification of WHO's Ninth Revision to the ICD. Essentially, the ICD-9-CM modifies the WHO's three-digit ICD diagnosis codes by adding a fourth and fifth digit where possible, to allow for greater specificity in classifying diagnoses.

ICD-9-CM has been in use since January 1979, with modifications. At present, a federal interdepartmental committee chaired by NCHS and HCFA, known as the Coordination and Maintenance Committee, updates and maintains the ICD-9-CM. Changes to ICD-9-CM are published annually in the Federal Register.

¹¹ [The attestation requirement was removed from the Code of Federal Regulations in 1994. See 59 Fed. Reg. 11003 (March 9, 1994).]

all diagnoses and procedures for each discharge, using the rules of the Uniform Hospital Discharge Data Set (UHDDS) and the *coding conventions known to Accredited Record Technicians (ARTs) and Registered Record Administrators (RRAs), the professional personnel trained in management of medical records and use of coding systems*. These codes are shown on the ‘face sheet’ of the medical record and on the claim for payment from Medicare.

United States Department of Health and Human Services Office of Inspector General, “National DRG Validation Study — Special Report on Coding Accuracy,” No. OIA-12-88-01010 (Feb. 1, 1988) (emphasis added) (Exh. 7).

Given the absence of a regulatory framework, several resources have helped shape industry coding convention. First among these sources is the previously discussed *International Classification of Diseases, Ninth Revision, Clinical Modification, Sixth Edition* (“ICD-9-CM Manual”), issued by the Department of Health and Human Services (“HHS”). This publication sets forth the actual codes and sequencing instructions for use in coding under ICD-9-CM.

A second important source for coding conventions is the *Official ICD-9-CM Guidelines*. (Exh. 12). The *Official Guidelines* are published by PHS and HCFA, and are developed and approved by HCFA, NCHS, AHA and the American Health Information Management Association (“AHIMA”). The *Official Guidelines* set forth general coding principles to assist coders where the *ICD-9-CM Manual* does not provide direction.

Another influential source of coding conventions is the *Coding Clinic for ICD-9-CM*. The *Coding Clinic* is published quarterly by the Central Office of the AHA, in cooperation with HCFA, NCHS and AHIMA. The *Coding Clinic* is intended to provide reference for official coding advice pertaining to questions regarding specific problems encountered during the coding process.

Additional resources include guidebooks, authoritative texts and journals, and various digest and periodical articles. *See, e.g., F. Brown, ICD-9-CM Coding Handbook, With Answers*, published by the AHA.

Finally, local Peer Review Organizations (“PRO”) and Fiscal Intermediaries sometimes offer guidance on coding matters through local medical review policies, or through the results and comments made in reviews and audits.

D. Historical Coding Conventions and Practice Are Not Free of Ambiguity

Medical record coding is not governed by federal regulations; rather, it is dependent upon informal industry convention. This informality creates some ambiguity about appropriate coding practice. These ambiguities are evident in the cases where a specific code cannot be assigned and the coder must use an “unspecified” or “other specified” code. Ambiguities also exist about which information should be used when coding. Changes in published coding instructions, such as in the case of mixed bacterial pneumonia, are another source of ambiguity.

1. The Distinction Between “Not Elsewhere Classified” and “Not Otherwise Specified” Is Confusing

The government’s theory asserts that code 482.89 (Pneumonia, Other Specified Bacteria) should rarely be used because “there are specific diagnosis codes for pneumonia-causing types of bacteria.” *OIG Semi-Annual Reports to Congress (1997-98)*.¹² Yet, the difference between codes for “other specified” conditions and codes for “unspecified” conditions has confused many coders, especially in the context of pneumonia coding. An “other specific” code is also referred to as a “not elsewhere classified” or “NEC” code, and an “unspecified” code is also referred to as a “not otherwise specified” or “NOS” code.

¹² A list of ICD-9-CM codes for bacterial pneumonia is attached as Exhibit 8.

When a more specific code is not available, coders are directed to use codes with either “Not Elsewhere Classified” (NEC) or “Not Otherwise Specified” (NOS) labels. According to the *Official Guidelines for Coding and Reporting*, NEC codes are used “when the information at hand specifies a condition but no separate code for that condition is provided.” *Official Guidelines* at 1.3. NOS codes are to be used “when the information at hand does not permit either a more specific or ‘other’ [NEC] code assignment.” *Id.*

In the context of pneumonia, ICD-9-CM code 482.89 (Pneumonia, Other Specified Bacteria) is an NEC code, and 482.9 (Bacterial Pneumonia Unspecified) is an NOS code. “Other specified bacteria” (NEC) means that the type of bacteria causing the pneumonia can be ascertained and “specified,” but no ICD-9-CM code corresponds to the particular specified bacterial pneumonia. An “unspecified bacteria” (NOS) means that the type of bacteria causing the pneumonia cannot be ascertained; all that is known is that the pneumonia is bacterial (as opposed to viral).

Exacerbating the confusion between NOS and NEC as applied to pneumonia, ICD-9-CM code 482.83 (pneumonia, other gram-negative bacteria) is considered *both* an NEC and an NOS code. Since 482.83 is a subdivision of code 482.8 (Pneumonia due to other specified bacteria), code 482.83 is considered an “other specified” or NEC code. But, code 482.83 is also defined to include “gram-negative pneumonia NOS” or unspecified gram-negative pneumonia.¹³ Under this latter definition, code 482.83 applies to patients with gram-negative pneumonia where the exact type of gram-negative bacteria is unknown or unspecified. As such, code 482.83 can be assigned, even when the exact pathogen is not “specified,” as long as the pathogen is known to

¹³ St. Anthony=s Publishing, *Premier ICD-9-CM Codebook*, 6th ed. (2001) at 210 (Exh. 8).

be gram-negative bacteria. The identification of the bacteria as gram-negative makes the diagnosis an “other specified” (NEC), while the lack of identification of a specific type of gram-negative bacteria makes the diagnosis “unspecified” (NOS). This subtle distinction significantly complicates superficially simple concepts.

At least one leading coding treatise has recognized the confusion created by NEC and NOS codes. In her coding handbook, published by the AHA, Faye Brown noted “Although their meanings appear simple, [NEC for not elsewhere classified and NOS for not otherwise specified] are often misunderstood and misapplied by coders.” F. Brown, *ICD-9-CM Coding Handbook, With Answers* (1991) at 17 (Exh. 9). Because articulating the distinction between “other specified” and “unspecified” is difficult for even experienced coders, there is little doubt why some coders have been confused. While some coders are reluctant to admit that they do not understand the distinction, such reluctance can impair a hospital’s ability to present a defense to an FCA allegation.

The likelihood of confusing “unspecified” and “not otherwise specified” is illustrated by an April 8, 1992 letter from the Morbidity Classification Branch Chief of the PHS to a health care industry consultant. Discussing proposed modifications to the ICD-9-CM codes for pneumonia, the PHS official wrote in part:

As you can see, under the proposed modifications, gram negative pneumonia NOS [not otherwise specified] will be assigned to 482.83, while gram positive pneumonia NOS will be assigned to 482.89. Both types of bacterial pneumonia are currently assigned to 482.8, since the ICD-9-CM currently makes no distinction between the two.

Exh. 6, Letter to F. Keifer from S. Meads, dated April 8, 1992. This letter shows that even the Branch Chief of PHS has confused pneumonia NOS and pneumonia NEC, because, contrary to the letter, 482.89 is an “other specified” or NEC diagnosis.

2. Medicare Policy and Coding Authorities Direct Coders To “Thoroughly Review” The Entire Medical Record To Select Most Specific ICD-9-CM Code Possible

In some instances, an admitting physician describes a patient’s illness as “pneumonia” in the medical record, but does not state whether the patient has a viral or a bacterial pneumonia. In other instances, the physician describes the patient’s illness as “bacterial pneumonia,” but does not further describe the organism or type of organism. The government now contends that in the first scenario, ICD-9-CM code 486 (Pneumonia, Organism Unspecified) must be selected because the physician failed to state whether the pneumonia was viral or bacterial. In the second scenario, the government now contends that ICD-9-CM code 482.9 (Bacterial Pneumonia Unspecified) must be selected because the physician failed to state the specific bacterial organism that caused the pneumonia. In these contexts, the government has accused hospitals of FCA violations for failure to use 486 and 482.9 (each of which leads to DRG 89).

The government’s position is correct that if nothing is known other than that the patient had “pneumonia” or “bacterial pneumonia,” then ICD-9-CM 486 and 482.9, respectively, are appropriate. Overlooked by the government’s theory, however, is the fact that a review of the entire medical record often turns up significant information beyond what is contained in the limits of a physician’s written diagnostic statement. In fact, reviewing the entire medical record (including information related to treatment, response to treatment, symptoms, laboratory results, and patient demographic information) can assist in coding a diagnosis of pneumonia with greater

specificity than the imprecise and generic statements of “pneumonia” or “bacterial pneumonia.”

See F. Brown, *ICD-9-CM Coding Handbook, With Answers* (1997) at 33-34 (Exh. 11).

The government’s position on coding is based on the premise that medical records personnel may not select an ICD-9-CM code based on information in the entire medical record. Rather, the coders are limited to the physician’s statements of the patient’s diagnosis in the medical record. As discussed below, the government’s position can be criticized on two separate bases: (1) hospitals have not defrauded Medicare when, after thoroughly reviewing the medical records, they selected the most specific ICD-9-CM code corresponding to the physician’s pneumonia diagnosis; and (2) many coding authorities — including government publications — instructed hospital coders to review the entire medical record (not just the physician’s statements) to select the most specific pneumonia ICD-9-CM code possible.

First, the Medicare prospective payment system was designed to reimburse hospitals based on the hospital resources typically consumed in treating patients with a particular diagnosis. *See* 42 U.S.C. § 1395ww(d)(4)(B) (directing Secretary to assign “an appropriate weighting factor” to each diagnosis-related group “which reflects the relative hospital resources used with respect to discharges classified within that group compared to discharges classified within other groups”). Therefore, determining a patient’s true condition by reviewing the entire medical record is consistent with the intent of the prospective payment system. Indeed, if one can determine that a patient probably had a type of pneumonia for which Medicare reimburses under DRG 79 based on a review of the entire medical record, then Medicare would have paid what it was supposed to pay. It appears incongruous to accuse a hospital of having violated the FCA by attempting to code a patient’s actual medical condition based on the entire medical

record, through review of the patient's symptoms, the treatment provided, the response to treatment, laboratory results, and patient demographic characteristics while insisting on accuracy.

Moreover, the precise bacterial organism is not always clinically relevant to a physician, even though it is relevant to the hospital. For the physician's purposes, it may often suffice to document the condition as "pneumonia" or "bacterial pneumonia." Because greater specificity in diagnosis coding is required for reimbursement purposes than may be required for treatment purposes, however, the documentation needed for proper treatment and the documentation the government now contends is necessary for Medicare reimbursement may not always coincide. Accordingly, relying solely on what the physician has documented may lead to reimbursement levels different from what Medicare was designed to pay if the record is not thoroughly reviewed.

Second, the government position that coding may only be based on the physician's own statements, without considering the entire medical record, conflicts with coding industry practices and authorities instructing otherwise. In fact, although some coding authorities support the government's position, there are many leading coding authorities that direct coders to review the entire medical record to determine the most specific ICD-9-CM code consistent with the physician's diagnosis. *See, e.g., Official ICD-9-CM Guidelines for Coding and Reporting* at 1.3; AHA, *Coding Clinic* (First Quarter, 1994) at 17-18; AHA, *Coding Clinic* (Third Quarter, 1994) at 10; F. Brown, *ICD-9-CM Coding Handbook, With Answers* (1994) at 34 (Exh. 10). These authorities are discussed below.

As a reimbursement proposition, the government's position is supported by the Second Quarter, 1998 edition of the *Coding Clinic* which restricts coding to the treating physician's diagnostic statements. According to this edition of the *Coding Clinic*, if a physician's diagnostic statement merely states "pneumonia," then the coder must use 486 (Pneumonia, Organism Unspecified). The Second Quarter, 1998 *Coding Clinic* also suggests that coders ask treating physicians to supplement their diagnostic statement in the medical record if a more specific diagnostic code would be supported by the medical records.¹⁴ Of course, even though HCFA is one of the Cooperating Parties for the *Coding Clinic*, that publication is not a statement of law or binding regulation.

On the other hand, the regulatory definition of "principal diagnosis" indicates that coders should "study" the medical record to determine the most specific code applicable to the diagnosis. "Principal diagnosis" is defined as "the diagnosis established *after study* to be chiefly responsible for causing the patient's admission to the hospital." 42 C.F.R. § 412.60(c)(1) (emphasis added). The regulation does not, however, specify what is meant by "after study," but that language appears to indicate, at least, that the medical record should be reviewed to determine the proper diagnosis.

Other coding authorities more explicitly directed coders to go beyond the physician's diagnostic statements to ascertain the most specific ICD-9-CM code supported by the entire medical record. While coders were only to code pneumonia if the physician made a diagnosis of pneumonia, coding authorities told coders to scrutinize the medical records to determine the most specific pneumonia ICD-9-CM code. For instance, the government's *Official ICD-9-CM*

¹⁴ AHA, *Coding Clinic*, (Second Quarter, 1998) at 3-6.

Guidelines For Coding And Reporting advised coders to review the entire medical record to select the most specific code possible, and directed coders not to use “unspecified” codes (such as 486 and 482.9) unless a thorough review of the medical record fails to disclose a more specific code for the diagnosis in question. Guidelines 1.2 and 1.3 of *Official ICD-9-CM Guidelines For Coding And Reporting* provide in part:

- *Guideline 1.2*: “Diagnostic and procedure codes are to be used at their highest level of specificity.”
- *Guideline 1.3*: “Codes labeled ‘otherwise specified’ (NEC — not elsewhere classified) or ‘unspecified’ (NOS — not otherwise specified) are used only when *neither* the diagnostic statement *nor a thorough review of the medical record provides adequate information to permit assignment of a more specific code.*”

Health Care Financing Administration, *Official ICD-9-CM Guidelines For Coding And Reporting* (1997) (emphasis added). Guideline 1.2 creates a presumption against the use of codes 486 and 482.9, and Guideline 1.3 directs coders not to use 486 and 482.9 unless a “thorough review of the medical record” fails to provide adequate information to permit assignment of a more specific code. In plain words, coders are directed to review thoroughly a medical record to determine the most specific ICD-9-CM code to use. In short, a cryptic diagnostic statement by a physician does not end the coder’s obligation to review the medical record and identify, where possible, a code at the “highest level of specificity.” *See id.*

The *Coding Clinic* has repeated the instruction in Guideline 1.3 that an “unspecified” code (such as ICD-9-CM codes 486 and 482.9) should not be used unless a “thorough review of the medical record” fails to provide adequate information to support a more specific code. *See, e.g.,* January-February, 1986 (quoting Guideline 1.3); First Quarter, 1997 (same). The Third Quarter, 1994 *Coding Clinic* addressed the issue of ICD-9-CM code selection in cases in which

“[a] patient is discharged with the diagnosis of pneumonia; however, the physician’s diagnostic statement does not specify the organism.” In response, the *Coding Clinic* stated:

Code assignment is always based on the physician’s diagnostic statement. If the physician has not specified the organism, then code 486, Pneumonia unspecified, should be assigned. All code assignments should be based upon the medical record documentation; therefore, it is inappropriate to assume the presence of an organism when the documentation cannot support the code assignment.

* * *

As stated in the January-February, 1986 *Coding Clinic* and the official coding guidelines (Guideline 1.3) unspecified codes ‘. . . are used only when neither the diagnostic statement nor a *thorough review of the medical records* provides adequate information to permit assignment of a more specific code.’ An unspecified code should be assigned when the information at hand does not permit either a more specific or ‘other’ code assignment.

Third Quarter, 1994 *Coding Clinic* (emphasis added). Though not free of ambiguity, this guidance appears to advise coders that: (1) a physician’s diagnostic statement of pneumonia is required to code pneumonia; and (2) the coder must review medical record documentation to determine which specific pneumonia code is appropriate.

As early as 1994, the *Coding Clinic* called upon coders to conduct a thorough review of the medical records to identify the most specific pneumonia code. The First Quarter, 1994 edition of the *Coding Clinic* considered the question: “Is code 482.89, Other bacterial pneumonia, the correct code assignment for a patient with pneumonia and a gram stain identifying gram positive cocci?” The *Coding Clinic* responded:

No, code 482.89, Other bacterial pneumonia, Other specified pneumonia, should not be assigned *solely* on the basis of a gram stain. A sputum gram stain finding of gram-positive cocci is not necessarily indicative of a bacterial pathogen and, therefore, should not be coded as a specified cause of bacterial pneumonia *without*

further chart documentation or definitive sputum cultures. If the physician states that the patient had a bacterial pneumonia without further specification, assign code 482.9, Bacterial pneumonia unspecified. If the physician does not specify an etiology, code 486, Pneumonia, organism unspecified, should be assigned.

First Quarter, 1994 *Coding Clinic* (emphasis added). Thus, the *Coding Clinic* instructs coders that the selection of a specific code corresponding to a particular bacterial pneumonia can be based on further “chart documentation or definitive sputum cultures,” sources which are expressly not limited to “physician statements.” The direction in the final two sentences of the response, that coders should use “unspecified” codes of 482.9 and 486 where the physician fails to specify the type of bacteria or etiology, apparently only applies to the situation where a more particular code is not ascertainable from the medical record or a definitive sputum culture.

Authoritative texts also instructed coders to determine the ICD-9-CM code based on a thorough review of the medical record to achieve greater specificity than provided in the physician’s diagnostic statement. As one leading text states in pertinent part:

The source document for coding and reporting diagnoses and procedures is the medical record. Although discharge diagnoses are usually recorded on the face sheet or the discharge summary of the record, further review of the medical record is needed to ensure complete and accurate coding. Operations and procedures often are not listed on the face sheet or are not described in sufficient detail, making a review of operative reports, pathology reports, and other special reports imperative.

* * *

If there is enough information to make it likely that an additional diagnosis should be reported, the physician should be consulted; no diagnosis should be added without the approval of the physician.

* * *

[D]iagnoses are not always recorded with sufficient information for required specificity in coding. A diagnosis of pneumonia may not indicate the organism responsible for the infection; a review of diagnostic studies of the sputum may provide this information. A diagnosis of fracture may indicate the bone but not the particular part of the bone,

information necessary for accurate code assignment; the X-ray report will provide this information. A diagnosis of myocardial infarction may not specify the wall affected; the electrocardiogram report includes this information. It is appropriate to use medical record information to provide more specificity in coding without obtaining concurrence from the physician.

[The text then offers four examples] “that are often recorded with less-than-complete information but can be coded more specifically by reference to diagnostic reports within the medical record,” [including:]

Diagnosis:	Pneumonia	486
Laboratory Report:	<i>Klebsiella present in sputum</i>	482.0

F. Brown, *ICD-9-CM Coding Handbook, With Answers* (1997) at 33-34 (Exh. 11). According to this text, while a coder may not determine a *diagnosis* without physician approval, a code may be assigned for that diagnosis using “medical record information to provide more specificity in coding without obtaining concurrence from the physician.”¹⁵

Therefore, according to this text, if a physician’s diagnostic statement merely provides “pneumonia” or “bacterial pneumonia,” a coder should review the entire medical record to identify a more specific ICD-9-CM code for pneumonia. In the textbook’s example, where the physician’s diagnostic statement simply stated “pneumonia” and a lab result indicated specific bacteria, the coder was instructed to use the code corresponding to that specific bacteria. Both the textbook’s general guidance — and its specific example on pneumonia coding — directly contradict the coding premise of the government’s investigative theory.

¹⁵ Until September 1, 1995, a HCFA regulation required the admitting physician to attest that the “narrative descriptions of the principal and secondary diagnoses and the major procedures performed are accurate and complete.” 42 C.F.R. § 412.46 (1994). While the regulation was in effect, if a coder believed that a more specific pneumonia code applied than the code appearing on the attestation, it may have been appropriate to obtain a revised attestation before finalizing the coding change. F. Brown, *ICD-9-CM Coding Handbook, With Answers* (1994) at 34 (Exh. 10).

The significant industry guidance that directed coders to supplement the physician's diagnostic statement with a review of the entire medical record is not contradicted by any Medicare rule or regulation. Indeed, there is no regulation that restricts diagnosis coding to the physician statement. Absent such a legal restriction, accurate coding requires the coder to review and consider all available information in order to choose the most accurate code possible.

3. Coding Instructions Changed For Mixed Bacterial Pneumonia

Changes in the instructions regarding coding for mixed bacterial pneumonia also caused confusion among many hospital coders. The Third Quarter, 1988 *Coding Clinic* provided instructions regarding the coding of mixed bacterial pneumonia that were "superseded" by the Second Quarter, 1997 *Coding Clinic*. The Third Quarter, 1988 *Coding Clinic* stated that the "diagnoses of gram-negative pneumonia, probable gram-negative pneumonia and mixed bacterial pneumonia should be assigned to ICD-9-CM Code 482.8 [now 482.89], Pneumonia due to other specified bacteria," resulting in DRG 79. Nine years later, the Second Quarter, 1997 *Coding Clinic* reversed this 1988 instruction as to mixed bacterial pneumonia, and advised that code 482.9 (Bacterial Pneumonia Unspecified), which results in DRG 89, should be used when the diagnosis cannot be determined with any greater specificity than mixed bacterial pneumonia. The *Coding Clinic* noted that "[t]his advice supersedes advice published in *Coding Clinic*, Third Quarter 1988, page 11." Second Quarter, 1997 *Coding Clinic*.

A government challenge to the coding of mixed bacterial pneumonia cases prior to the second quarter of 1997 reasonably can be defended on the grounds that coders were following express instructions then in effect. Even after the second quarter of 1997, it is unreasonable to

expect that all hospital coders immediately learned of the change in coding convention as expressed in the *Coding Clinic*, and that publication is neither a law nor a Medicare requirement.

E. Many Coding Errors Do Not Have Reimbursement Consequences

Depending on the facts, a hospital may also have defenses available that coding errors identified by the government did not result in billing errors. A number of different pneumonia ICD-9-CM codes lead to DRG 79. Accordingly, even if the government has identified an error in ICD-9-CM coding, the provider should still review the medical record to determine whether the coding error actually resulted in an incorrect payment.

For example, the government has challenged many hospitals' usage of ICD-9-CM 482.89 (Pneumonia, Other Specified Bacteria) in cases when the hospital could legitimately have assigned code 482.83 (Pneumonia, Other Gram-Negative Bacteria). Both 482.89 and 482.83 result in DRG 79 reimbursement. Therefore, the alleged coding error did not lead inevitably to an increase in reimbursement to the hospital.

The Third Quarter, 1988 *Coding Clinic* set out a number of clinical factors that support a diagnosis of gram-negative pneumonia:

The findings in a debilitated, chronically ill, or aged patient that suggest a complicating gram-negative pneumonia include: (1) worsening cough, dyspnea, reduction of oxygen level, (2) fever, (3) purulent sputum, (4) patchy infiltration on chest x-ray (in addition to those previously noted densities caused by a primary underlying disease), and (5) elevated leukocyte count or a normal count in aged and debilitated patients. . . . Gram negative pneumonia usually appears as a complication of anesthesia, surgery . . . , trauma, or various chronic illnesses, such as cardiac failure, advanced carcinoma, uremia, or alcoholism. Gram-negative pneumonia is a common complication of COPD and immunosuppressive states.

Third Quarter, 1988 *Coding Clinic*; see also L. Tierney, M.D., S. McPhee, M.D. & M. Papadakis, M.D., *Current Medical Diagnosis & Treatment* (1997) at Table 9-8. Where these clinical factors are present and suggest a gram-negative pneumonia, hospitals can take the position that using ICD-9-CM code 482.89, even if inaccurate, did not result in increased payment because the ICD-9-CM code for gram-negative pneumonia [482.83] is also assigned to DRG 79.

One reason that some coders used 482.89 instead of 482.83 to code gram-negative pneumonia cases may have been confusion engendered by the Third Quarter, 1988 *Coding Clinic* and a 1992 redesignation of pneumonia ICD-9-CM codes. As noted above, the Third Quarter, 1988 *Coding Clinic* instructed coders to assign the ICD-9-CM code for pneumonia due to other specified bacteria, which is now 482.89, to gram-negative pneumonia cases. In 1988, code 482.8 was the code for pneumonia due to other specified bacteria. On October 1, 1992, the ICD-9-CM codes were restructured, and former code 482.8 was divided into four new codes including: 482.83 (Pneumonia, Other Gram-Negative Bacteria) and 482.89 (Pneumonia, Other Specified Bacteria). Thus, after October 1, 1992, pneumonia due to unspecified gram-negative pneumonia should have been coded to 482.83. Because the Third Quarter, 1988 *Coding Clinic* stated that gram-negative pneumonia should be assigned to the then-existing code for pneumonia due to other specified bacteria, some coders after 1992 used 482.89, persisting in using the code for other specified bacterial pneumonia. Such coders were apparently unaware that newly created 482.83 had been created for unspecified gram-negative pneumonia, and could have employed that code. Hospitals under investigation for alleged excessive usage of 482.89 should determine

whether coders believed this code was the code to use for cases of probable gram-negative pneumonia.

F. Significance of Physician Attestation

Until September 1, 1995, hospitals were required to obtain a signed attestation from the attending physician certifying the principal diagnosis, secondary diagnoses and the names of any major procedures performed. The attestation provided:

I certify that the narrative descriptions of the principal and secondary diagnoses and the major procedures performed are accurate and complete to the best of my knowledge.

42 C.F.R. § 412.46 (1994). HCFA explained this requirement as a protective mechanism to ensure the validity of the data on each claim. During the time the regulation was in effect, HCFA “believed that the physician was in the best position to attest to th[at] information.” *See* 60 Fed. Reg. 45778, 45807 (1995). Thus, HCFA believed, if the physician attested to the data included in the hospital claim, the accuracy of that claim could be accepted.

In an effort to reduce the administrative burden on physicians, HCFA eliminated the requirement that a physician attest to the validity of each individual hospital claim submitted. *See* 60 Fed. Reg. at 45779. Many hospitals, however, continued to obtain signed physician attestations similar to those formerly required by regulation with each Medicare claim submitted.

Depending on the facts and circumstances, the signed physician attestations may provide some hospitals with a defense, at least as to certain challenged claims. If the attending physician attested to the validity of a diagnosis or ICD-9-CM code set forth on a face sheet before the claim is submitted for payment, the attestation provides ample support for the hospital’s coding and would undermine any notion that the hospital violated the FCA.

G. Reasonable Reliance Upon Advice of Consultants

It is eminently reasonable for healthcare providers to seek guidance from qualified consultants to help prepare, review and submit claims to Medicare on behalf of the provider. The complex and ever-changing web of rules relating to Medicare claims submission all but demands that even the most sophisticated hospitals seek specialized expertise. The use of such consultants in many cases arises from a hospital's desire both to comply with the Medicare billing rules and to ensure that the hospital receives all the reimbursement to which it is entitled for patient care. Indeed, those charged with managing a hospital have fiduciary duties to ensure the hospital receives the full payment to which it is entitled, in addition to their obligations to follow the law.

A hospital's good faith reliance on the advice of an expert coding consultant may afford a defense to a FCA violation.¹⁶ The FCA imposes liability on one who "knowingly" presented or caused to be presented a false or fraudulent claim for payment. *See* 31 U.S.C. § 3729(a). A hospital that engaged a qualified expert billing consultant to assist in coding, to ensure that inpatient claims were accurately presented and properly submitted, can argue that it did not "knowingly" submit a false claim, even if the government now attacks the claim as mis-coded. Hospitals can press that good faith reliance on a qualified consultant demonstrates a lack of fraudulent intent. On the other hand, the reliance on a consultant defense would not be available where a hospital knowingly relied upon dubious advice. *See United States v. Lorenzo*, 768 F.

¹⁶ Cases outside the healthcare context hold that reasonable reliance on consultants is a defense to fraud or other culpable conduct. *See, e.g., Sammons v. Commissioner*, 838 F.2d 330, 337 (9th Cir. 1988); *Wehri v. Security Bank of Hebron*, 212 B.R. 963 (D.N.D. 1997); *Vaughan v. Murray*, 116 B.R. 473 (E.D. Va. 1990); *Ewing v. Commissioner*, 91 T.C. 396, 423-24 (1988).

Supp. 1127, 1132 (E.D. Pa. 1991) (provider liable under FCA, where provider knew that consultant's advice was based on incomplete portrayal of the facts).

Although there are thus many factual issues to consider in preparing a defense based on "good faith reliance," the defense should be available where a provider relied in good faith on a qualified consultant.

III. AFFIRMATIVE COMPLIANCE MEASURES

By now, most hospitals have implemented a compliance program. Whether pursuant to a hospital's formal compliance program or otherwise, there are a number of affirmative compliance measures that hospitals should consider in connection with pneumonia coding. These measures include: (1) reviewing current pneumonia coding practices; (2) conducting a self-review of past pneumonia cases; and (3) making refunds to Medicare in the event the hospital concludes it was overpaid for pneumonia cases. While these compliance measures are discussed here in the context of pneumonia, they also provide a basis for hospitals to review other areas of government inquiry that pose a risk of coding error, such as septicemia (DRG 416).

Each of the topics discussed below warrants a more complete discussion and analysis that is beyond the scope of this document. Only the key considerations and basic points are addressed here. Hospitals should confer with qualified counsel for legal advice, and should read the discussion below to help them identify issues to discuss with their counsel.

A. Review Current Coding Practices and Operations

In light of the attention the government's Pneumonia Coding Project has received and the clarifications to pneumonia coding conventions set forth in the Second Quarter, 1997 and Second Quarter, 1998 editions of the *Coding Clinic*, the government now expects hospitals to be coding

pneumonia cases based solely on the physician's written diagnostic statement (which the physician may supplement based on coder inquiry). Similarly, the government now expects hospital coders to distinguish correctly 482.89 (Pneumonia, Other Specified Bacteria) from 482.9 (Bacterial Pneumonia Unspecified), and to make the other fine distinctions among the ICD-9-CM pneumonia codes.

Accordingly, hospitals should consider undertaking compliance measures to ensure and document that their coders have a good understanding of current pneumonia coding standards. This can be accomplished through inservice training, evaluation by qualified outside consultants, or having compliance department personnel discuss pneumonia coding with the medical records staff to ensure that the coders feel confident. Education of the medical staff is also beneficial so that their diagnostic statements can be as accurate as possible.

As an additional measure, hospitals should consider monitoring and auditing for a period of time all claims coded with 482.83 or 482.89, or with DRG 79. Such monitoring will validate and document that the coders have a competent grasp of current pneumonia coding standards.

As noted, this review of current coding measures need not be limited to pneumonia. Although the educational message can be diluted if hospitals attempt to squeeze too many different topics into the inservice training, hospitals may wish to select other difficult to code conditions that can create a potential for allegations of "upcoding," such as diagnostic codes relating to DRGs 416 (septicemia), 296 (nutritional and miscellaneous metabolic disorders) and 127 (heart failure and shock).

B. Evaluate Whether Self-Review Of Past Coding Is Warranted

Hospitals may wish to evaluate whether a review of their past pneumonia coding practices is warranted. An important component of compliance is to correct past instances of regulatory noncompliance that are known to the hospital. Indeed, if a Medicare provider knows that it has received overpayments by Medicare, it may be required to disclose the overpayment to the fiscal intermediary. The Medicare Fraud and Abuse Statute prohibits the knowing failure to disclose the “occurrence of any event affecting [one’s] initial or continued right to ...[a] payment... with intent fraudulently to secure such... payment...either in greater amount than is due or when no such...payment is authorized.” 42 U.S.C. § 1320a-7b(a)(3). Though the statute is awkwardly worded, the government has interpreted it to mean that it is a felony for a healthcare provider to fail to disclose an overpayment from a federal health program even if the provider was not the cause of the overpayment. *See* HHS-OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8987, 8998 (Feb.23, 1998). As noted, the statute only applies where a provider has “knowledge” that it has been overpaid.

In some cases, past regulatory noncompliance may not necessarily be known, but there may be indications of one kind or another indicating past regulatory noncompliance. If the indications are great enough, then hospitals may feel they are on “inquiry notice” sufficient to warrant a further self-review. Obviously, the particular facts and circumstances will determine whether a self-review is warranted.

Another reason to determine whether a self-review is warranted is to anticipate a possible government investigation of pneumonia coding. A hospital that conducts a self-review of pneumonia coding (or other coding), determines that it has been overpaid, and refunds an

overpayment, ought to be viewed more favorably by the government than an otherwise similarly situated hospital that did not take such compliance measures.¹⁷ Some hospitals and their attorneys, however, report that they did not appear to have received more lenient treatment due to their self-reporting. Indeed, in some instances, internal reviews and disclosures may have provoked investigations that might not otherwise have occurred. The government should be held to its assurances of lenience and should be more accommodating with providers who have taken such affirmative compliance measures, as a matter of fairness and sound public policy.

Following an assessment of current coding practices, a hospital may find a self-review of past coding is warranted. If the hospital's coders do not understand well the intricacies of pneumonia coding and have been at the hospital for some time, there is a possibility of prior inaccurate coding.

In addition, hospitals may wish to compare their utilization of DRG 79 and ICD-9-CM codes 482.83 and 482.89 against national, regional or state norms. Hospitals whose past usage of such codes substantially exceeded national norms may be subject to government investigation, and may wish to conduct a self-review. Many state hospital associations, consulting firms, and Peer Review Organizations have readily accessible information about state and national DRG utilization averages, which can be used by hospitals for compliance comparisons in their state or region. Utilization studies should also consider changes in code utilization from year to year. A significant increase or decrease in the use of a given code may indicate that further review is necessary.

¹⁷ See HHS-OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8987, 8998 (Feb. 23, 1998); *see also* DOJ Guidelines at 4.

A review of the historic coding process may also indicate that a self-review is warranted. For instance, some hospitals may discover that in the past they outsourced the coding function to a consultant or otherwise relied upon the input or advice of an outside consultant. To the extent the consultant had an incentive under the compensation arrangement to maximize reimbursement without a corresponding financial incentive to identify overpayments, the consultant's advice may have been tainted. Obviously, not all consultants paid on a contingency basis provided faulty advice. Moreover, some consultants have considerable experience and enjoy excellent reputations for high quality work, and their use would not raise concerns. Depending on the facts and circumstances, however, the past use (or non-use) of consultants is a factor to consider in determining whether a self-review is warranted.

Hospitals that used in-house resources to code may also conclude from investigating the historic coding process that a self-review is warranted. Coders may disclose, for example, that they believe that they or their peers did not understand how to code pneumonia cases correctly or that their manner of coding did not conform to the government's current position on coding. Again, depending on the particular facts and circumstances, a hospital may conclude that it should conduct a self-review.

C. Performing A Self-Review

Once it is determined that a self-review of past pneumonia coding is warranted, there are a number of issues that must be considered before such a review is undertaken. For example, should the review be privileged? Who should review the charts? What is the scope of the review? What is the proper standard for reviewing charts? A hospital that launches a self-review without first addressing these issues may incur considerable time and expense later

redoing or fixing an improperly conducted self-review. In addition, a poor experience conducting a pneumonia self-review could have the unfortunate effect of deterring an institution from undertaking important self-reviews in the future.

1. Privileged and Non-Privileged Reviews

An initial issue to consider is whether the self-review should be performed under the direction of legal counsel. Of course, self-reviews can be done without the assistance of counsel, and many compliance reviews are routine business operations that do not involve legal counsel. Many hospitals conduct non-privileged “compliance reviews” as part of their compliance program and may decide to review their pneumonia coding as part of that process. Further, reviews done with the expectation that the results will be disclosed to the government (*e.g.*, reviews mandated by a corporate integrity agreement) are not likely to be privileged, even if done under the direction of counsel.

In the context of a pneumonia coding self-review, engaging legal counsel can add additional protections that may be advisable. Since pneumonia coding is an active area of enforcement, pneumonia self-reviews directed by counsel — unlike routine compliance reviews conducted in the ordinary course of business — would seemingly be protected under both the attorney-client privilege and attorney work product doctrine. As the Supreme Court has noted, the purpose of the attorney-client privilege is to encourage individuals to communicate with and provide information to an entity’s lawyer, so the lawyer can provide the best possible legal advice. *See Upjohn Co. v. United States*, 449 U.S. 383, 390 (1981). Communications with internal legal resources, such as the General Counsel’s office, are also afforded the protections of

the attorney-client privilege as long as the lawyers can demonstrate that they were acting as attorneys and not as business advisers.¹⁸

2. Identifying The Review Team

After determining whether the self-review will be conducted on a privileged basis, hospitals must decide who will conduct the review. Should it be performed using internal resources or external resources? Issues of expense and professional competence are obviously relevant. The use of hospital employees may pose some problems if the reviewers are too close to the individuals who did the original coding or set historic coding practices. Even where such a concern is not justified, some hospitals prefer to use an outside consultant rather than internal resources in the belief that the findings of the self-review would have greater credibility if investigated by the government. When the review is being conducted under the direction of counsel, the attorneys need to engage and give instruction to either the internal or external reviewer.

The review team should include individuals with expertise in coding, auditing, and the relevant clinical issues. A single coder, nurse or physician may have all the necessary skill sets, but in some instances it may be preferable to have a team conduct the review.

3. Setting The Review Parameters

Before commencing the review, the review team should discuss and agree upon the parameters of the review. The parameters of the review should be recorded in a work plan that clearly identifies the codes to be reviewed, the standards to be applied by the reviewers, the time

¹⁸ Some courts, however, have noted difficulty in determining whether an in-house attorney is providing (privileged) legal advice or whether the attorney is providing business or operational advice (which would not be privileged). *See, e.g., United States Postal Service v. Phelps Dodge Refining Corp.*, 852 F. Supp. 156, 160 (E.D.N.Y. 1994).

period under scrutiny, sampling and extrapolation plans, fact gathering beyond medical record reviews, and the format of the final report.

The work plan should clearly identify the coding standards that the reviewers will apply. As discussed above, coding guidance has not been consistent as to whether coding may be based on a review of the entire medical record to determine the most specific pneumonia code or whether coding must be based solely on the physician's written diagnostic statement which may not have the necessary specificity to allow for coding for the patient's actual pneumonia pathogen. Since pneumonia coding conventions have changed over time, the reviewers should apply the correct standards for the time period in question. Otherwise, the self-review would be either too lenient or too harsh. Guidance on pneumonia coding from the local PRO and FI should also be considered to assist in determining the standards for review. Both PRO and FI general communications and memoranda, and specific communications to the hospital (*e.g.*, correspondence and results of audits and reviews) should be considered.

The work plan should also identify the time frame for review. As a general rule, HCFA's Hospital Manual suggests that in the absence of fraud, hospitals are liable for recoupment of Medicare overpayments within four years of the payment determination. *See* Hospital Manual § 488. This is not to say that all self-reviews should go back four years, but that period has a reasonable basis in the regulations. A hospital's particular facts and circumstances may point to a particular time frame to review, such as a time period determined by changes in hospital operations or personnel, the presence of particular coding consultants, or sudden shifts in the frequency of DRG 79 or particular ICD-9-CM codes.

Sampling and extrapolation decisions should be made before the commencement of a self-review. The hospital's reviewers should determine whether they will be reviewing all cases under review, or just review a sample that will be projected over a wider universe of claims. While situations vary, it may make sense to review initially a probe sample to determine whether a full review is necessary.

The work plan should also identify the facts to be gathered beyond the medical records. Hospitals should consider interviewing coders, those involved in the hiring and management of coding consultants, as well as others who may have relevant knowledge within the hospital. These individuals' accounts of how pneumonia cases were coded may help determine the nature of any disclosure to be made and will also help a hospital understand its potential vulnerability. If attorneys are hired to provide legal advice and direct these interviews, the attorney-client privilege and work product doctrine protections will be available. Conducting interviews and taking notes of such interviews outside of a privileged context can unnecessarily result in the creation of inculpatory evidence and may require disclosure of sensitive information. Consider also whether employees are more willing to be candid where their statements are not subject to the privilege. Beyond the coder interviews, prior consulting advice and prior PRO audits (if any) should be reviewed.

Finally, consultants or in-house personnel preparing reports should be cautioned against reaching legal conclusions, such as whether the hospital committed "fraud," or violated the FCA. Whether the hospital committed fraud or violated the FCA are legal conclusions, not factual findings. Internal review reports should focus on objective facts and analysis (*e.g.*, does the medical record and/or physician's diagnostic statement support the code selected or another code

leading to the same DRG payment?). Needlessly stating in a report that the hospital may have violated the FCA, without full consideration of all facts and potential defenses, can be unfairly prejudicial to a hospital. Similarly, recommendations for employee discipline or legal claims against previous consultants are generally inadvisable in such reports.

D. Disclosing and Refunding Overpayments to Medicare

If a hospital determines, following a self-review, that it has been overpaid, there are a number of means by which the hospital may disclose the overpayment. Repayments related to the correction of mistakes, absent fraud and or intentional misconduct, can and should be made promptly to the entity responsible for claims processing and payment (*i.e.*, the fiscal intermediary in the case of Medicare). Repayments under these circumstances can be made without the involvement of law enforcement agencies. Such a disclosure should identify the claims for which the refund is being made or at least the relevant time period. If the refund was calculated based on a projection of the review of a sample of claims, then the methodology for making the calculation should be disclosed as well. The disclosure should also discuss the training, monitoring and other affirmative compliance measures being undertaken to ensure accurate pneumonia coding in the future and/or identify reasons why the hospital believes there is no basis for continuing concern regarding pneumonia coding.

If the hospital's pneumonia coding conduct potentially involved fraud or FCA violations, however, it may be appropriate or prudent to disclose to the local United States Attorney's Office and to the OIG, either under the OIG's formal Self-Disclosure Protocol or otherwise. Qualified counsel can advise hospitals on the "who, what, when and how" of such self-disclosures.

IV. CONCLUSION

The government is devoting considerable resources to its Pneumonia Coding Project. Both civil and criminal pneumonia coding investigations are underway. Depending on particular facts and circumstances, hospitals may have a number of defenses to FCA allegations, and should confer with qualified counsel. Hospitals may be able to contest the coding standards and approaches applied by the government or develop defenses from the particular facts within the hospital. In addition, there are a number of affirmative compliance measures that hospitals may wish to consider implementing before any government inquiry begins. Prompt repayment of any determined overpayments, however, should always be made by the hospital.

EXHIBITS

1. Complaint, United States ex. rel. Health Outcomes Technologies v. [under seal], Civ. No. 96-1552 (E.D. Pa.)
2. Deputy Attorney General Eric H. Holder, Jr., Address to The American Hospital Association (February 1, 1999)
3. Redacted contact letter from DOJ
4. Redacted “model” subpoena from OIG
5. Deputy Attorney General Eric Holder, “Guidance on the Use of the False Claims Act in Civil Health Care Matters” (June 3, 1998)
6. Letter to F. Keifer from S. Meads, dated April 8, 1992
7. United States Department of Health and Human Services Office of Inspector General, “National DRG Validation Study — Special Report on Coding Accuracy,” No. OIA-12-88-01010 (Feb. 1, 1988)
8. St. Anthony’s Publishing, *Premier ICD-9-CM Codebook*, 6th ed. (2001) (selected pages)
9. F. Brown, *ICD-9-CM Coding Handbook, With Answers* (1991) (selected pages)
10. F. Brown, *ICD-9-CM Coding Handbook, With Answers* (1994) (selected pages)
11. F. Brown, *ICD-9-CM Coding Handbook, With Answers* (1997) (selected pages)
12. Official ICD-9-CM Guidelines for Coding and Reporting (2000)