SUMMARY REPORT

ICD-9-CM COORDINATION AND MAINTENANCE COMMITTEE

May 17 - 18, 2001

May 17, 2001 - Procedures Discussions

Introduction and Overview

Pat Brooks welcomed the participants to the ICD-9-CM Coordination and Maintenance (C&M) Committee meeting. Over 125 participants attended the meeting. All participants introduced themselves. An overview of the C&M Committee was provided. It was explained that the Committee meetings serve as a public forum to discuss proposed revisions to the ICD-9-CM. The public is given a chance to offer comments and ask questions about the proposed revisions. No final decisions on code revisions take place at the meeting. As this is strictly a coding meeting, no discussion is held concerning DRG assignment or reimbursement issues. After the meeting, a summary of the procedure part of the meeting is posted on the home pages of HCFA. The diagnosis part of the meeting is conducted by the National Center for Health Statistics (NCHS). NCHS posts a summary of the diagnosis part of the meeting on their home page. May 17 was devoted to procedure issues, while May 18 was devoted to diagnosis issues. We encourage the public to submit written comments by mail or e-mail concerning issues raised at the meeting. The deadline for these comments is January 8, 2002 on the proposed code revisions or the possible implementation of ICD-10-PCS (Procedure Coding System).

Copies of the timeline were presented to participants. This timeline discusses important events relating to the updating of ICD-9-CM. Topics discussed at this meeting were for code changes effective on October 1, 2002.

HCFA Update

The FY-2002 addendum for the ICD-9-CM procedure revisions has been posted on HCFA's homepage at: http://www.hcfa.gov/stats/icd9fy02.htm. This addendum goes into effect on October 1, 2001.

The Medicare Program Notice of Proposed Rule Making (NPRM) on proposed changes to the inpatient prospective payment system was published May 4, 2001. This can be accessed at: http://www.hcfa.gov/regs/regsnotices.htm. Participants were urged to pay close attention to information relating to the Benefits Improvement and Protection Act of 2000 (BIPA). Section 533 of Public Law 106-554 addresses requirements for incorporation of new medical services and technologies into the inpatient prospective payment system. Some of these requirements involve improving the ICD-9-CM coding process. Congress has expressed concern about the length time it takes to get a new code, as well as the lack of detail and shortage of available codes in the current coding system. The Secretary of Health and Human Services was required to prepare a report to Congress on improvements to the coding process. The Department was required to seek public comment on these proposed changes. The NPRM describes issues

considered in attempting to speed up the process and provide for additional codes.   Participants were urged to carefully read these proposals and provide comments within the comment period.

The Departments' recommendations included shortening the update process by moving the November meeting to December. It was also proposed that new procedure codes discussed at the spring meeting go into effect the following October 1. This would reduce the minimum time between code request and implementation from 11 to 6 months.   Potential problems with this proposal were described. An additional proposal to utilize 100 codes from Chapter 17 of the ICD-9-CM procedure book was also described. Ann Fagan's proposal on high-dose Interleukin (below) illustrates what the use of this chapter could look like. The audience was asked to carefully consider these issues and then to provide comments on the NPRM by July 3, 2001, the end of the comment period.

Query Forms

Mark Krushat announced a Town Hall meeting which HCFA will host on query forms. Hospital coders use query forms to ask physicians to clarify or augment diagnostic and/or procedural information about the patient. Coders then use this information from the physician in order to add or change codes on the medical record. The forms vary considerably in how they are constructed. HCFA's position has been that query forms should not substitute for documentation in the medical record. This Town Hall meeting will be held to discuss the nature of query forms and how they should be constructed and used. A federal register notice is being prepared to notify the public about the meeting scheduled for July 27 in the HCFA auditorium. Additional information will be posted on the HCFA homepage under Meetings, Events, and Workgroups.

High-Dose Interleukin-2

Ann Fagan led the discussion on the proposed coding revision concerning this antineoplastic drug therapy. Dr. Michael Atkins provided support for the clinical aspects of this discussion. One participant questioned whether it was a good idea to create a unique code for a drug dispensed in this manner, pointing out that if practice changes and the drug was dispensed in a different manner, this code would immediately be obsolete. Another participant questioned why this was being referred to as a new technology, when in fact this drug has been used for a while. Dr. Atkins replied that the high-dose use of Interleukin-2 is new and that the Food and Drug Administration recently approved this dosage.

Another participant asked how coders would know whether the dose given was high-dose or not. Dr. Atkins replied that generally those patients given high-dose Interleukin-2 are treated in the intensive care unit and require careful monitoring. The participant asked how one would code the administration of low-dose Interleukin. After discussion, meeting participants agreed that low-dose Interleukin regimens should continue to be assigned to code 99.28, Injection or infusion of biological response modifier [BMR] as an antineoplastic agent.

A participant asked how many patients might receive this therapy. Dr. Atkins estimated that approximately 1,000 patients a year might benefit from the therapy.   A participant asked if a more generic code title might be appropriate. A suggestion was made to title the code "Intensive biologic agent used as antineoplastic agent". Others concurred, agreeing that this code title was

more appropriate than limiting the code to Interleukin-2, and suggested that Interleukin-2 be used as an "includes note", as well as specifically indexed.

ICD-10-PCS - Should it replace ICD-9-CM as the procedure coding system for inpatients?

It was explained that the rest of HCFA's part of this Committee meeting would be devoted to ICD-10-PCS. The discussion would center on whether or not HCFA should proceed to have ICD-10-PCS named as a national standard, replacing the current ICD-9-CM procedure codes for inpatient hospital use. Organizations were given the opportunity to submit a position paper and make a presentation on this issue. Eleven organizations requested the opportunity to present on this issue.   The position papers developed are attached. The presenter's remarks summarized these position papers.   The following are excerpts from the testimony.

> " ICD-10-PCS represents a significant improvement over ICD-9-CM and substantially meets the characteristics of a procedural coding system outlined by the NCVHS as described above. ICD-10-PCS also meets all of the HIPAA requirements outlined earlier… Replacement with a new procedural coding system for inpatient services is absolutely necessary and ICD-10-PCS meets the criteria for such a replacement system."
> *American Health Information Management Association*

> "AHA has worked closely with institutional members in the field-testing of ICD-10-PCS. The field-testing results are very positive. Results indicate that ICD-10-PCS can easily accommodate the expansion of new procedure codes. Coders working with ICD-10-PCS also found the new system to be efficient, logical, and easy to understand and learn…Based on the testing, the new procedure classification system holds a great deal of promise and should be considered for future use…Therefore, the AHA supports the HIS industry in requesting that ICD-10-PCS implementation be carried out in tandem with the migration to ICD-10-CM."
> *American Hospital Association*

> "Our position is that ICD-9-CM is not adequate for long-term future use and that providers, payers, and Medicare beneficiaries would be well served by a conversion to ICD-10-PCS."
> *Federation of American Hospitals*

> "Based on AMA's support for the elimination of complex regulatory burdens mandated by the Medicare program, the AMA does not support the adoption of ICD-10-PCS. The AMA believes that the implementation of ICD-10-PCS will only add to the regulatory burden faced by physicians and other health care providers. ICD-10-PCS is a substantial departure from ICD-9 and from all existing health care code sets. As a result, it would require significant resources to implement and problems inherent in the system suggest that it may not be worth the cost."
> *American Medical Association*

> "ASHA appreciates having had the opportunity to provide input on the development of this system and is pleased to see that many of our recommendations have been incorporated into the final version of the ICD-10-PCS…Again, ASHA supports the implementation of the ICD-10-PCS as a replacement for Volume 3 of the ICD-9-CM."
> *American Speech-Language Hearing Association*

"AdvaMed supports the rapid adoption of the International Classification of Disease, Procedural Coding System, 10th Edition, (ICD-10-PCS) for use in hospital inpatient billing…It is a system that has been developed over the past decade with substantial input from the clinical community and offers tremendous versatility in describing the differences in the use and characteristics of medical technologies."`
                    AdvaMed

"The transition from ICD-9-CM to ICD-10-PCS will help enhance the quality of care available for Medicare beneficiaries and provide better management tools for healthcare professionals…ICD-10-PCS should be implemented to bring our coding system up to the standards of the rest of the world, to improve our ability to understand the impact on procedure and technology selection on patient outcomes, and to provide better options for paying hospitals appropriately for the care they provide."`
                    Medical Technology Partners

"Importantly, ICD-10-PCS has the capacity to grow as medical science grows…ICD-10-PCS may have the flexibility and durability to span this century - a statement that cannot be made about any other medical coding system currently proposed or in use. A coding system that could be updated decade after decade would provide an unprecedented continuity of medical data."
                    Ingenix Syndicated Content Group

"We believe that the ICD-10-PCS fulfills these criteria, and we urge the Health Care Financing Administration to implement the ICD-10-PCS as a national standard for coding inpatient procedures as quickly as possible."
                    Princeton Reimbursement Group

The only organization that did not support the adoption of ICD-10-PCS as the national standard for inpatient procedure coding was the American Medical Association.

While the comments on ICD-10-PCS itself were very positive, the more contentious question was the implementation date. The *Federal Register* stated that implementation could not occur before October of 2003. Commenters who were providers wanted ICD-10-CM diagnoses implemented at the same time as ICD-10-PCS procedures. Linking the ICD-10-PCS implementation date to ICD-10-CM or the selection of a uniform procedure coding system could postpone the implementation of ICD-10-PCS well beyond 2003. ICD-10-CM diagnosis codes have not yet been released by the National Center for Health Statistics, so there has not been any public evaluation or testing of that system.

Many commenters also tended to argue that there should be a single procedure coding system for inpatient and ambulatory care and that a decision on a uniform procedure coding system should be made before ICD-10-PCS implementation. We would like to reiterate that the ICD-10-PCS is a coding system designed specifically to replace the inadequate, outdated ICD-9-CM procedures currently used for inpatient reporting. There are no plans to implement ICD-10-PCS as a single procedure coding system.

While providers raised the ICD-10-CM and uniform procedure coding system issues, the technology companies (i.e., AdvaMed) pushed for the rapid adoption of ICD-10-PCS for inpatient care. BIPA requires new technology to be incorporated into the inpatient PPS in a

timely manner. The implementation of ICD-10-PCS would allow the BIPA requirements to be met. There may be an inherent conflict between HIPAA and BIPA. HIPAA requires uniformity and a protracted decision process on national standards for coding systems. BIPA requires immediate action on the coding and payment of new technology. How this conflict gets resolved may largely determine the ultimate implementation date for ICD-10-PCS.

This concluded the procedure part of the meeting. Donna Pickett, NCHS then took over as chair of the diagnosis part of the meeting.

AGENDA

ICD-9-CM Coordination and Maintenance Committee
Department of Health and Human Services
Health Care Financing Administration
HCFA Auditorium
7500 Security Boulevard
Baltimore, MD 21244-1850
ICD-9-CM Volume 3, Procedures
May 17-18, 2001

Patricia E. Brooks
Co-Chairperson

Thursday, May 17, 2001
9:00 AM   ICD-9-CM Volume 3, Procedure presentations and public comments

Topics:

1.   Introductions and overview of meeting   Pat Brooks

2.   HCFA update   Pat Brooks
   - Notice of Proposed Rule Making (NPRM) federal register publication on
     inpatient PPS - May 4, 2001, http://www.hcfa.gov/regs/regsnotices.htm
   - Benefits Improvement and Protection Act of 2000 (BIPA) coding
     requirements

3.   Announcement of HCFA plans for Query Forms - Mark Krushat

4.   Overview of ICD-10-PCS   Rich Averill
                                                          Bob Mullin, MD

5.   Implementation Issues concerning ICD-10-PCS   Pat Brooks, chair

Presenters will include:
   - AHIMA   Linda Kloss
   - American Hospital Association   Nelly Leon-Chisen

- Federation of American Hospitals   Susan Postal
- American Medical Association   Michael Beebe
- American Speech-Language   Maureen Thompson
-    Hearing Association
- AdvaMed   Brian Firth. MD, PhD, MBA
- Medical Technology Partners   Sajini Thomas
- McKesson HBOC   Mark McLaughlin
- DRG Review, Inc.   William Haik, MD
- Ingenix Syndicated Content Group   Sheri Poe Bernard
- Princeton Reimbursement Group   Judith M. Hickey
- Others may be added

6.   ICD-9-CM Procedure Proposals:

- High-Dose Interleukin   Ann Fagan

ICD-9-CM Volume 3, Procedures
Coding Issues:

Mailing Address:

    Health Care Financing Administration
    CHPP, PPG, Division of Acute Care
    Mail Stop C4-07-07
    7500 Security Boulevard
    Baltimore, MD 21244-1850

FAX: (410) 786-0169

Patricia Brooks   **(410) 786-5318 email: pbrooks@hcfa.gov**

Ann Fagan   **(410) 786-5662 email: afagan@hcfa.gov**

Amy Gruber   **(410) 786-1542 email: agruber@hcfa.gov**

<u>Summary of Meeting:</u>

A complete report of the meeting, including handouts, will be available on HCFA's homepage within one month of the meeting. Written summaries will no longer be routinely mailed. The summary can be accessed at:
      http://www.hcfa.gov/medicare/icd9cm.htm

NCHS will present diagnosis topics at the conclusion of the procedure topics. For information pertaining to the diagnosis topics, please contact Donna Pickett or Amy Blum at (301) 458-4200 or visit the NCHS Classification of Diseases website at:
www.cdc.gov/nchswww/about/otheract/icd9/maint/maint.htm

Notice:
In the interest of security, the HCFA building has instituted stringent procedures for entrance into the building for non-government employees. Persons without a government I.D. will need to show photo I.D. and sign in. Due to Fire Code Restrictions, should the number of participants exceed the room size, the guards will have to close the meeting.

ICD-9-CM TIMELINE

A timeline of important dates in the ICD-9-CM process is described below:

Oct. 1, 1999   Revisions to the Hospital Inpatient Prospective Payment System go into effect.

Nov 12, 1999   ICD-9-CM Coordination and Maintenance Committee meeting. Last meeting of the year to discuss proposed code revisions for October 1, 2000.

December 1999   Summary report of the Procedure part of the November 12, 1999 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on HCFA≈s homepage as follows:

http://www.hcfa.gov/medicare/icd9cm.htm
The Diagnosis part of the report will be posted on NCHS=
homepage as follows:
www.cdc.gov/nchswww/about/otheract/icd9/maint/maint.htm

January 7, 2000   Deadline for receipt of public comments on proposed code revisions. **Revisions will include all those discussed at FY 1999 (June 4, 1998 and November 2, 1998) and FY 2000 (May 13, 1999 and November 12, 1999) ICD-9-CM Coordination and Maintenance Committee meetings.**

March 11, 2000   Those members of the public requesting that topics be discussed at the May 11-12, 2000 ICD-9-CM Coordination and Maintenance Committee meeting should have their requests to HCFA for procedures and NCHS for diagnoses.

April 2000   Tentative agenda for the Procedure part of the May 11, 2000 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on HCFA≈s homepage as follows:

http://www.hcfa.gov/medicare/icd9cm.htm

The Diagnosis part of the agenda will be posted on NCHS=
homepage as follows:
www.cdc.gov/nchswww/about/otheract/icd9/maint/maint.htm

May 5, 2000   Notice of Proposed Rulemaking published in the Federal Register as mandated by Public Law 99-509. This included the final decisions on all ICD-9-CM code titles. It included proposed revisions to the DRG system, on which the public may comment.

May 11, 2000   ICD-9-CM Coordination and Maintenance Committee meeting.

June 2000	Summary report of the <u>Procedure part</u> of the May 11, 2000 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on HCFA=s homepage as follows: http://www.hcfa.gov/medicare/icd9cm.htm
	The <u>Diagnosis part</u> of the report will be posted on NCHS= homepage as follows: www.cdc.gov/nchswww/about/otheract/icd9/maint/maint.htm
July 1, 2000	Hosptial Inpatient Prospective Payment System final rule to be published in the <u>Federal Register</u> as mandated by Public Law 99-509.
August 17, 2000	Health Insurance Reform: Standards for Electronic Transactions; Announcement of Designated Standard Maintenance Organizations; Final Rule published in <u>Federal Register</u>. Online version may be accessed through HCFA's homepage (www.hcfa.gov) through links for Administrative Simplification.
Sept. 17, 2000	Those members of the public requesting that topics be discussed at the November 17, 2000 ICD-9-CM Coordination and Maintenance Committee meeting should have their requests to HCFA for procedures and NCHS for diagnoses.
September 2000	Complete, updated ICD-9-CM available on CD ROM through the Government Printing Office at (202) 512-1800. Order number 017-022-01499-8. Cost $18. This version of ICD-9-CM will be in effect from October 1, 2000 through September 30, 2001.
October 1, 2000	New and revised ICD-9-CM go into effect along with all other DRG changes.
October 2000	Tentative agenda for the <u>Procedure part</u> of the November 17, 2000 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on HCFA=s homepage as follows: http://www.hcfa.gov/medicare/icd9cm.htm
	The <u>Diagnosis part</u> of the report will be posted on NCHS= homepage as follows: www.cdc.gov/nchswww/about/otheract/icd9/maint/maint.htm
Nov. 17, 2000	ICD-9-CM Coordination and Maintenance Committee meeting in HCFA Auditorium.

| December 2000 | Summary report of the Procedure part of the November 17, 2000 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on HCFA≡s homepage as follows: http://www.hcfa.gov/medicare/icd9cm.htm |
| | |

December 2000   Summary report of the Procedure part of the November 17, 2000 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on HCFA≡s homepage as follows: http://www.hcfa.gov/medicare/icd9cm.htm

The Diagnosis part of the report will be posted on NCHS≡ homepage as follows: www.cdc.gov/nchswww/about/otheract/icd9/maint/maint.htm

January 8, 2001   Deadline for receipt of public comments on proposed code revisions discussed at the May 11, 2000 and November 17, 2000 ICD-9-CM Coordination and Maintenance Committee meetings. These proposals are being considered for implementation on October 1, 2001.

March 17, 2001   Those members of the public requesting that topics be discussed at the May 17-18, 2001 ICD-9-CM Coordination and Maintenance Committee meeting should have their requests to HCFA for procedures and NCHS for diagnoses.

April 2001   Agenda for ICD-9-CM Coordination and Maintenance Committee Meeting posted on HCFA's homepage as follows: http://www.hcfa.gov/medicare/icd9cm.htm

May 4, 2001   Notice of Proposed Rulemaking published in the Federal Register as mandated by Public Law 99-509. This included the final decisions on all ICD-9-CM code titles as well as proposed revisions to the DRG system on which the public may comment. This can be accessed at: www.hcfa.gov/medicare/ippsmain.htm

May 17-18, 2001   ICD-9-CM Coordination and Maintenance Committee Meeting in HCFA's auditorium. Code revisions discussed are for potential implementation on October 1, 2002.

July 1, 2001   Hospital Inpatient Prospective Payment System final rule to be published in the Federal Register as mandated by Public Law 99-509.

September 1, 2001   Those members of the public requesting that topics be discussed at the November 1-2, 2001 ICD-9-CM Coordination and Maintenance Committee meeting should have their requests to HCFA for procedures and NCHS for diagnoses.

October 1, 2001   New and revised ICD-9-CM go into effect along with all other DRG changes.

October 2001   Agenda for ICD-9-CM Coordination and Maintenance Committee
                   Meeting posted on HCFA's homepage as follows:
                   http://www.hcfa.gov/medicare/icd9cm.htm

Nov.1-2, 2001   ICD-9-CM Coordination and Maintenance Committee Meeting.
                   Code revisions discussed are for potential implementation on
                   October 1, 2002.

AHIMA's Statement Regarding Replacement of ICD-9-CM Procedural Coding System

Good morning, I am Linda Kloss, chief executive officer of the American Health Information Management Association (AHIMA). On behalf of the Association, I thank you for this opportunity to provide input on replacing the ICD-9-CM procedural coding system with ICD-10-PCS.

AHIMA is a professional association representing more than 40,000 members who manage patient information in the form of health records and databases in provider, health plan, governmental, and private organizations.

The responsibilities of our members include coding, and our most recent membership survey data shows that nearly 50 percent of active members cite coding as one of their primary job functions, whether they manage coding functions, or are a coding professional or a consultant. The responsibility of health information management (HIM) professionals for coding dates back to the 1930s when the use of the new Standardized Nomenclature of Disease was being promulgated and Dr. H. B. Logie, Executive Secretary of the National Conference on Nomenclature of Disease asked our members to take on this role.

The educational curricula for HIM professionals at the baccalaureate and master's level includes nomenclature and classification systems, management of healthcare coding, and derivative systems. Health information technicians with an Associate's degree learn to code with ICD, CPT, and specialty code sets. Thus, the entry-level credentials of our field — the registered health information administrator (RHIA) and the registered health information technician (RHIT) — denote academic preparation in coding and classification systems. The Clinical Coding Specialist credentials offered by AHIMA — the CCS and CCS-P — are the marks of highest clinical coding mastery in the industry.

AHIMA is proud to serve as one of the Cooperating Parties along with the Health Care Financing Administration and the American Hospital Association, assisting the National Center for Health Statistics with maintenance of the International Classification of Diseases (ICD) as adapted for use in the US. This relationship, begun in the 1960s, has always been dedicated to enhancing data integrity, and I know the dedication of each organization's representatives, current and former. This is a very challenging job, and one that has become immeasurably more difficult in recent years.

The Need for a New Procedural Coding System

The ICD-9-CM procedural coding system is obsolete and must be replaced. It was designed and implemented over 20 years ago and no longer accommodates adding new codes to reflect advances in medical treatment. The limitation of ICD-9-CM's four-digit structure allows little room to make substantive changes. In fact, the Coordination and Maintenance Committee has not approved implementation of some meritorious code proposals due to insufficient space to create a new code. In 1993, eight years ago, the National Committee on Vital and Health Statistics (NCVHS) reported to the Department of Health and Human Services (DHHS) that ICD-9-CM was running out of available code numbers and pointed out that ICD-9-CM: [1]

- Contains overlapping and duplicative codes,
- Includes inconsistent and outdated terminology,
- Lacks codes for certain types of services,
- Lacks sufficient specificity and detail (such as laterality or surgical approach), and
- Has insufficient structure to capture new technology.

In the DHHS proposed rule for electronic transactions and code sets, under the Health Insurance Portability and Accountability Act of 1996 (*Federal Register,* Vol. 63, No 88), DHHS noted that ICD-9-CM "lacks a desirable level of flexibility and steps should be taken to improve the flexibility of these code sets or replace them with more flexible options sometime after the year 2000. [2]

But this is not an academic matter of coding system architecture. ICD-9-CM no longer meets the most basic definition of "fitness for use." The uses being made of coded data today go well beyond the purposes for which the system was designed or even contemplated in the 1970s. Coded data are used for:

- Measuring the quality, safety, and efficacy of care
- Payment system design and processing claims for reimbursement
- Research, epidemiological studies, and clinical trials
- Setting health policy
- Designing healthcare delivery systems
- Monitoring resource utilization
- Identifying fraudulent practices
- Managing care and disease processes
- Tracking public health and risks
- Providing data to consumers regarding costs and outcomes of treatment options

Providers are routinely required to use multiple coding systems to code single episodes to meet the needs for reimbursement, medical research, case-mix management, practice profiling, and outcomes measurement.

Many coding practices are driven by payment policies requiring providers to add, bundle, or omit selected codes based on health insurance plan coverage. Payer-created codes are
often overlapping or duplicative of codes in established coding systems. Individual payers, and even different contractors for the same payer, develop their own rules and definitions for the proper reporting of a given code. Payers do not always implement new versions of a code set

according to the official implementation schedule, thus new codes are disallowed and continued reporting of obsolete codes is mandated. These practices vary significantly across the country and are creating a data integrity nightmare that we have yet to quantify much less deal with. These practices are contrary to the administrative simplification and uniformity goals of HIPAA, and serve to increase the risk of unintentional data errors and accusations of fraud or abuse. AHIMA coding experts cite this conflict between payer mandates and established coding conventions as the number one barrier to correct coding and the number one cause of professional anxiety.

The NCVHS recommended that a procedural coding system should have these characteristics:[1]
- Each code number should have a unique definition which does not change over time.
- The same procedure should be coded the same way regardless of treatment site or provider.
- It should not incorporate diagnoses.
- The explicit structure improves terminology and provides clarity and accuracy.
- It should be a multi-axial structure with discrete categories.
- It should be comprehensive, flexible, and easy to use.

A new code set today must also meet the requirements for adoption and maintenance established by HIPAA.   To be designated as a HIPAA standard, each standard should:[3]
- Improve the efficiency and effectiveness of the healthcare system by leading to cost reductions for or improvements in benefits from electronic healthcare transactions
- Meet the needs of the health data standards user community, particularly healthcare providers, health plans, and healthcare clearinghouses
- Be consistent and uniform with the other HIPAA standards — their data element definitions and codes and privacy and security requirements — and, secondarily, with other private and public sector health data standards
- Have low additional development and implementation costs relative to the benefits of using the standard
- Be supported by an ANSI-accredited standards developing organization or other private or public organization that will ensure continuity and efficient updating of the standard over time
- Have timely development, testing, implementation, and updating procedures to achieve administrative simplification benefits faster
- Be technologically independent of the computer platforms and transmission protocols used in electronic health transactions, except when they are explicitly part of the standard
- Be precise and unambiguous, but as simple as possible
- Keep data collection and paperwork burdens on users as low as is feasible
- Incorporate flexibility to adapt more easily to changes in the healthcare infrastructure, such as new services, organizations, and provider types, and information technology

In the DHHS proposed rule for electronic transactions and code sets, DHHS noted that ICD-9-CM does not meet all of the HIPAA requirements for adopted standards. In particular, they noted lack of precision, ambiguity, and lack of desired level of flexibility.[4]

ICD-10-PCS

ICD-10-PCS was developed as a replacement for ICD-9-CM Volume 3 for reporting hospital inpatient procedures. The design objectives were to improve coding accuracy and precision, reduce training efforts, and improve communication with clinicians.[5] The system was tested formally by the two Clinical Data Abstraction Centers (CDACs) and AHIMA hosted a session in 1996 to train volunteer credentialed HIM professionals to participate in system testing. AHIMA also served on a technical advisory panel throughout system development.

ICD-10-PCS represents a significant improvement over ICD-9-CM and substantially meets the characteristics of a procedural coding system outlined by the NCVHS as described above. ICD-10-PCS also meets all of the HIPAA requirements outlined earlier. For example, the system is very flexible, as evidenced by the ease with which new root operations were added as a result of the testing process. It is precise and unambiguous, as indicated by the use of standard terminology and distinct identification of body part affected, approach used, and device inserted.

The results of the ICD-10-PCS testing were generally positive. Individuals involved in the testing indicated that it is a clinically elegant and logical system, and that the system can be understood relatively quickly, resulting in reduced training time. The assignment of codes to particularly challenging cases from the Editorial Advisory Board of *Coding Clinic* was accomplished more expeditiously in ICD-10-PCS.

Based on feedback from those involved in the ICD-10-PCS testing, comprehensive re-training of coding personnel will be needed as this system is substantively different from other classification systems in use today. After an initial learning period to familiarize themselves with the new system, AHIMA-credentialed coding professionals understood and applied the system with relative ease. However, because ICD-10-PCS requires a more extensive knowledge of anatomy and physiology than ICD-9-CM, additional training in this area may be needed by some coders.

Also, because of its precision, ICD-10-PCS requires more complete and accurate medical record documentation. This will be challenging for some organizations though it will ultimately result in improved patient care and safety, reduction in medical errors, better data, and greater compliance. Physicians, nurses, and other caregivers will need to be oriented to the data requirements.

AHIMA commends the extensive work that has gone into the development of the ICD-10-PCS, and is prepared to support its implementation subject to the cautions and recommendations regarding implementation and maintenance that follow.

Implementing a New Procedural Coding System

Retraining a Workforce
It has been over 20 years since the US converted to a new procedural classification system. Because today's payment systems are based on coded data, there are many more stakeholders. The size of the workforce directly engaged in coding has grown, as has the range of coding skill. Today, there are thousands of mastery level coders as the CCS and CCS-P credentials signify. But workforce shortages also mean there are many on-the-job trained coders for whom retraining will be more demanding.

While the transition poses significant challenges, we have more sophisticated tools and channels for retraining today. AHIMA currently offers coding education through Web-based training, independent study, audio seminars, publications, and workshops. It has promulgated model curricula for coding certificate programs and approves programs that can demonstrate compliance with recommended course content. AHIMA also develops coding educational manuals for use by collegiate, public, and private training organizations. AHIMA's Society for Clinical Coding (SCC) is a strong network of coding experts and the SCC will soon be expanding its scope and reach through dynamic Internet-based Communities of Practice.

AHIMA's component state and local associations, including state coding roundtables, offer educational programs throughout the country. In 1979, this network from national to local, was deployed in a massive "train the trainer" effort which successfully supported the transition from ICD-8 to ICD-9. This strategy can be deployed once again, this time backed up by media and support networks that were not available when we did this last.

Orienting the Industry
Given the many uses of coded data outlined earlier, multiple categories of users of coded data will require varying levels of training on any new coding system. These categories of users include:
- Clinicians
- Information systems personnel
- Quality management personnel
- Utilization review personnel
- Accounting personnel
- Compliance staff
- Auditors
- Data quality management personnel
- Data analysts
- Researchers
- Software vendors
- Claims reviewers
- Epidemiologists
- Fraud investigators

AHIMA is prepared and committed to be an industry leader in the provision of training and orientation on a new coding system for both coding professionals and other segments of the healthcare industry requiring education.

Code Set Maintenance
Like the retraining issue, the challenges of maintenance, particularly for a procedural system, are exponentially more complex today than 20 years ago. Yet our process is not fit for the pace of change or the needs of our stakeholders. As we examine how and when to implement new code sets, we must commit ourselves to modernizing the process for their maintenance.

AHIMA believes the following five principles should guide code set maintenance in the future:
• Due to the rapid advances in medicine and technology and the immediate need for codes to describe these advances, the maintenance process should be more streamlined, with consideration being given to the feasibility of more frequent system update.
• The length of time between proposal of a new code and its implementation should be minimized.
• There should be an established process for developing rules and guidelines for the correct application of the coding system. The process should be open and permit broad input from all stakeholders *prior* to finalization of a significantly revised or changed guideline. The coding system rules and guidelines (as well as consequent payment system changes) should be updated on the same schedule as the code set and made part of the official version.
• All requisite materials — code sets, guidelines, and other directives — should be in formats that may be available from government or private entities, but it would ensure that all stakeholders know where to go for unfettered access to the official, most up-to-date version and interpretive materials.

Sound maintenance processes are as important as sound system design and AHIMA believes the process must meet today's requirements. There should be a unified and logical process that encompasses ICD-9-CM, ICD-10-CM when it is released, and ICD-10-PCS. Responsibility for maintenance of these coding systems and development of the associated rules and guidelines should be the domain of a single agency so that decisions balance the needs of users, payers, and providers, to ensure that data integrity is not compromised. Authority is currently too dispersed, and the leadership vacuum allows all the conflicting practices, such as local customization, described earlier. Other countries, such as Australia, can be a model for the US as we redesign maintenance. Australia's National Centre for Classification in Health is responsible for development and maintenance of diagnosis and procedure classification and is the convenor of industry-wide advisory groups.

Given the multiple uses of coded data described earlier, the recognized lead authority for system maintenance and guideline development should not be primarily focused on the needs of any one particular group, so that it is able to objectively balance the various needs of different groups of stakeholders. The logical choice for this authority should be the National Center for Health Statistics, as NCHS is the US agency responsible for the International Classification of Diseases. The NCHS is also the country's principal health statistics agency, charged with providing statistical information that will guide actions and policies to improve the health of the American people.

An advisory group comprised of representatives of stakeholders should be established to provide input into the maintenance and guideline development processes. We also recommend that the current Cooperating Party structure be continued, as it has served as a successful process for the development of guidelines that best meet the needs of the major constituent groups.

HIPAA provides the impetus to address these issues now. We can't focus on implementation and ignore what will happen the day after.

AHIMA's Position on a Single Procedure Classification System

Our testimony would not be complete if we did not raise the question of whether a single procedure classification system could meet the nation's data needs across all care settings, inpatient and ambulatory. In 1993, AHIMA issued a position statement entitled "National Data Quality" calling for a single procedural classification system.[6] The NCVHS also recommended a single procedure classification system in its June 1997, recommendations to the DHHS regarding standards for codes and classifications for administrative transactions. The Committee stated: "we recommend that you advise the industry to build and modify their information systems to accommodate…[a] major change to a unified approach to coding procedures…[we] recommend that you identify and implement an approach for procedure coding that addresses deficiencies in the current systems, including issues of specificity and aggregation, unnecessary redundancy, and incomplete coverage of healthcare providers and settings."[2]

AHIMA continues to support in principle its position favoring a single procedure classification system. Clinical data are being compromised today, and future longitudinal analysis will be impossible. The current state of affairs is extraordinarily costly. If ICD-10-PCS goes into effect, the push for a single system will escalate because it will be readily apparent that we will have two highly specific systems with different codes for the same entities.

Based on our belief that we must at some point move to a single procedural coding system, we recommend that there be federally funded research on the feasibility of moving to a single system which examines:
- The efficacy of alternative systems across all healthcare settings, for all payer types, and all types of healthcare services
- The implementation and long-term cost and benefits of a single system compared to the implementation and long-term cost and benefits of operating multiple systems
- A recommended strategy for implementation that takes into account the need to implement ICD-10-CM.

Any system adopted as a single procedural coding system must have the complete support and commitment of all federal and private health insurance programs and providers identified in HIPAA, in order to ensure consistent application of the coding rules and guidelines for patients receiving care paid for by the government.

While we believe that ICD-10-PCS is a potential candidate as a single procedural coding system, we do not think the system has been adequately tested in all of the areas that would be necessary

for use beyond hospital inpatient services. Since the system was designed to replace Volume 3 of ICD-9-CM, the testing was primarily done on inpatient medical and surgical cases. Most of the testing done by the CDACs utilized Medicare records, since these were the records primarily available to them. Only a limited sample of outpatient records (primarily Medicare) and OB/GYN cases were tested. Therefore, we believe it would be premature to recommend ICD-10-PCS as the *single* procedural coding system. ICD-10-PCS should undergo the same rigorous evaluation process as any other coding system that is a potential candidate for the single procedural coding system.

I offer AHIMA's full support and assistance in this evaluation process.

Implications of Adopting a New Coding System

AHIMA recognizes that there are significant resource implications of implementing new coding systems. These include:
- Software changes for providers, payers, and data users
- Costs of retraining coders and users of coded data
- Maintenance of crosswalks among coding systems for longitudinal data analysis
- Redevelopment of systems based on coded data, including groupers, payment policy, and performance measurement systems

There will undoubtedly be resistance to changing from the status quo. However, as we and others have pointed out, we are paying a very high cost for having delayed this long. We are already at least a decade behind in implementing new ICD modifications, and like any system maintenance experience, catching up is more costly than staying current. Further delay will not reduce the direct costs. We cannot ignore the indirect costs any longer.

The research we recommend will permit development of a logical, supportable, and explicit transition and implementation strategy. This, in turn, will allow us to realize the many, many efficiencies that can accrue from system and process modernization. For example, the conversion to one source for official coding guidelines would save healthcare organizations significant time and money in researching reporting requirements and processing claims denials and rejections for correctly coded services. It would ensure that patients are not adversely affected by arbitrary local codes that make benefits, even for Medicare beneficiaries, uneven across the country.

Conclusion

In summary, AHIMA's position regarding replacement of ICD-9-CM procedure codes is as follows:
- Replacement with a new procedural coding system for inpatient services is absolutely necessary and ICD-10-PCS meets the criteria for such a replacement system.
- The feasibility of a single procedural coding system should be evaluated now so an informed national decision can be made about the best long-term solution for all healthcare settings, services, and payers.

- All existing procedural coding systems should be evaluated, including testing the systems in all healthcare settings and for all payer types and all types of healthcare services, in order to select the system that can best meet the needs of the various stakeholders
- A new model and process for code set maintenance is needed in the US and the final authority of NCHS for code changes and guidelines must be acknowledged and reinforced.
- The ICD-10-PCS implementation question is not separable from that of ICD-10-CM. While this requires further study, our judgement is that the two systems should be implemented at the same time.

AHIMA and its national network of coding professionals is uniquely capable of assisting in the research on the right system and the best implementation strategy, as well as design of a new maintenance model and process. AHIMA is also uniquely capable of taking the lead in national workforce re-training and user education for new procedural and diagnosis systems.

Thank you for the opportunity to present our views regarding replacement of ICD-9-CM procedure codes with ICD-10-PCS. This decision should not be made in a vacuum from the other major issues relating to diagnosis and procedure classification in the US.

AHIMA is deeply committed to working with the Department of Health and Human Services, the National Center for Health Statistics, and other healthcare industry groups to advance coding practice and improve our nation's healthcare data through adoption of new code set standards.

STATEMENT
of the
AMERICAN HOSPITAL ASSOCIATION

To the

ICD-9-CM Coordination and Maintenance Committee
May 17, 2001

Re: ICD-10-PCS Implementation Issues

Presented by:
Nelly Leon-Chisen, RHIA
Director, Central Office on ICD-9-CM
American Hospital Association
Chicago, IL 60606

My name is Nelly Leon-Chisen. I am the Director of the Central Office on ICD-9-CM at the

American Hospital Association (AHA). On behalf of our 5,000 member hospitals, health

systems, networks, and other providers of care, I would like to thank you for the opportunity to

provide comments. The Central Office on ICD-9-CM serves as the United States clearinghouse

for issues related to the use of ICD-9-CM. The Central Office on ICD-9-CM is also the

publisher of *Coding Clinic for ICD-9-CM. Coding Clinic* is the official publication for ICD-9-

CM coding guidelines and advice, as designated by the Cooperating Parties: the Health Care

Financing Administration (HCFA), the National Center for Health Statistics (NCHS), the

American Hospital Association (AHA) and the American Health Information Management

Association (AHIMA). The need for standardization of clinical codes is extremely important to

our members, particularly as they relate to transactions identified in the Health Insurance

Portability and Accountability Act (HIPAA).

Accurate reporting of clinical codes is extremely important because the clinical codes are a key

data component used for benchmarking, quality assessment, research, public health reporting,

and strategic planning. These uses also require accurate and precise data reporting. Coded data

is used to analyze outcomes, create clinical critical pathways and develop clinical guidelines.

Standardizing clinical data reporting requirements also enables providers to deliver high quality

and coordinated care across health care settings.

For instance, a hospital would typically develop critical pathways for those diagnoses or

procedures that are high volume, high risk, or high cost, and those in which the course of

treatment is similar between patients. The hospital can determine which procedures are high volume by examining their clinical abstracted data and selecting the ICD-9-CM codes that appear with highest frequency. At the Johns Hopkins Hospital, forty pathways are in place in the department of surgery alone, including one for coronary artery bypass graft surgery (CABG). If the CABG codes were inconsistently applied, case identification for the initial development of the pathway would be flawed. The cases are reviewed to determine which patients had the best outcome and pinpointing which factors in their care may have influenced the outcome. These factors are then used to develop critical pathways that are used to treat patients. Critical pathways for cardiac surgery at Johns Hopkins Hospital have resulted in improvements in many targeted areas such as decrease in laboratory testing, reduced length of stay, reduced preoperative stays and additional improvements in radiology usage.

Although ICD-9-CM has been in use for more than twenty years, its inability to enumerate many new procedures stemming from innovations in medical practice indicate that it is due for an overhaul. The ability to expand enumeration for a particular procedure category is limited because of the physical numbering constraints contained in the current ICD-9-CM system. Consequently, some categories provide vague and imprecise procedure codes.

There are several distinct procedures performed in different parts of the body that have widely different resource utilization that are grouped together under the same procedure code. For example, code 99.29, Injection or infusion of other therapeutic or prophylactic substance, has been used to report a wide variety of procedures such as: an injection of epinephrine to cauterize

a rectal ulcer, infusion of a narcotic into a pump for pain relief, insertion of an implant in the eye for slow release of an antiviral drug, and injection into the uterine artery to treat a fibroid.

Due to insufficiently detailed information in code assignments, our members are faced with:

- Increased requirements for submission of documentation to support claims
- Inability to collect accurate data on new medical advances such as percutaneous or endoscopic vs. surgical approaches or new minimally invasive procedures
- Lack of data to support performance measurement, outcomes analysis, cost analysis, and monitoring resource utilization

AHA has worked closely with institutional members in the field testing of ICD-10-PCS. The field-testing results are very positive. Results indicate that ICD-10-PCS can easily accommodate the expansion of new procedure codes. Coders working with ICD-10-PCS also found the new system to be efficient, logical, and easy to understand and learn. To test the new system's ability to be more precise, the AHA also provided the Clinical Data Abstraction Centers (CDACs) with examples of difficult coding questions submitted to the Coding Clinic Editorial Advisory Board over the past 10 years. Based on the testing, the new procedure classification system holds a great deal of promise and should be considered for future use.

However, AHA believes, that before implementation takes place, the new system should be tested for all services in all settings. Thus far, the testing has been limited to primarily the medicine and surgery sections in the inpatient hospital setting. Other sections yet to be

thoroughly tested are Obstetrics, measurement and monitoring, imaging, nuclear medicine, radiation oncology, osteopathic, rehabilitation, audiology, therapies, and mental health. Additionally, the testing should also consider the compatibility of the new system with existing payment systems—whether DRGs, APCs or simple fee schedules.

Another issue to consider is the timeline for implementing the new system. There are a significant number of regulatory changes hospitals are facing over the next several years (see attachment). Therefore, careful consideration of the ability of hospitals to absorb all of these regulatory changes must be assured. The vast majority of hospitals are dependent on their hospital information system (HIS) vendors for programming changes. Therefore, the AHA supports the HIS industry in requesting that ICD-10-PCS implementation be carried out in tandem with the migration to ICD-10-CM. The AHA also supports them in recommending implementation of ICD-10 three years beyond HIPAA implementation.

Implementation to ICD-10 will be a very complex and costly process. Therefore Medicare along with other health plans should be sensitive to these increased regulatory costs and adjust payment accordingly. For instance, the AHA believes that the cost of implementing significant new regulations should be worked into the Medicare prospective payment rate updates. Further, we believe that Congress should establish grants to help hospitals with the enormous costs of complying with the HIPAA rules, including conversion to an entirely new coding system such as ICD-10.

For hospitals, the bulk of the cost associated with the adoption of a new procedure classification system will be the costs associated with training personnel. Hospital support staff such as coders and billers will have to attend training seminars to familiarize themselves with the new coding guidelines, rules and definitions. Hospitals will have to work with their medical staff to ensure that the appropriate documentation is available to support the new coding system. ICD-10-PCS code selection requires that more specific and detailed physician documentation be available in the medical record. This greater level of specificity may also require that coders and billers expand their knowledge of medical terminology, anatomy and physiology, and disease process.

A change to the coding system also requires extensive and costly modifications to information systems. Hospitals use a combination of purchased software and in-house developed applications. The software applications that will require modification encompass functions such as code assignment, medical records abstraction, aggregate data reporting, utilization management, clinical systems, billing, claim submission, groupers, and other financial functions. In essence, every electronic transaction requiring an ICD-9-CM code would need to be changed. These changes include software interfaces, field length formats on screens, report formats and layouts, table structures holding codes, expansion of flat files, coding edits, and significant logic changes. Hospitals will have to bear the financial burden associated with software changes as well as possible hardware upgrades. During the transition period, information systems will have to support both ICD-9-CM and ICD-10 coding systems, therefore requiring additional data storage space. Small and rural health care providers are further handicapped in their ability to accommodate such changes and therefore may require special support to help them acquire information and coding system support programs.

We ask that you consider the following implementation issues:

- We would support migration to a new classification system after testing and funding options are established.

- Medicare, as well as other payors, should be sensitive to the increased regulatory costs resulting from this migration and should adjust payment accordingly.

- We support a well-defined maintenance and implementation process. The process should be broad-based and take into consideration the needs of all users. It should also be predictable and take into account the capabilities of the users to adapt to coding changes when they occur. This includes the establishment of routinely scheduled meetings to review coding changes and a date certain for using approved coding changes. The AHA supports the current ICD-9-CM Coordination and Maintenance process and would support the same process for ICD-10-PCS. This process is well positioned to reach the broadest audience possible.

- We believe there should be clear, unambiguous instructions, and consistent official coding and reporting guidelines. These should be readily available and accepted by all payers.

- We would like to reaffirm the role of the Cooperating Parties (AHA, AHIMA, HCFA and NCHS) in the development of guidelines and clarification.

- The AHA has a long-standing memorandum of understanding with DHHS to provide ICD-9-CM coding advice and training. We will continue in this capacity under ICD-10. The AHA is uniquely positioned and ready to take a leadership role in the training of our members. Our members include hospitals and health systems providing services across the continuum of care—rehabilitation, skilled nursing, home health and outpatient services in addition to acute, subacute and long-term inpatient hospital care. AHA members look to the AHA for guidance and support in coding training and education.

- The AHA's *Coding Clinic for ICD-9-CM* and the Editorial Advisory Board serve as the nationally-recognized source for coding advice. As such, they have established a process that reduces confusion and provides for clarification and consistent interpretation of coding rules. We believe the same process would be beneficial under ICD-10.

Again, thank you for the opportunity to provide comments to you. I will be happy to answer any questions you may have.

FEDERATION OF AMERICAN HOSPITALS

Presenter: Susan Postal

Introduction

As medical technology continues to advance, it is appropriate to consider whether or not the current code set used for capturing inpatient medical procedures is adequate and whether or not it will be adequate for the long term. Our position is that ICD-9-CM is not adequate for long term future use and that providers, payers, and Medicare beneficiaries would be well served by a conversion to ICD-10-PCS with appropriate consideration of the issues noted below.

Limitations of ICD-9-CM

Lack of space to capture new procedures/approaches which will impact analysis of quality of are and resource use.

Advantages of ICD-10-PCS

Public domain
Defined and consistency of terms throughout the system
Update schedule can be coordinated with federal fiscal year
UB-92 compatible
UHDDS compatible
Unique codes
Expandable
Allow reporting of all procedures performed
Minimum need to change
Multiaxial allowing easy retrievability of information
Absence of diagnostic information contained in the procedure description
Initial learning curve but user friendly in the long term
Codeable from paper records (not dependent upon an EPR)
Development of coding guidelines to support new procedure classification system

ICD-9-CM to ICD-10-PCS Conversion Considerations

Education
> Scope
> Process
> HCFA responsibility

Provider responsibility
Professional organization responsibility

Payer synchronization
Open development/maintenance
Coding guidelines to support new procedure classification system
Reimbursement
Information systems
Implementation Plan and Schedule
ICD-10

Summary: Position of the American Medical Association on the Adoption of ICD-10-PCS

The American Medical Association (AMA) strongly supports Administration initiatives to reduce regulatory burdens on physicians and their practices. Complex federal regulations means hours of paperwork and time not spent caring for patients. Failure to comply with the myriad of federal regulations could result in delayed payment for services. reduced payment, or worse, criminal fines. To quote Secretary Tommy Thompson, "Patients and providers alike are fed up with excessive and complex paperwork. Rules are constantly changing. Complexity is overloading the system, criminalizing honest mistakes and driving doctors, nurses, and other health care professionals out of the program."

The AMA supports the Physician's Regulatory Issues Team (PRIT), a cross-agency effort by the Health Care Financing Administration to improve responsiveness to the day to day concerns of practicing physicians. The AMA also backs the Medicare Education and Regulatory Fairness Act (MERFA). This act would, among other things, target existing education funds to provide better outreach and education to physicians and health care providers on the complexities of Medicare. MERFA would also protect health care professionals from unfunded mandates by requiring that Medicare payment rates reflect the cost of mandates imposed on physicians and other health care providers.

Based on the AMA's support for the elimination of complex regulatory burdens mandated by the Medicare program, the AMA does not support the adoption of ICD-10-PCS. The AMA believes that the implementation of ICD-10-PCS will only add to the regulatory burden faced by physicians and other health care providers. ICD-10-PCS is a substantial departure from ICD-9 and from all existing health care code sets. As a result, it would require significant resources to implement and problems inherent in the system suggest that it may not be worth the cost. The following issues concern the AMA with respect to any implementation of ICD-10-PCS:

- complexity and excessive formalism of it structure;

- content and composition of it's descriptors;

- ability to expand some chapters/sections;

- maintenance and update process, and

May 4, 2001

Patricia Brooks, RRA
Health Care Financing Administration
Office of Clinical Standards and Quality
Information Systems Group
7500 Security Blvd. C5-0624
Baltimore, MD 21244-1850

Re: International Classification for Diseases 10th Revision Procedure
        Classification System
        (ICD-10-PCS)

Dear Ms. Brooks:

As president of the American Speech-Language-Hearing Association (ASHA), the
professional and scientific organization with more than 100,000 member
audiologists, speech-language pathologists, and speech, language, and hearing
scientists, I am writing to support the use of the International Classification for
Diseases 10th Revision Procedure Classification System (ICD-10-PCS). If
implemented, the ICD-10-PCS would provide a comprehensive procedural coding
system to audiologists and speech-language pathologists.

ASHA initially provided comments on the tenth revision of the International
Classification of Diseases at the request of the World Health Organization (WHO)
in 1988. The Association also served as a member of the Health Care Financing
Administration's (HCFA) Technical Advisory Panel and provided substantial input
regarding the development of the procedure codes within the Diagnostic Audiology
and Rehabilitation section of the ICD-10 PCS.   ASHA appreciates having had the
opportunity to provide input on the development of this system and is pleased to see
that many of our recommendations have been incorporated into the final version of
the ICD-10-PCS.

The ICD-10-PCS incorporates the principles necessary for a coding system for
procedures that are performed by audiologists and speech-language pathologists.
Specifically, those principles are:

- The ability to easily incorporate new procedures with new codes. The
  professions of speech-language pathology and audiology are dynamic
  - and expanding with constantly developing technological and clinical
    advances. As such, ASHA welcomes a procedure coding system that

can be easily expanded as new procedures and technologies are developed.

- The seven-character alphanumeric coding system more than doubles the number of three-character categories currently employed in the CPT coding system. This affords audiologists and speech-language pathologists the ability to describe their services to payers with greater specificity. For example, with the ICD-10-PCS, an audiologist can specify whether an Auditory Brainstem Response evaluation was conducted with tone bursts or clicks; while a speech-language pathologist can delineate the type of assessment being performed (e.g., fluency, articulation, phonology). ASHA notes that the use of the ICD-10-PCS is supported by the two organizations used by HCFA to evaluate the practicality of using the system. While the organizations contracted by HCFA to evaluate the ICD-10-PCS reported that additional training time was needed to become familiar with the system, they indicated that the precision of the ICD-10-PCS resulted in greater detail about the nature of the procedure and resulted in improved accuracy and efficiency of coding.

- The increased specificity offered by the ICD-10-PCS will also facilitate data being more effectively and accurately incorporated into treatment outcomes data systems. Treatment outcomes data are an important tool for audiologists and speech-language pathologists and other practitioners to employ in demonstrating the effectiveness of their services and in responding to questions posed by payors about the prognosis and functional outcomes of treatment.

- The proposed equipment codes will allow audiologists and speech-language pathologists to describe the procedures they perform in terms of instrumentation and equipment used, which will provide payors with a more accurate picture of the costs involved in providing speech, language, and hearing services.

Again, ASHA supports the implementation of the ICD-10-PCS as a replacement for Volume 3 of the ICD-9-CM. The ICD-10-PCS will establish a comprehensive procedure coding system for audiology and speech-language pathology.

If you require additional information, please contact Maureen Thompson, Director of Private Health Plan Advocacy at 301-897-0126, ext. 4431 or email *mthompson@asha.org*.

Sincerely,

John Bernthal

John Bernthal, PhD
President

Statement of the Advanced Medical Technology Association

Adoption of the ICD-10-PCS System for Medicare Inpatient Billing

May 17, 2001

International Classification of Disease

Coordination and Maintenance Committee, 9ᵗʰ Edition

Health Care Financing Administration

Submitted By

Brian Firth, M.D., Ph.D., M.B.A.

Good afternoon. My name is Dr. Brian Firth, of Cordis, a Johnson & Johnson subsidiary, and I am here on behalf of the Advanced Medical Technology Association, also known as AdvaMed, to share the views of my association related to adoption of a new coding system for hospital inpatient procedures.

AdvaMed supports the rapid adoption of the International Classification of Disease, Procedural Coding System, 10th Edition, (ICD-10 PCS) for use in hospital inpatient billing. The ICD-10 system offers a seven-digit, alpha-numeric coding system with over 170,000 different permutations. It is a system that has been developed over the past decade with substantial input from the clinical community and offers tremendous versatility in describing the differences in the use and characteristics of medical technologies.

Current ICD-9 Coding Is Inadequate

AdvaMed is concerned that the present billing system for inpatient care, the ICD-9-CM procedure system, lacks the capacity for additional codes to keep pace with advances in modern medicine. Out of about 10,000 possible ICD-9 procedure codes, just over 3,500 already have been assigned. However, codes must be assigned according to the rational construction of the ICD-9 system, and there often is not room for placement of a new procedure code in the appropriate section.

The paucity of available codes under the ICD-9 system may be one of the reasons we have seen relatively slow change in the ICD-9 system. To illustrate, this year, there were over 420 modifications added to the coding system used for physician billing, the Current Procedural Terminology (CPT-4) level 1 codes maintained by the American Medical Association. These modifications included 203 new codes, used to describe new clinical procedures. By contrast, the Medicare inpatient payment system added only nine new ICD-9 codes for billing new procedures in 2001.

It is important to recognize that an optimal inpatient billing system must be capable of describing multiple aspects of a medical procedure, including the body system, organ,

surgical approach, specific procedure, and the specific technology used during the procedure. The current ICD-9 system lacks the ability to capture all of these factors for many procedures, and often fails to distinguish between significantly different technologies.

Patient Access to Technology Depends on Accurate Coding

By training, I am an interventional cardiologist and have seen first hand the way in which our reimbursement systems can affect the availability of the highest quality healthcare. The financial pressures on modern hospitals are substantial and they simply cannot afford to absorb the cost of breakthrough technologies that are not adequately compensated by our payment systems.

Appropriate payment under the DRG system depends on the accurate capture of data that describe the different services performed in the inpatient setting. Since clinical services and new technologies can only be represented by ICD codes in the national data, the accuracy of this coding system in describing health care is a critical element of our reimbursement system. In short, accurate codes allow for accurate billing, proper calibration of DRGs over time and adequate payment for needed hospital services.

The Coding Assignment Process Also Must be Revised

AdvaMed supports rapid implementation of the ICD-10 system, but also urges HCFA to implement important changes to the process for assigning new codes. AdvaMed believes the present approach to assigning ICD-9 procedure codes is not timely and does not result in a sufficient number of new codes to describe technologies.

The current ICD-9 code assignment process currently takes from 14 to 25 months for a coding request to be considered, assigned and implemented. AdvaMed proposes that this process be shortened significantly, such that new codes can be requested and assigned on a quarterly basis. AdvaMed also urges HCFA to consider the assignment of new codes for procedures related to technologies that are still undergoing clinical trials. Earlier

assignment of codes would allow for tracking and analysis of clinical and economic benefits and better outcomes research for new types of medical therapy.

Adoption of ICD-10 Codes Must Reflect Flexibility and Public Comment

As with any new major system, adoption of the ICD-10-PCS system will require a detailed public comment process and review of specific changes in coding that may affect DRG assignment of certain procedures. As part of its public notice process, we recommend that HCFA post on its website information on the specific codes, in a "cross-walk" format, so that interested parties can understand how procedures under the current ICD-9 system will be transitioned to the new ICD-10-PCS codes and provide comments. We urge HCFA also to publish, in similar format, any revisions to the DRG grouper that may be driven by the adoption of ICD-10-PCS codes and to provide an opportunity for comments on these revisions.

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On behalf of AdvaMed, thank you for the opportunity to share our comments on this important issue.

Jerry Stringham
President
Medical Technology Partners

Presented by Sajini Thomas, Principal, Medical Technology Partners

Medical Technology Partner's (MTP's) Position on ICD-10-PCS: The transition from ICD-9-CM to ICD-10-PCS will help enhance the quality of care available for Medicare beneficiaries and provide better management tools for healthcare professionals. Medical Technology Partners supports the transition from ICD-9-CM to ICD-10-PCS.

There are several benefits to switching to ICD-10-PCS:

The transition from ICD-9-CM to ICD-10-PCS will provide an inexpensive source of information.

Financial data on the treatment of Medicare beneficiaries represents an important and inexpensive source of information to track the short and long term outcomes for Medicare patients receiving different therapies. The restrictive use of ICD-9-CM procedural codes severely limits the quality of data available for providers, payors and manufacturers of lifesaving or life-enhancing technology. In the era where bar scanners are used for 5-cent items at the grocery store, it should be possible to expand the information available for researchers without burdening hospitals. Procedure codes should not be coveted like 50-year old wine, but be available like bottled water. These unnatural limitations could be reduced with the implementation of ICD-10-PCS.

The information available today through the MedPAR database and Standard Analytical File are important. While costly to analyze, these database analyses can be performed on a far greater scale for a far smaller cost than controlled clinical studies. The Standard Analytical File, cross-referenced over several years is frequently used to provide researchers with a profile of what future treatments a particular group of patients receive after a diagnosis or particular type of treatment. For example, it is an interesting question from an insurer, physician, or public policy standpoint to evaluate the comparative future treatment costs for patients a group of comparable patients who receive a particular style left ventricular assist device or a different add-on product. These can ultimately influence patient treatment guidelines. The additional coding options created with ICD-10-PCS will help make both the MedPAR database and the SAF files more valuable tools.

The transition from ICD-9-CM to ICD-10-PCS will ease the tight controls over codes.

Those who have participated in the ICD-9-CM coding process over the past many years have been frustrated by tight control over codes. We have been told that the code book is "near full" and either had worthwhile applications turned down or codes placed in a section of the book that is difficult for a coder to locate. ICD-10-PCS would remove the space limitation and allow for more discrimination between patients, procedures and the products without corrupting the current coding system.

ICD-10-PCS will provide a more logical rationale for the necessary codes for new technology payments.

HCFA now proposes to use ICD-9-CM codes to pay for new technologies, a proposal that is long overdue. In the past, HCFA followed a "survival of the fittest" strategy with new medical technology. If a new technology is good enough to survive five years of systemic underpayment, then it must be good enough for our beneficiaries. If it does not survive, then it probably is not. HCFA's policy of deliberately underpaying for therapies that add to the cost of an admission (even for those that can demonstrate overwhelming cost-effectiveness by reducing post-admission recovery and retreatment costs) provides incentives for hospitals to use existing technology, and many do. Those hospitals that try to incorporate the new, better technology, find themselves at a financial disadvantage to their neighbors.

Manufacturers know that chains won't normally touch new technologies affected by the 5-year transition incentives created by the DRG system. Congress has mandated HCFA to pay for new technologies outside of the DRG to help Medicare beneficiaries and foster technological improvements. The ICD-9-CM coding system is a barrier to doing this effectively. Each new technology would have to have a unique ICD-9-CM code. With the vast amount of expensive inpatient biopharmaceuticals and other technologies, it will not take long for the ICD-9-CM book to fill up. It will also be difficult to organize the codes properly. ICD-10-PCS will provide a more logical rationale for the necessary codes for new technology payments.

Conclusion: ICD-10-PCS should be implemented to bring our coding system up to the standards of the rest of the world, to improve our ability to understand of the impact on procedure and technology selection on patient outcomes, and to provide better options for paying hospitals appropriately for the care they provide.

February 26, 2001

E-MAIL & REGULAR MAIL

Patricia Brooks, RHIA
Health Care Financing Administration
CHPP, PPG, Division of Acute Care
Mail Stop C4-07-07
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Ms. Brooks:

Thank you for asking for public comments regarding ICD-9-CM Volume 3 and the proposed ICD-10-PCS.

As a pulmonary medicine physician and ICD-9-CM coding consultant, I have found ICD-9-CM Volume 3 extremely difficult with which to work, being nonspecific and highly restrictive regarding future code development. Additionally, nonspecific physician descriptive terms of procedures such as "excisional biopsy" are not adequately addressed in ICD-9-CM Volume 3. Furthermore, the operative approach is not often delineated in the index or the tabular portion of ICD-9-CM Volume 3; therefore, meaningful differences in resource utilization cannot be discerned (such as a pleural biopsy performed via an open thoracotomy).

ICD-10-PCS not only is useful because the system is multiaxial and expansive, providing multiple possible unique codes for substantially different procedures, but it also assigns specific definitions to procedural terminology. Therefore, terms such as biopsy which physicians may intend to mean a complete excision or merely a partial excision of a structure is more clearly addressed with the qualifier "diagnostic biopsy" reported with the specific root operation.

Additionally, since the approach is also defined within the seven-character alphanumeric structure, there are no limitations as mentioned above with a pleural biopsy.

Therefore, based on the above, I urge HCFA to implement a more detailed and precise coding system such as ICD-10-PCS.

Thank you for allowing my personal comments.

With kindest regards,

WILLIAM E. HAIK, M.D

**STATEMENT
of the
Ingenix Syndicated Data Group
to the
Coordination and Maintenance Committee on ICD-9-CM**

**RE: ICD-10-PCS
Sheri Poe Bernard, CPC
May 17, 2001**

Good morning. My name is Sheri Bernard. I am Director of Essential
Regulatory Products for Ingenix Syndicated Data Group, which publishes
Medicode and St. Anthony coding and reimbursement products and
provides software, consulting, and seminars from offices in Utah and
Virginia.

Formed in 1997, Ingenix was created in a merger of many of the industry's leading health
companies. More than 100,000 providers and 1,500 payers – including 100 Fortune 500
companies – now rely on Ingenix software, services and expertise to improve their health
care delivery and operations.

On a personal level, I am a Certified Professional Coder and a member of the National
Advisory Board of the American Academy of Professional Coders. I have been
developing medical reimbursement products for nine years, specializing in ICD-9-CM,
CPT, and HCPCS Level II coding.

On behalf of Ingenix, I would like to thank co-chairperson Patricia
Brooks for convening today's meeting to discuss the Health Care
Financing Administration's proposed ICD-10-PCS.

Ingenix supports a change from ICD-9-CM Volume 3 to ICD-10-PCS.

I'll briefly outline within this testimony how this position was determined
from Ingenix's unique perspective as a data collector and as a publisher
of coding and reimbursement products. I'll then outline some critical
questions and concerns that would naturally follow any decision to
implement ICD-10-PCS.

Within the context of its position as publisher and data gatherer, Ingenix
targets two important benchmarks as it reviews any significant change to
coding systems:

- What are the risks or costs to the provider and payer community?
- How will the change affect data collection and data integrity?

Risks and Costs
I've been providing seminars on ICD-10-CM and ICD-10-PCS for more than a year now. In these seminars, I'm not teaching how to code using the proposed systems; I'm teaching impact mitigation. Some of the issues we discuss are systems requirements and physician training for documentation. Budgeting and staffing are always big concerns.

Equipment upgrades, manpower requirements, training time
Conversion to a new coding system would be very costly to providers and to payers. Whether evaluating training time, equipment upgrades, or manpower requirements, it's clear the costs will place a tremendous burden upon both. The payoff – a future of improved outcomes and more cost-effective medical treatment – often does not seem worthwhile to those most affected by these changes.

The community of providers I have worked with feels overwhelmed by recent government campaigns for compliance, fraud and abuse, and by HIPAA. The financial impact to some of these providers has already been substantial. When I discuss the potential new coding system with some of these professionals, they look afflicted. Their frustration is palpable.

Streamline Claims

The granularity of ICD-10-PCS will help coders present a more complete clinical picture that can ultimately answer questions that normally would be answered only through correspondence between provider and payer. This will streamline the claims process.

Update and Edit Costs

The grids of ICD-10-PCS should simplify the update process for coders, and prove more cost effective than annual book updates over time. However, many HCFA edits are now presented directly with each code in ICD-9-CM Volume 3 books. In the tables of ICD-10-PCS, these individual edits will not be possible in printed form. This will either force providers to an electronic version of ICD-10-PCS, or force them to buy additional references to review appropriate government edits for each code.

How HCFA Could Help
Change is seldom welcomed and rarely cost-free. None of us believes we should forego change simply to avoid costs. But if we migrate to the new coding systems, I believe we need to be sensitive to the burgeoning costs to providers. To mitigate these costs, HCFA could:
- Develop a site on the Internet, similar to what HHS has already developed for the Health Insurance Portability and Accountability Act section of their Web site, where medical reimbursement employees can post questions and obtain feedback. Initially, the site would be a forum for questions regarding IS requirements and other implementation issues. Later, the site would also be a

clinical coding resource. Responses would be maintained on the Internet site for reference.

- Make available education and training materials and other resources and services to providers. The materials should be free and accessible on-line, but should also be available in a print format. Again, these references should address both clinical and practical application issues of ICD-10-PCS.

- Educate not only the provider community, but also the payer community and its own staff and those of its contractors, so that the reimbursement cycle is not unduly disrupted.

Data Collection and Integrity

Inarguably, ICD-9-CM Volume 3 doesn't have the capacity necessary to do its job. This is a common quandary at ICD-9-CM Coordination and Maintenance Meetings: We have a need for a new code, but where can we put it?

Many of the ICD-9-CM Volume 3 code descriptions fall short of providing the level of detail necessary to outcomes studies, payment schedules, and other uses. For example, subcategory 04.3 *Suture of cranial or peripheral nerve*: The anatomies addressed in this Volume 3 code are classified in one code because there are not enough available places in the classification to identify each nerve separately. Twenty codes in CPT map to this ICD-9-CM Volume 3 code. More than 800 in ICD-10-PCS map to that single ICD-9-CM Volume 3 code.

Compare the granularity in codes for the repair of the facial nerve:

> ICD-9-CM Volume 3: *04.3 Suture of cranial or peripheral nerve*
> CPT: *64864 Suture of facial nerve; extracranial*
> ICD-10-PCS: *00NQ07Z Open repair facial nerve with nerve*
> *autograft*

CPT offers one other code for facial nerve repair; ICD-10-PCS offers 14 more. When evaluating outcomes, costs, procedure frequency, or any benchmark, 04.3 does not provide sufficient information for an effective study.

Granularity of ICD-10-PCS Needs to Increase

There are sections in which the granularity of ICD-10-PCS falls short. For example, many ophthalmologic procedures are performed with laser techniques that all fall into the procedural category "destruction." The methods of destruction vary greatly, and can alter outcomes. Under the draft ICD-10-PCS system, there is no effort to differentiate the varying destruction techniques. Even ICD-9-CM Volume 3 has separate codes for destruction of chorioretinal lesions, depending upon whether cryotherapy, diathermy, xenon arc, or laser photocoagulation is employed. In ICD-10-PCS, the sixth- or seventh-digits could accommodate identification of destruction method for all anatomical sites to provide additional granularity.

Anatomy May Vex Coders

ICD-10-PCS presents its codes in tables that are both intuitive and simple to use, whether in an electronic or printed format. It is complete, has room for extensive expansion, and is easily updated. However, the codes require a higher level of anatomic understanding than CPT or ICD-9-CM Volume 3 due to the granularity of the information presented. The language of the medical record likely will not parallel the language of the ICD-10-PCS coding grids, and data integrity may be compromised by coding errors if coders are not properly educated or provided with effective coding references.

Change and Data Integrity
Clearly, any change in a coding system, whether annual changes we see in ICD-9-CM Volume 3, or the sweeping changes proposed in ICD-10-PCS, has both positive and negative effects upon the integrity of data. Change opens the door to errors of interpretation as coders adapt, and also creates the potential for mapping errors in analyses that span the old and new systems.
But change also provides us with an opportunity for better data collection, a potential that can lead to significant gains in medical outcomes, economies, and a greater understanding of the health of our nation. It has been said that combined with today's computers, good data has the ability to propel medicine from an art into a science.
The language of ICD-10-PCS is concise, and could provide the data to achieve that goal.
Importantly, ICD-10-PCS has the capacity to grow as medical science grows. Only a fraction of its potential codes are used in the current draft. I have suggested in some of my coding seminars that ICD-10-PCS may have the flexibility and durability to span this century – a statement that cannot be made about any other medical coding system currently proposed or in use. A coding system that could be updated decade after decade would provide an unprecedented continuity of medical data.

Critical Concerns Upon Implementation
HCFA, in evaluating the efficacy of ICD-10-PCS, must also consider whether it is in the nation's best interest to continue to apply two procedural coding systems within the healthcare industry. Currently, CPT is used for physician reporting, and ICD-9 Volume 3 for facility reporting. Since the advent of outpatient surgical centers and APCs, this has required the use of two procedural coding systems at facilities, and necessitates the creation of mapping tools to allow facilities to track frequencies and costs for procedures that are performed as both inpatient and outpatient procedures. A move to a single procedural coding system may be an efficient and effective alternative to current coding methods, and is a past recommendation of the National Committee of Vital and Health Statistics.

So, then, a third question arises: CPT or ICD-10-PCS? This is a politically charged question, and not the topic of today's meeting. But as you study the possibility of

changing from dual procedural coding systems, you may want to consider the following questions:

- Is the coding system maintained in a public domain, with public input and public meetings?
- Is the language of the coding system consistent and intuitive?
- Does the coding system meet the reporting needs of providers, payers, and healthcare statisticians?
- Can reimbursement values be applied effectively and efficiently to the coding system?
- What is the coding system's capacity for growth?

On behalf of Ingenix, I thank you very much for the opportunity to share our thoughts with you today. Ingenix realizes that choosing the nation's future hospital procedural coding system is an extremely difficult and complex task, and we offer our staff as a resource as you continue your examination of this critical issue.

April 24, 2001

Department of Health and Human Services
Health Care Financing Administration (HCFA)
7500 Security Blvd
Baltimore, Maryland

To: ICD-9 Coordination and Maintenance Committee,

McKessonHBOC, Inc. is a Fortune 35 corporation and the world's largest healthcare
services company, providing a full range of supply management solutions and
information technologies to improve performance at each point in the healthcare delivery
system. With approximately 25,000 employees worldwide, McKessonHBOC's focus is
on delivering value-added logistical services, materials management, third-party
reimbursement support, scheduling, clinical data capture/analysis, billing/cost
accountability and decision support. This breadth of capabilities coupled with the largest
customer base in the healthcare industry uniquely positions McKessonHBOC to help
reduce costs and improve quality for customers across the full continuum of care.
McKessonHBOC offers products and services to the following groups of customers:

- 5,000 hospitals
- 25,000 retail pharmacies
- 200,000 physicians
- 10,000 long-term care sites
- 750 home-care agencies
- 450 pharmaceutical manufacturers
  - 2,000 medical surgical manufacturers
- 600 healthcare payors

HBO & Company, a wholly owned subsidiary of McKessonHBOC, Inc., has carefully
reviewed the Draft ICD-10-PCS. Listed below are comments we will present at the May
17, 2001 ICD-9 Coordination and Maintenance Committee meeting related to the
implementation ICD-10-PCS.

Timing

- The implementation timing is a critical issue with regard to the Health Insurance
  Portability and Accountability Act. Information system vendors as well as providers
  and payors are currently focusing resources toward enabling compliance with the

HIPAA transactions and codes sets as mandated by the Implementation Guides per the final regulations.

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Timing (continued)

- A time frame after the compliance date of the HIPAA transactions and codes sets would be desirable and an allowance for adequate timeline within which to make the changes. The impact for payors is immense; therefore, we would like to recommend at least three years for implementation once the final regulations are published.
- ICD-10-CM needs to be a consideration when discussing ICD-10-PCS. For an information system vendor, it would be preferable to implement ICD-10-CM and ICD-10-PCS concurrently.
- Coordination among software vendors is another issue to be considered. Timing must allow for adequate coordination between third party software and software programs in use by a health care system from multiple vendors. This is critical in order to avoid data integrity issues.

Moving forward with a new procedure coding system:

- It is important to note that the 7 digit field and alphanumeric character requires software developers to make significant changes to systems in order to expand the current field in every location in the software that ICD-9-CM currently exists. Therefore, many software applications will be impacted.
- Third party claims vendors will be required to accept ICD-10's and establish new payment methodologies for the new codes.
- If a decision is made to adopt ICD-10-CM for diagnosis and continue to maintain ICD-9-CM Volume 3 for procedure coding, it would be difficult to properly use both ICD-9 and ICD-10 together for inpatient DRG calculations and for the Medicare outpatient APC calculations.
- Software changes will include software systems logic, screen and interface modifications, and system changes for reporting and analyses of codes.
- Increased storage capability is a concern if the transition to the new coding system requires storage of both the ICD- 9 and the ICD-10 codes for the same patient encounter.

Training Requirements:

- Training will be required on several levels for software vendors. Software developers will need to learn the new coding system in order to make appropriate functional/programming changes to the applicable software; software implementation/support staff will need to understand the new coding system in order

to provide assistance to the end-users and documentation manuals will need to be completely rewritten to appropriately reflect the new coding system.

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Public Maintenance Committee:

- The process for public maintenance on ICD-9-CM in place today works extremely well.   However, we would like to suggest that at least for the initial implementation of this new coding system, there is an identified body within HCFA that can and will promptly respond to questions which may arise when software developers are making software changes.

Thank you for allowing us the opportunity to provide comments on the ICD-10-PCS implementation. We look forward to working closely with you as this new coding structure is rolled-out to the market. Should you have any questions or need additional information, please do not hesitate to contact us.

Sincerely,

McKessonHBOC, Inc.

Pat H. Hamby

Pat H. Hamby
Vice President
Regulatory Affairs

May 11, 2001

PRINCETON
REIMBURSEMENT
GROUP

Patricia Brooks
Co-Chair, Coordination and Maintenance
DAC, PPG, CHPP
HCFA
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Baltimore, MD 21244-1850

Dear Pat:

The purpose for my testimony is to express our growing concern with the ICD-9-CM procedural coding restrictions for assignment of codes to new procedures/new technologies. With the space limitations within the current ICD-9-CM procedural area, there will soon be (if not already) little or no space to establish new codes for these procedures. This may translate into new procedures being bundled into existing codes that may not adequately describe the procedure, which may lead to inadequate DRG assignment. The development of new technology may be inhibited if payment is perceived as inadequate to reflect its true value.

The ICD-9-CM system is a good system, but a limited and somewhat dated system. We need to replace the ICD-9 procedural codes with a system that can capture all of the new breakthrough procedures and services that are being introduced into the health care system at an ever-increasing rate.

The criteria developed by the National Committee on Vital and Health Statistics is excellent. There are three points within the criteria that are vitally important to the Medical Device clients we represent – completeness, expandability and standardized terminology.

In terms of completeness, we need a system that allows for new or substantially different procedures to have their own unique code. Under the current system, it is difficult to track data on new procedures when they are bundled into non-specific codes. We have also had situations in which there are no codes that fit and therefore, have been instructed not to code the procedure. New procedures need unique codes to be able to capture utilization and cost date in order to secure appropriate coverage and payment.
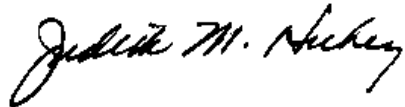
We need a system that is expandable. Based on the May 4, 2001 *Federal Register*, the ICD-9-CM procedure coding system is limited to a maximum of 10,000 codes, most of

which are already assigned. For example, what happens with a new, unique pacemaker procedure that does not fit into any of the established pacemaker codes? There are no available codes to which a new procedure could be assigned.

We need a system that is understandable. Many of the terms used to describe procedures can have a variety of meanings/interpretations. The new system must have standardized terminology so that confusion and coding errors are eliminated.

We believe that the ICD-10-PCS fulfills these criteria, and we urge the Health Care Financing Administration to implement the ICD-10-PCS as a national standard for coding inpatient procedures as quickly as possible.

Sincerely,

Judith M. Hickey
President

JMH/mll

Administration of High-Dose Interleukin-2 (IL-2)

Issue

There is no specific procedure code to uniquely capture the administration of high-dose interleukin-2 therapy. Currently, high-dose interleukin-2 or IL-2 therapy is assigned to ICD-9-CM procedure code 99.28, Injection or infusion of biological response modifier [BRM] as an antineoplastic agent.

Background

High-dose IL-2 therapy is a hospital inpatient-based set of services for treatment of patients with advanced renal cell cancer and advanced melanoma. Currently, this treatment modality is the only approved therapy in Stage IV metastatic renal cell carcinoma and the only immunotherapy approved in Stage IV metastatic melanoma. The Food and Drug Administration (FDA) approved Proleukin® for the treatment of Stage IV metastatic renal cell carcinoma in 1992 and Stage IV metastatic melanoma in 1998. Unlike traditional cytotoxic chemotherapies which attack cancer cells themselves, interleukin-2 enhances the body's defenses by mimicking the way natural IL-2 activates the immune system and stimulates the growth and activity of cancer-killing cells.

High-dose IL-2 therapy is performed in highly specialized treatment settings such as an intensive care unit (ICU) or bone marrow transplant unit. The procedure requires oncology health care professionals experienced with high-dose IL-2 therapy administration and management of patients. Patients may require a one-to-one, two-to-one, or three-to-one critical care nursing staff ratio and physician critical care evaluation and management over extended portions of their stay. Unlike most cancer therapies, high-dose IL-2 therapy is associated with predictable toxicities requiring extensive monitoring, though these toxicities have been shown to be manageable during the stay and reversible soon after completion of therapy. Below is a description of the set of procedures involved in high-dose IL-2 therapy administration.

> **I.** **Pre-administration guidelines.** *Upon admission, patients undergo a series of lab tests to ensure they are otherwise healthy enough to undergo high-dose IL-2 therapy, including: vital signs; cardiopulmonary functioning (pulse oximetry reading, cardiac monitoring, oxygen); intake and output monitoring, and blood tests. A complete blood cell count comprehensive metabolic package, and EKG is also performed. Prior to administration of each dose of IL-2 therapy, nurses will repeat a series of lab tests to ensure patients can tolerate the next dose.*

> **II.** **Dosing Regimen.** *For the first cycle, the IL-2 (per product insert, Proleukin°, aldesleukin for injection) is administered in a 600,000 IU/kg dose every 8 hours by a 15-minute IV bolus infusion over 5 days. After the 5 days of drug administration, patients remain in the hospital for another 2 days for recovery, often in a less intensive care setting.*

Patients are then discharged to rest at home for 7-9 days and then admitted again for the second cycle of therapy, in which the same regimen and dosing is repeated.

The two cycles complete the first course of high-dose IL-2 therapy. Following the first course of therapy, physicians assess patients for response through a physical exam and radiographic studies performed 4-6 weeks post-therapy. Responding patients are then offered further high-dose IL-2 therapy.

III. **High-dose IL-2 Administration.** Prior to drug administration, clinicians will administer analgesic/antipyretics, NSAIDs, and H2 blockers. A triple-lumen central venous catheter is inserted into the patient, through which IV fluids (e.g., 5% dextrose/.9% sodium chloride with 20 mEq KCl/liter) are administered at 100 cc/hr. If signs of capillary leak syndrome occur, clinicians may administer dopamine (1-5 ug/kg/min) prior to the onset of hypotension. Antibiotics are often administered after central line placement for prophylaxis of staphylococcus infection.

Between 30-60 percent of patients require additional medications to maintain blood pressure. By hospital protocol, these usually require intensive care monitoring.

Treatment is fairly standardized in terms of the number and type of associated procedures and costs. As a result, patients who undergo the high-dose IL-2 treatment regimen experience predictable, short-term toxicities requiring extensive monitoring.

Code 99.28 broadly describes several other immunotherapy classifications, none of which mimic the procedure of high-dose IL-2 therapy. There are a number of immunotherapies that work through different mechanisms of action, use widely disparate associated services and resources, and are administered with heterogeneous treatment regimens and doses. For instance, interferon alfa, GM-CSF, and G-CSF are all examples of immunotherapies. However, they are in large part administered in the outpatient setting and do not involve standardized sets of services or therapy guidelines requiring close monitoring. The healthcare community is calling for a more specific code to track services and adequately describe resource utilization and outcomes associated with high-dose IL-2 therapy.

Currently, Proleukin® (aldesleukin for injection), a recombinant form of interleukin-2, is the only interleukin-2 approved for marketing in the US. However, other interleukin-2 agents are currently in development. Proleukin® data was recently updated in 2000, demonstrating long-term remission that suggest cure in a number of patients with a heretofore-incurable disease. These updated data show a median 80+ months survival for metastatic renal cell carcinoma complete responses (range of 7 to 131+ months, or over 11 years) and 59+ months for complete responses in metastatic melanoma (range of 3 to 122+ months, or over 10 years).

Options

1. **Continue to use code 99.28,** Injection or infusion of biological response modifier [BRM] as an antineoplastic agent.

2. Create a new code in subcategory 99.7
New code   99.76 High-dose infusion of interleukin-2 therapy
                   CIV administration
                   IL-2 therapy
                   IV bolus administration

Add an excludes note under code 99.28:
                   Excludes: administration of interleukin-2 (IL-2) therapy

Options, continued
3. Create a new chapter in response to BIPA-533

3.a. TECHNOLOGY (17)

17   New Technology
     17.0 Drugs
New code   17.01 High-dose infusion of interleukin-2 therapy
                   CIV administration
                   IL-2 therapy
                   IV bolus administration

Add an excludes note under code 99.28:
                   Excludes: administration of interleukin-2 (IL-2) therapy

Recommendation
We recommend that Option 2, the creation of a new code, be adopted as follows:

99, Other nonoperative procedures

99.7   Therapeutic apheresis or other injection, administration, or infusion of other therapeutic or prophylactic substance

New code   99.76 High-dose infusion of interleukin-2 therapy
                   CIV administration
                   IL-2 therapy
                   IV bolus administration

Add an excludes note under code 99.28:
                   Excludes: administration of interleukin-2 (IL-2) therapy

Addition of a new code that specifically describes administration of high-dose IL-2 will allow effective tracking of this procedure for the healthcare community without significant disruption to the ICD-9-CM system.

In the interim, continue to code high-dose IL-2 therapy with code 99.28, Injection or infusion of biological response modifier [BRM] as an antineoplastic agent.

[1] National Committee on Vital and Health Statistics. *"Recommendations for a Single Procedure Classification System."* November 1993.

[2] *Federal Register* 63, no. 88, May 7, 1998; p. 25282.

[3] *Federal Register* 63, no.88, May 7, 1998; p. 25274.

[4] *Federal Register* 63, no. 88, May 7, 1998; p. 25286.

[5] Averill, Richard, et al. "Development of the ICD-10 Procedure Coding System (ICD-10-PCS)." *Journal of AHIMA* 69, no. 5 (1998): 65-72. Available at www.ahima.org/journal/coding/coding.9805.html.

[6]"National Data Quality." Position Statement of the American Health Information Management Association; July 1993.