July 2008

National Organizations Urging Appropriate Time to Convert to ICD-10 after 5010 Implementation

Insurers
Blue Cross and Blue Shield Association
America's Health Insurance Plans
Physicians
American Academy of Dermatology Association
American Academy of Facial, Plastic and Reconstructive Surgery
American Academy of Family Physicians
American Academy of Ophthalmology
American Academy of Otolaryngology-Head and Neck Surgery
American Association of Clinical Endocrinologists
American Association of Clinical Urologists
American Association of Neurological Surgeons
American Association of Orthopaedic Surgeons
American College of Chest Physicians
American College of Emergency Physicians
American College of Gastroenterology
American College of Osteopathic Internists
American College of Osteopathic Surgeons
American College of Radiology
American College of Rheumatology
American College of Surgeons
American Gastroenterological Association
American Geriatrics Society
American Medical Association
American Medical Directors Association
American Osteopathic Academy of Orthopedics
American Osteopathic Association
American Society for Clinical Pathology
American Society for Gastrointestinal Endoscopy
American Society of Anesthesiologists
American Society of Cataract and Refractive Surgery
American Society of Plastic Surgeons
American Thoracic Society
American Urological Association
College of American Pathologists
Congress of Neurological Surgeons
Heart Rhythm Society
Infectious Diseases Society of America
Medical Group Management Association
National Hispanic Medical Association
Society for Cardiovascular Angiography and Interventions
Society for Vascular Surgery
Society of Gynecologic Oncologists
Society of Interventional Radiology
Other Providers
American Academy of Professional Coders
American Chiropractic Association
American Clinical Laboratory Association
American Physical Therapy Association
HEAL Coalition (institutions certifying medical coding and billing professionals)

Other National Organization Opposed to Moving to ICD-10

American College of Physicians

State Medical Societies/Other State Organizations Urging More Time for ICD-10

Medical Association of the State of Alabama
Alaska State Medical Association
Arizona Medical Association
Arkansas Medical Society
California Medical Association
Medical Society of Delaware
Medical Society of the District of Columbia
Florida Medical Association
Medical Association of Georgia
Idaho Medical Association
Illinois State Medical Society
Iowa Medical Society
Kansas Medical Society
Louisiana State Medical Association
Maine Medical Association
Massachusetts Medical Society
MedChi, the Maryland State Medical Society
Michigan State Medical Society
Minnesota Medical Association
Mississippi State Medical Association
Montana Medical Association
Nebraska Medical Association
Nevada Department of Health and Human Services
Nevada State Medical Association
New Hampshire Medical Society
Medical Society of New Jersey
New Mexico Medical Society
Medical Society of the State of New York
North Carolina Medical Society
Ohio State Medical Association
Oregon Medical Association
Rhode Island Medical Society
South Carolina Medical Association
Tennessee Medical Association
Texas Medical Association
Utah Medical Society
Vermont Medical Society
Medical Society of Virginia
Washington Healthcare Forum
Washington State Medical Association
West Virginia State Medical Association
Wisconsin Medical Society
Wyoming Medical Society

Views on Sequencing Version 5010 and ICD-10

NCVHS September 26, 2007 – Letter to the Secretary – Revisions to HIPAA transaction standards urgently needed

- Stakeholders testified that concurrent implementation of the Version 5010 standard with the changeover to ICD-10 would be burdensome to industry and result in errors, escalating system change costs and other barriers.

- *Recommendation 2.1: HHS should consider establishing two different levels of compliance for the implementation of HIPAA transaction and code sets. Level 1 compliance would mean that the covered entity could demonstrate that it could create and receive compliant transactions. Level 2 compliance would demonstrate that covered entities had completed end-to-end testing with all of their partners*

- *Recommendation 2.2:* ***The implementations of Version 5010, ICD-10 and claims attachments should be sequenced so that no more than one implementation is in Level 1 at any time.*** *HHS should also take under consideration testifier feedback indicating that for Version 5010, two years will be needed to achieve Level 1 compliance.*

Don Bechtel, Co-Chair ASC X12N Health Care Task Group – Presentation to NCVHS, July 30, 2007

- Moving from version 4010 to 5010 will take time and resources from all entities, providers, health plans, clearinghouse, and software vendors.

- The effort will require significant time as there is much to be done to identify all the changes that will be necessary in each entity's systems, to capture and handle the new data, changes in business rules, thoroughly test internal applications, and then test and migrate to these new transactions with all our various trading partners.

- We should not underestimate the time that will be required to complete this work.

- **There is general agreement within ASC X12 that implementing version 5010 should be done independently of ICD-10.**

- We should not try to implement both 5010 version upgrade and ICD-10 code set at the same time or even within a few months of each other. Both implementations will require significant time to complete. We recommend that adequate time is allowed for version 5010 issues to settle before we start moving forward with ICD-10, to the extent practical.

Illustrative Timeline of Actions to Transition from ICD-9 to ICD-10[1]

Time Frame	5010	ICD-10
March 2008		• CMS announces that it will update the ICD-10 to ICD-9-CM cross-walks (as part of the 2009 updates to the ICD-10 files) by adding a new field for payment mapping to permit proper analyzing of the conversion of payment systems
August 1, 2008	• HHS issues **NPRM** and begins notice and comment period • Industry begins preliminary planning and budget allocations for implementation process: allocate funds through normal budgeting processes	
January 2009	• HHS issues **final 5010 rule**	• CMS publishes findings from AHIMA contract (awarded in October 2007) on the impact of replacing ICD-9 with ICD-10 to inform industry[2] • Industry & HHS begin planning for electronic and paper-based pilot testing of ICD-10: identify "real world" cross-walks, optimal methods for provider education. Emphasis placed on providers with limited technical resources and safety net providers • CMS publishes new payment mapping field for ICD-10 to ICD-9-CM cross-walks • Industry & HHS start electronic and paper-based ICD-10 pilot testing • Industry begins educational process as well as planning and budget allocations for implementation process: allocate funds through normal budgeting processes, reallocate/hire staff • HHS releases evaluation of ICD-10 pilot: lessons learned and proposed education strategies • NCHS, CMS, and industry complete analysis, remediation, and automation of ICD-10-CM/PCS crosswalks, based in part on experience from pilot projects • HHS issues **NPRM** (informed by lessons learned from pilot) and begins 90-day notice and comment period
February 2009	• Industry begins to carry out **"Level 1" compliance**; starts **Analysis Phase**: gap analysis, system specifications	
July 2009	• Industry begins **Design Phase**: design programming, policy, and process changes needed for internal systems and new business processes	
November 2009	• Industry begins **Development Phase**: Application developers create the computer codes to comply with Analysis Phase specifications for transaction standards; code the interfaces between transactions standards and other internal applications such as processing and eligibility systems; and perform unit testing to verify that every logical path through the revised computer code is implemented and functions as designed	
July 2010	• Industry begins **Internal Testing Phase**: defect identification, debugging	
January 2011	• Industry completes internal testing and achieves **Level 1 compliance** (per NCVHS) • Industry begins **External Trading Partner Testing Phase**: test and correct new functionalities, schedule deployment and conversions (to achieve Level 2 compliance)	• HHS issues **final ICD-10 rule** (per NCVHS recommendation to sequence ICD-10 after 5010 Level 1 compliance) • Industry begins ICD-10 implementation, starting with **Analysis Phase**: identify "gaps" in claims processing, benefits design and management, medical management, data warehouses, private and

[1] Consistent with NCVHS recommendations in 9/26/2007 letter to HHS to establish two different levels of compliance for implementing HIPAA mandates: Level 1 compliance would mean that covered entities could demonstrate that they could create and receive compliant transactions; Level 2, that covered entities had completed end-to-end testing with all of their partners. NCVHS recommended that HHS (1) consider two years for 5010 Level 1 compliance; and (2) sequence implementations of Version 5010 and ICD-10 so that no more than one implementation is in Level 1 at any time."

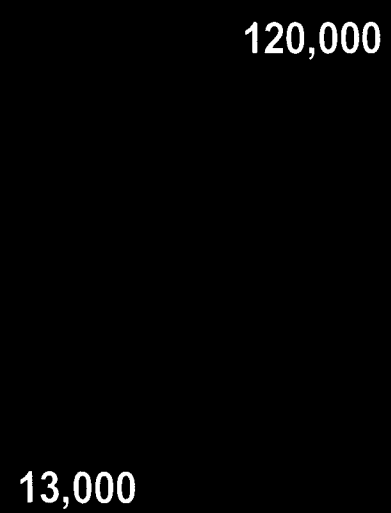
[2] The National Uniform Claim Committee (NUCC) – a voluntary organization that is formally named in the administrative simplification section of HIPAA as one of the organizations to be consulted by HHS when HHS modifies national standards for health care transactions – made this recommendation in a March 7, 2008, letter to CMS.

Time Frame	5010	ICD-10
		government reporting, enrollment, trading partner contracting, other business processes. Also major changes to be driven in payer-provider benefit agreements, reimbursements (e.g. DRGs, RBRVS, fee schedules), fraud and abuse monitoring, and medical policy. Identify changes required for internal system formats, file structures, processing logic and related business processes
September 2011		• Industry begins **Design Phase**: design programming, policy, and process changes needed for internal systems and new business processes
January 2012	• Industry begins **Implementation Phase**: Install completed code to the production system and perform regression testing to make sure the code is working as designed	• Industry begins **Development Phase**: application developers create the computer codes to comply with the specifications for front-end and back-end applications determined in the Design Phase • Text books and curriculum developed to train coders and providers on ICD-10
March 2012	• Industry achieves **Level 2 compliance**[3]	
July 2012		• Industry begins **Internal Testing Phase**: end-to-end testing to identify errors and de-bug programs, educate clinical and administrative staff • Aggressive education efforts begin to train coders and providers on massive new code set • Vendors develop code selection software
January 2013		• Industry completes internal testing and achieves **Level 1 compliance** • Industry begins **External Trading Partner Testing Phase**: assure that the exchange of electronic data between trading partners work at a minimum as efficiently/ accurately as current operations • Education efforts continue • Providers buy and implement code selection software
November 2013		• Industry begins **Implementation Phase**: Install completed code to the production system and perform regression testing to make sure the code is working as designed. Assure operational staffers are fully trained to use the new version of the system
January 2014		• Industry ends Implementation Phase[4]

[3] **It took approximately 54 months to implement the original 4010 version of the HIPAA transactions.**

[4] This end date is consistent with the NCVHS recommendation that "it is critical that the industry is afforded the opportunity to test and verify Version 5010 up to two years prior to the adoption of ICD-10." However, although all HIPAA electronic transactions will be using ICD-10 at this time, full implementation will not be achieved until industry completes a post-implementation measurement/benchmarking period. For some period industry will need to continue to rely on crosswalks to correlate data compiled under the ICD-9 and ICD-10 systems.

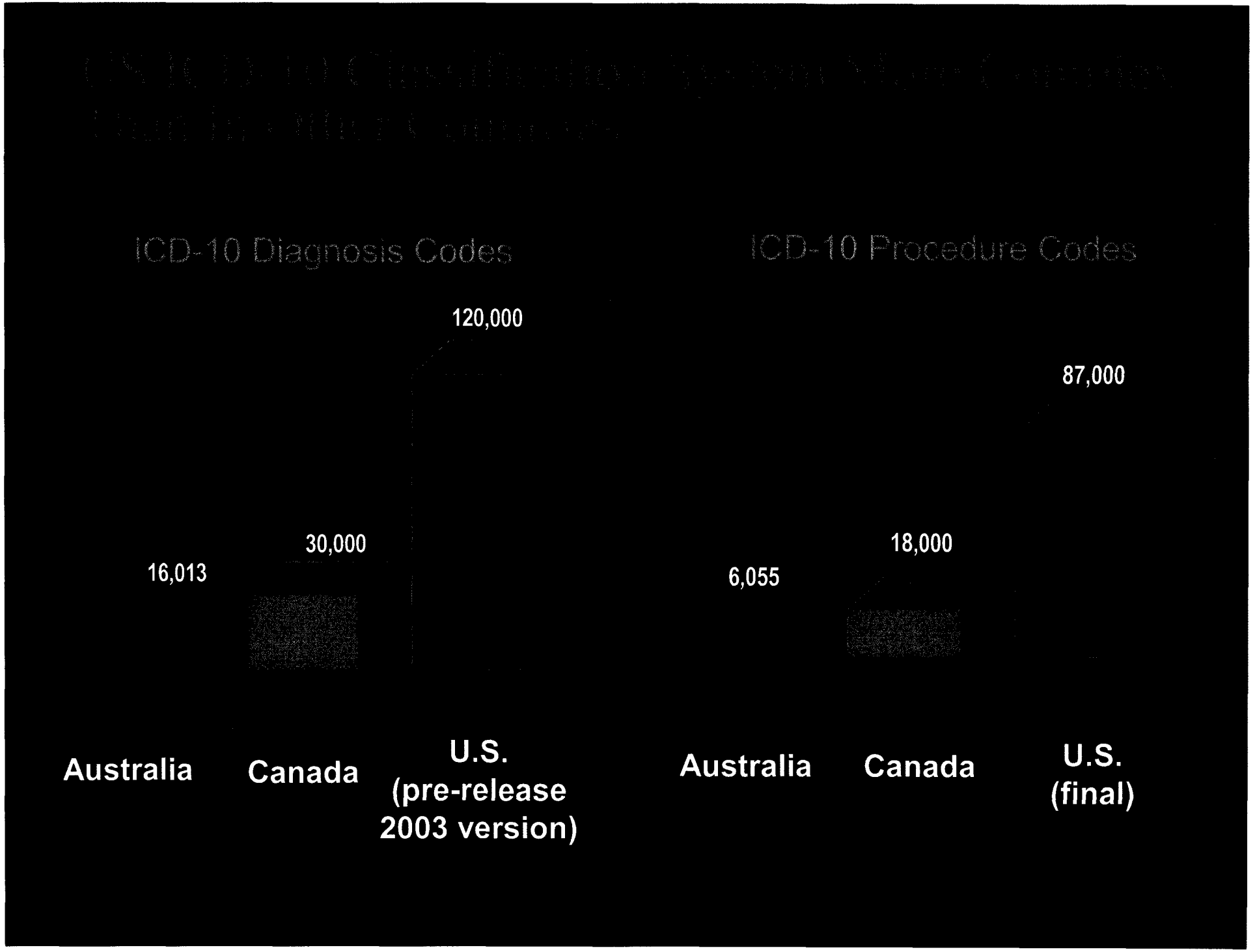
Diagnosis Codes

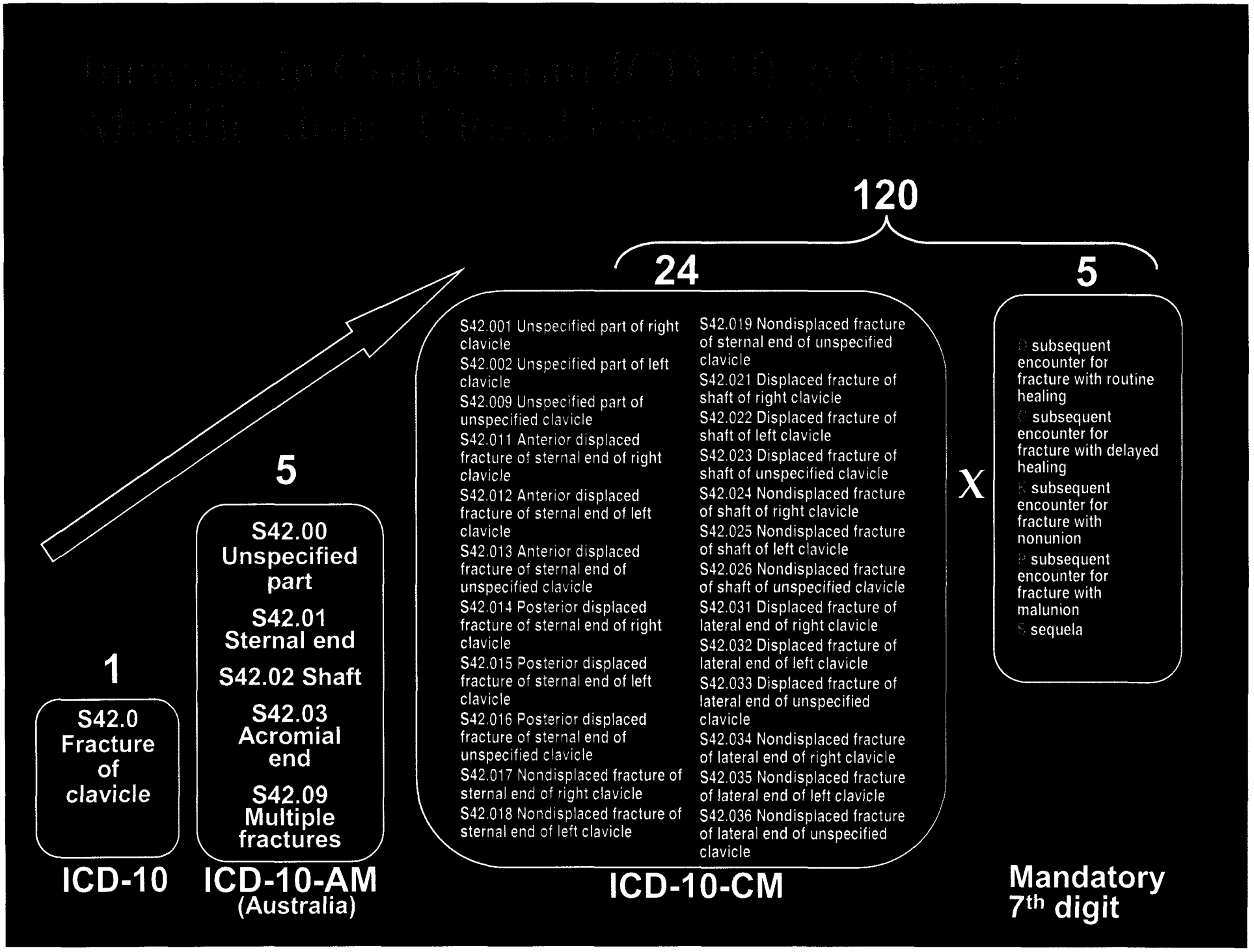


ICD diagnosis codes are used by inpatient and outpatient providers for billing and reimbursement.

Procedure Codes

ICD procedure codes are used by only inpatient providers for billing and reimbursement.


ICD-10 Diagnosis Codes
120,000
30,000
16,013
Australia
Canada
U.S.
(pre-release
2003 version)
ICD-10 Procedure Codes
87,000
18,000
6,055
Australia
Canada
U.S.
(final)


120
24
5
1
5
S42.0 Fracture of clavicle
S42.00 Unspecified part
S42.01 Sternal end
S42.02 Shaft
S42.03 Acromial end
S42.09 Multiple fractures
S42.001 Unspecified part of right clavicle
S42.002 Unspecified part of left clavicle
S42.009 Unspecified part of unspecified clavicle
S42.011 Anterior displaced fracture of sternal end of right clavicle
S42.012 Anterior displaced fracture of sternal end of left clavicle
S42.013 Anterior displaced fracture of sternal end of unspecified clavicle
S42.014 Posterior displaced fracture of sternal end of right clavicle
S42.015 Posterior displaced fracture of sternal end of left clavicle
S42.016 Posterior displaced fracture of sternal end of unspecified clavicle
S42.017 Nondisplaced fracture of sternal end of right clavicle
S42.018 Nondisplaced fracture of sternal end of left clavicle
S42.019 Nondisplaced fracture of sternal end of unspecified clavicle
S42.021 Displaced fracture of shaft of right clavicle
S42.022 Displaced fracture of shaft of left clavicle
S42.023 Displaced fracture of shaft of unspecified clavicle
S42.024 Nondisplaced fracture of shaft of right clavicle
S42.025 Nondisplaced fracture of shaft of left clavicle
S42.026 Nondisplaced fracture of shaft of unspecified clavicle
S42.031 Displaced fracture of lateral end of right clavicle
S42.032 Displaced fracture of lateral end of left clavicle
S42.033 Displaced fracture of lateral end of unspecified clavicle
S42.034 Nondisplaced fracture of lateral end of right clavicle
S42.035 Nondisplaced fracture of lateral end of left clavicle
S42.036 Nondisplaced fracture of lateral end of unspecified clavicle
X
D subsequent encounter for fracture with routine healing
G subsequent encounter for fracture with delayed healing
K subsequent encounter for fracture with nonunion
P subsequent encounter for fracture with malunion
S sequela
ICD-10
ICD-10-AM (Australia)
ICD-10-CM
Mandatory 7th digit

MGMA

MGMA Center for Research
American College of Medical Practice Executives
Medical Group Management Association

ICD-10-CM Implementation Concerns and Recommendations

As the health care industry moves forward with health information technology, we would like to take this opportunity to raise concerns regarding a rapid timeline for adopting the International Classification of Diseases, 10th Edition, Clinical Modification (ICD-10-CM) code set.

Concerns with the Rapid Adoption of ICD-10-CM:

- Complex software changes must be completed before ICD-10-CM could be utilized. Vendors that will be required to produce these modifications are non-covered entities under HIPAA.
- The move to ICD-10-CM would be extremely expensive and would divert critical resources from the purchase of electronic health record (EHR) systems.
- The industry is currently challenged with other federally mandated clinical and administrative initiatives, including the NPI in 2007-2008, Electronic Claims Attachments (expected 2008-2009), HIPAA transactions modifications (expected 2008-2009), and e-prescribing final standards (expected 2009). A switch to ICD-10-CM would overtax the system, particularly for providers.
- Nations such as Canada and Australia have decided against switching to ICD-10 in physician practices due to its complexity and high cost.

Recommendations:

- National implantation plan. In an effort to avoid the type of costly challenges the industry faced and continues to face with implementation of the numerous HIPAA requirements such as electronic transactions and the NPI, HHS should create a task force of both government and industry representatives to map out a logical and cost-effective migration to ICD-10. With a change of this magnitude, affecting each sector of the healthcare industry, it is critical that an implementation plan be created with the support and participation of every major stakeholder impacted by the change.
- Cost-benefit analysis. HHS should closely examine the impact that moving to ICD-10-CM will have on each sector of the heath care industry. In particular, HHS should identify the costs for the provider community including "safety net" providers that typically have limited resources to spend on software upgrades and staff training.
- Full pilot testing of ICD-10-CM. HHS should fully understand what impact the change to a complex new code set will have on each industry stakeholder through the use of pilots. It will be important to identify potential implementation issues and solutions on a smaller scale long before they become expensive and disruptive national issues.
- Develop Code Set Crosswalks. HHS should develop a fully automated and publicly available crosswalk between ICD-9-CM, ICD-10-CM, and SNOMED-CT. This will allow providers, payers, vendors and others to fully test systems and minimize breaks in historical data.
- Restructure ICD-9-CM. As the appropriate ICD-10 implementation process is being developed, HHS should examine the current ICD-9-CM code development, allocation, and removal process and make the necessary changes to permit the full utilization of the current code set and the rapid assignment of necessary codes.
- Fully implement HIPAA 5010 before ICD-10-CM. The latest iteration of the HIPAA electronic transactions standards is expected to be released in 2008. This will be a difficult and costly transition on its own. The move to ICD-10-CM should not be made until after the 5010 standards have been fully implemented and tested.

Summary: Switching too rapidly to ICD-10-CM would create significant problems for the entire health care industry, especially providers. We recommend mandating extended compliance timelines in recognition that the transition to ICD-10-CM will be extremely challenging and costly for the entire industry.

MGMA looks forward to working with you as the health IT adoption process moves forward. If you have any questions or would like additional information, please feel free to contact MGMA senior policy advisor Robert Tennant at (202) 293-3450.

Implementation Steps for Adoption of ICD-10 in Medical Practices

The cost for medical practices to move to ICD-10 is expected to be considerable, yet, to date, there has not been a comprehensive study that fully examines the impact of this new code set. A group of health care organizations have contracted with a consulting group to begin to identify the impact of the transition to ICD-10. This report is expected to be finalized later this summer. The following examples, drawn from the forthcoming report, are some of the time-consuming and costly changes practices will have implement in order to submit ICD-10 codes on claims. Steps that medical practices will have to take in order to implement ICD-10 include:

1. **PURCHASE AND CONDUCT EDUCATION**—Practices will be required to educate clinical personnel and all staff involved in coding and billing about ICD-10, detracting from patient care and costing significant time and money. (Note: textbooks, curricula, training modules, and other training systems and aids are not yet available and will have to be developed.)

2. **MODIFY WORKFLOW**—Practices will need to analyze the impact of the change to ICD-10 on their business flow and make the necessary modifications. It is expected that many practices will be forced to retain consulting services.

3. **PURCHASE SOFTWARE UPGRADES**--Update and/or replace their current electronic health record (EHR) and practice management systems. Depending on their systems, this can cost the practice tens of thousands or even hundreds of thousands of dollars.

4. **INCREASE DOCUMENTATION**--Documentation of conditions to support the increased specificity of ICD-10 will need to be increased, causing an estimated permanent 3-4% increase in their workload.

5. **ASSESS MEDICAL REVIEW POLICIES**—Practices will need to review and revise their treatment and billing practices based on constantly changing medical review policies developed by each health plan with which they deal. Note that they will not know what to do until receiving these revised policies from their health plans, which is not expected to happen until well after the publication date of the final regulation.

6. **REVIEW PLAN PARTICIPATION**—Practices will need to review and redetermine their participation in health plans based on changes made by health plans in their coverage and medical review policies. In many cases the review of revised contracts will require practices to retain legal services.

7. **MODIFY SUPERBILLS**—Practices will need to modify their "superbill" claim form to reflect ICD-10 coding. With the tenfold increase in codes, it will be difficult to maintain a simple paper superbill. While many practices currently utilize ICD-9 coding books, it is expected that with the increased number of codes under ICD-10, providers will be required to purchase expensive code selection software (currently not available).

8. **CONDUCT TRADING PARTNER TESTING**--Test their systems with each of the health plans with which they submit claims. This will require the health plans (and clearinghouses) to be ready to accept ICD-10 claims well in advance of the compliance date. With the previous HIPAA mandates, extensions to compliance dates were required due to the fact that sufficient testing had not occurred.

9. **REVISIT QUALITY REPORTING**—Practices will have to modify their reporting systems for quality and other measures to reflect ICD-10 coding. (Note that currently all quality reporting measures developed by the NQF and AQA are ALL based on ICD-9-CM codes and each quality measure will have to be carefully reviewed and assigned one or more ICD-10-CM codes.)

10. **MANAGE DECREASED PRODUCTIVITY**—Practices will experience decreased productivity during the transition phase of moving from ICD-9 to ICD-10. How long this decreased productivity lasts will be dependent upon vendor upgrades of billing and clinical software, trading partner testing, and clinical and administrative staff training.

Practices will be forced to plan for the transition to ICD-10 without knowing the dates of the final rule publication, the implementation period, or the final compliance date. In addition, they are faced with waiting for each of their vendors (non-covered entities under HIPAA) to provide the appropriate upgrades to their software and wait for health plans to make their coverage decisions and billing revisions. It is expected to take practices up to one year to understand and revise their procedures to create accurate codes.

While the change to the 4010 version of the HIPAA transactions standards has been extremely difficult and resource intensive, we have learned what a change of this magnitude requires in terms of timing and process. Given that the change from ICD-9 to ICD-10 will be even more complex and challenging than the transition to the HIPAA 4010 electronic standards, it is critical that we apply lessons learned from our previous experiences to the implementation of the 5010 standards, and ultimately to the transition ICD-10.

Summary: it is clear that implementation of ICD-10 in ambulatory care settings will involve numerous steps and consume significant human and financial resources. Rushed implementation of ICD-10 will lead to widespread disruption in the US health care system and could impact the delivery of care to patients. In addition, rapid adoption of ICD-10 will also hinder progress towards physician adoption of health information technology and become a tipping point for a segment of the physician population to retire early rather than spend the resources implementing ICD-10.

Implementing ICD-10

Comparison: Canada/Australia vs. United States

Number of Codes

- Canada—an estimated 17,000 diagnoses codes for ICD-10-CA.
- Australia—an estimated 22,000 diagnoses codes from ICD-10-AM
- *United States*--an estimated 120,000 ICD-10-CM diagnoses codes (3M/HFMA).

Designated/Proposed Clinical Settings

- Canada—Inpatient ONLY (no plans currently to move ICD-10-CA to the outpatient physician office setting where they continue to use ICD-9).
- Australia--Inpatient ONLY (ambulatory/outpatient services in hospitals and physician offices not included).
- *United States*—Inpatient AND outpatient. Every clinical setting would be mandated to use ICD-10-CM.

Implementation Period

- Canada—Phased in by province. Process began in 2001 and was not completed until 2006.
- Australia—Staggered phase in by state—took more than two years.
- *United States*—Current regulatory proposal calls for full nationwide implementation by 2011.

Productivity Decrease

- Canada—Hospital professional coders took between six weeks to six months to become ICD-10-CA proficient, depending on level of technical expertise.
- Australia—In the hospital coding setting, it was six months before productivity was back to normal.
- *United States*—Unknown

Pilots

- Canada—Implemented several provincial pilots.
- Australia-- dual coding pilot was done which involved a "lab test" where coders coded records using both the old ICD-9-CM and ICD-10-AM
- *United States*—Current regulatory proposal expected to contain no provision for pilots.

Funding

- Canada—Software upgrades to hospitals and training of clinical and administrative staff funded by provincial governments.
- Australia— Software upgrades to public hospitals and training of clinical and administrative staff funded by state/territory health authorities.
- *United States*—Current regulatory proposal expected to call for all covered entities to self-fund.

Sources: Canadian Institute for Health Information/ National Centre for Classification in Health (Australia)

▲Measure #7: Beta-blocker Therapy for Coronary Artery Disease Patients with Prior Myocardial Infarction (MI)

DESCRIPTION:
Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease and prior myocardial infarction (MI) who were prescribed beta-blocker therapy

INSTRUCTIONS:
This measure is to be reported a minimum of once per reporting period for patients with prior myocardial infarction (MI) seen during the reporting period. This measure may be reported by clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding.

This measure is reported using CPT Category II codes:
ICD-9 diagnosis codes, CPT E/M service codes, and patient demographics (age, gender, etc.) are used to identify patients who are included in the measure's denominator. CPT Category II codes are used to report the numerator of the measure.

When reporting the measure, submit the listed ICD-9 diagnosis codes, CPT E/M service codes, and the appropriate CPT Category II code **OR** the CPT Category II code **with** the modifier. The modifiers allowed for this measure are: 1P- medical reasons, 2P- patient reasons, 3P- system reasons, 8P- reasons not otherwise specified.

NUMERATOR:
Patients who were prescribed beta-blocker therapy

Definition: "Prescribed" includes patients who are currently receiving medication(s) that follow the treatment plan recommended at an encounter during the reporting period, even if the prescription for that medication was ordered prior to the encounter.

Numerator Coding:
Beta-blocker Therapy Prescribed
CPT II 4006F: Beta-blocker therapy prescribed

OR

Beta-blocker Therapy not Prescribed for Medical, Patient, or System Reasons
Append a modifier (**1P, 2P, or 3P**) to CPT Category II code **4006F** to report documented circumstances that appropriately exclude patients from the denominator.

- **1P:** Documentation of medical reason(s) for not prescribing beta-blocker therapy
- **2P:** Documentation of patient reason(s) for not prescribing beta-blocker therapy
- **3P:** Documentation of system reason(s) for not prescribing beta-blocker therapy

OR

Beta-blocker Therapy not Prescribed, Reason not Specified
Append a reporting modifier (**8P**) to CPT Category II code **4006F** to report circumstances when the action described in the numerator is not performed and the reason is not otherwise specified.

- **8P:** Beta-blocker therapy was not prescribed, reason not otherwise specified

DENOMINATOR:
Patients aged 18 years and older with a diagnosis of coronary artery disease who also have prior myocardial infarction (MI) at any time

Denominator Coding:
An ICD-9 diagnosis code for coronary artery disease* and myocardial infarction and a CPT E/M service code are required to identify patients for denominator inclusion.
ICD-9 diagnosis codes: 411.0, 411.1, 411.81, 411.89, 413.0, 413.1, 413.9, 414.00, 414.01, 414.02, 414.03, 414.04, 414.05, 414.06, 414.07, 414.8, 414.9, V45.81, V45.82, 410.00*, 410.01*, 410.02*, 410.10*, 410.11*, 410.12*, 410.20*, 410.21*, 410.22*, 410.30*, 410.31*, 410.32*, 410.40*, 410.41*, 410.42*, 410.50*, 410.51*, 410.52*, 410.60*, 410.61*, 410.62*, 410.70, 410.71*, 410.72*, 410.80*, 410.81*, 410.82*, 410.90*, 410.91*, 410.92*, 412*
AND
Patients who had a prior MI at any time
ICD-9 diagnosis codes: 410.00, 410.01, 410.02, 410.10, 410.11, 410.12, 410.20, 410.21, 410.22, 410.30, 410.31, 410.32, 410.40, 410.41, 410.42, 410.50, 410.51, 410.52, 410.60, 410.61, 410.62, 410.70, 410.71, 410.72, 410.80, 410.81, 410.82, 410.90, 410.91, 410.92, 412
AND
CPT E/M service codes: 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99238, 99239, 99241, 99242, 99243, 99244, 99245, 99304, 99305, 99306, 99307, 99308, 99309, 99310, 99324, 99325, 99326, 99327, 99328, 99334, 99335, 99336, 99337, 99341, 99342, 99343, 99344, 99345, 99347, 99348, 99349, 99350

Denominator inclusion for this measure requires the presence of a prior MI diagnosis AND at least one E/M code during the measurement period. Diagnosis codes for Coronary Artery Disease (which include MI diagnosis codes) may also accompany the MI diagnosis code, but are not required for inclusion in the measure.

RATIONALE:
In the absence of contraindications, beta-blocker therapy has been shown to reduce the risk of a recurrent MI and decrease mortality for those patients with a prior MI.

CLINICAL RECOMMENDATION STATEMENTS:
Chronic Stable Angina: Class I – Beta-blockers as initial therapy in the absence of contraindications in patients with prior MI. Class I – Beta-blockers as initial therapy in the absence of contraindications in patients without prior MI. (ACC/AHA/ACP-ASIM)

Unstable Angina and Non-ST-Segment Elevation Myocardial Infarction: Class I – Drugs required in the hospital to control ischemia should be continued after hospital discharge in patients who do not

NCVHS NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS

September 26, 2007

Michael O. Leavitt
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C. 20201

Dear Secretary Leavitt:

Revisions to HIPAA transaction standards urgently needed

Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the National Committee on Vital and Health Statistics (NCVHS) studies and recommends healthcare information standards. To fulfill this responsibility, NCVHS' Subcommittee on Standards and Security held hearings on proposed new versions of the HIPAA transaction standards on July 30 and 31, 2007. The purpose of this letter is to summarize those hearings and make recommendations.

Background

The original HIPAA transaction standards were adopted in 2000 and amended in 2002. Since that time, hundreds of requests for changes have been submitted to the National Council for Prescription Drug Programs (NCPDP) and the Accredited Standards Committee (ASC) X12N, the Standards Development Organizations (SDOs) responsible for maintaining the transaction standards. Both have developed and approved new versions of the existing HIPAA transaction standards. The NCPDP has also developed and approved a new transaction.

The HIPAA regulation process for reviewing and adopting proposals for modifications and additions to the transaction standards flows through the Designated Standards Maintenance Organizations (DSMOs), consisting of SDOs and content committees (e.g. the National Uniform Claim Committee). They review the proposed standards after SDO approval, and make recommendations to the NCVHS regarding adoption. On July 30 and 31, 2007, the Subcommittee on Standards and Security heard testimony from providers, health plans, vendors, SDOs and others on the need to implement the new standards forwarded in May 2007, the impact on industry, and implementation issues.

3311 Toledo Road • Room 2341 • Hyattsville, MD 20782 • (301) 458-4200 • Web site: www.ncvhs.hhs.gov

ASC X12N Standards

ASC X12N has developed a modified version of their standards, Version 5010, to replace the current HIPAA standards, Version 4010 (as modified by Version 4010A1) for the following transactions:

- ASC X 12 834, health plan enrollment;
- ASC X12 820, premium payments;
- ASC X12 270/271, eligibility inquiry and response;
- ASC X12 278, health care services – request authorization;
- ASC X12 837, health care claims/encounters (institutional, professional and dental);
- ASC X12 276/277, health care claim status request and response; and
- ASC X12 835, health care claim payment/remittance advice.

There are four basic types of changes in Version 5010: structural, front matter, technical improvements and data content changes. Structural changes involve the physical components and either add new data elements; modify length of existing elements, data type, optional status; or remove data elements. Front matter changes are organizational revisions to ensure that each technical report covers the same topics in the same location, and that the standardization of topics is clear, more instructional and accurate. Technical improvements better accommodate the data collected and transmitted. Specifications for Implementation Guides reduce ambiguities from the same data having multiple codes or qualifiers, or from appearing in different segments. Loop and segment repeat counts that were not always logical and sometimes excessive were reduced or removed. Unnecessary data content was removed and redundancies lessened. Needed additions of new information occurred, as in the ASC X12N 278 health care services-request authorization transaction, where a lack of data content for medical decisions about authorizations limited significant industry implementation.

New Version 5010 functions, added in response to industry requests, include: additional audit controls in enrollment transactions; qualifiers when adding or deleting dependents; support of ICD-10-CM for reporting diagnoses and other health conditions and support of ICD-10-PCS for reporting inpatient procedures; privacy issues, such as drop-off locations for other than home residences; a place to report additional deductions to payments; indications of the remittance method used by health plans; added support for 38 patient service type codes; support for reconsideration requests, made prior to a formal appeal; present on admission indicators; ambulance pick-up and drop-off locations; remaining patient liability; national health plan ID (when an identifier is adopted) ; alternate search options; requirements for the health care eligibility response that improve the value of the transaction and tighten situation rules; and information on the patient's portion of payment responsibility. Certain functions such as "purchased service provider" and "referring provider specialty" were removed.

NCPDP Standards

The NCPDP HIPAA standards currently in place are the Telecommunications message format standard, Version 5.1 and its equivalent NCPDP Batch Standard Batch Implementation Guide,

Version 1.1, used for transactions involving pharmacy providers or their authorized billing agents for pharmacy drug claims. These are the main transactions between pharmacies, payers, pharmacy benefit managers (PBMs), and clearinghouses/switches. NCPDP has developed a revised Telecommunications Standard, Version D.0, to replace Version 5.1, and an equivalent batch standard, Version 1.2, to continue support for eligibility verification, claim, service, information report and prior authorization transactions.

Version D.0 modified field and segment defined situations to be "not used", "required if", "required" or "optional", addressing the situational versus optional data requirements from the HIPAA privacy regulations. Segment usage matrices now clarify which segments and fields are sent for each transaction type, and segments and fields within each transaction type. Enhancements to accommodate Medicare Part D include the addition of a "facilitator" entity and eligibility transaction, to provide coded patient eligibility information for Medicare Part D; and enhancements to identify and process Medicare Part D long term care claims. Medicare Part B enhancements include additional segments for processing of Medicare certificates of medical necessity and new data elements for processing those transactions and assistance in the crossover of claims from Medicare to Medicaid.

Version D.0 also supports coordination of benefits (COB) and collection of rebates for compounded claims; clarification for pricing guidelines; the addition of new data elements that give more specificity to the COB process; a new section on prior authorization added to the implementation guide; a prescription/service reference number increase to 12 digits; and transaction codes for service billings.

A new Medicaid Subrogation Standard Implementation Guide, Version 3.0, addresses the business need for a standard that addresses the process whereby a Medicaid agency has reimbursed a pharmacy provider for a covered claim, and is pursuing reimbursement from other payers for these claims. Some states may choose to "pay" all claims in full, through a federal waiver at the point of receipt, and "chase" reimbursements from responsible third parties after the fact. In the absence of such a standard, a proprietary interpretation of the Batch standard or other proprietary standards often are used. This is a new HIPAA transaction.

Observations and Recommendations

Observation 1: Industry urges and supports transition to X12N Version 5010 and NCPDP Version D.0, and adoption of NCPDP Medicaid Subrogation Standard Version 3.0.

Based on the testimony to the Subcommittee from providers, vendors, clearinghouses, pharmacies and other industry segments, testifiers supported the move from X12N Version 4010A1 and NCPDP Version 5.1 to Version 5010 and Version D.0, respectively. The majority of the changes and modifications to these updated standards are a direct result of requests by industry to address demonstrated business needs and, in their totality, reflect a long list of positive changes. There appears to be widespread consensus on the business case for adopting D.0. While there needs to be more work to further quantify the overall business case for adopting Version 5010, there was general industry support for the move. Moreover, there are specific and urgent business drivers (e.g., the need to accommodate ICD-10 codes) that justify its

adoption. There is support for adopting the new Medicaid subrogation transaction, which will standardize the subrogation process across states.

Recommendation 1.1: The Secretary should expedite the development and issuance of a Notice of Proposed Rule Making (NPRM) to adopt NCPDP D.0 and its equivalent batch standard as modifications.

Recommendation 1.2: The Secretary should expedite the development and issuance of a Notice of Proposed Rule Making (NPRM) to adopt the ASC X12N Version 5010 suite of transactions.

Recommendation 1.3: The Secretary should expedite the development and issuance of a Notice of Proposed Rule Making (NPRM) to adopt the NCPDP Medicaid Subrogation Standard Version 3.0 as a new HIPAA transaction.

Observation 2: The timing of standards implementation is complex, and critical to success.

Testifiers acknowledged that there were no implementation issues with NCPCP Version D.0, but there was a need to test Version 5010 in real-life settings to ensure its interoperability and ability to support the transactions for which its adoption is proposed. The process for pilot testing and the parameters of that testing remain to be resolved. Three types of testing needs were identified: 1) testing of the standards themselves for workability; 2) conformance testing of products and applications that send and/or receive the transactions; and 3) end-to-end testing to assure interoperability among trading partners. NCVHS has observed that in previous HIPAA transaction implementation these three types of testing occurred unevenly, resulting in delays. These delays may be minimized or avoided by staging the various types of testing.

Testifiers expressed the need to test and verify Version 5010 before the implementation of ICD-10 code sets. Stakeholders testified that concurrent implementation of the Version 5010 standard with the changeover to ICD-10 would be burdensome to industry and result in errors, escalating system change costs and other barriers.

Because implementation of the ICD-10 code sets is dependent on the implementation of Version 5010, it is critical that the industry is afforded the opportunity to test and verify Version 5010 up to two years prior to the adoption of ICD-10. In addition, the compliance date for the new Claim Attachment standards, for which a Final Rule has not yet been published, will also necessitate significant system changes, and should not be done at the same time as Version 5010 or ICD-10.

Testifiers discussed lessons learned from prior HIPAA implementations, and identified potential barriers and resource issues. The importance of vendor compliance was stressed, as practice management system vendors are key to provider compliance, and delays in vendor rollouts of compliant products have delayed end-to-end testing. The resource-intensive nature of testing, particularly end-to-end testing, was also noted.

A variety of options for staggering the implementation of the Version 5010 and D.0 modifications were offered. For example, the compliance date for plans and clearinghouses

could be a year before the date for providers in order to facilitate end-to-end testing. Alternatively, different compliance dates could be assigned to different transactions (e.g., implement the claim and related transactions first.) Testifiers also attested to the importance of allowing dual processing (old plus new versions) for a sufficient period to allow end-to-end testing to occur.

Testifiers indicated that it is important to engage industry in end-to-end testing as soon as possible. It was noted that widespread use of compliance testing services, which allow entities to test products and applications to assure they can create and accept compliant transactions, could simplify end-to-end testing by assuring that individual products are compliant in advance. An alternative to staggering implementation would be to phase in compliance by establishing consecutive periods for compliance testing and end-to-end testing.

Recommendation 2.1: HHS should consider establishing two different levels of compliance for the implementation of HIPAA transaction and code sets. Level 1 compliance would mean that the covered entity could demonstrate that it could create and receive compliant transactions. Level 2 compliance would demonstrate that covered entities had completed end-to-end testing with all of their partners.

Recommendation 2.2: The implementations of Version 5010, ICD-10 and claims attachments should be sequenced so that no more than one implementation is in Level 1 at any time. HHS should also take under consideration testifier feedback indicating that for Version 5010, two years will be needed to achieve Level 1 compliance.

Observation 3: Various types of testing are needed.

NCVHS recognizes the value of compliance testing services as a precursor to end-to-end testing of system changes, and the need to pilot the use of the standards within organizations, as well as between partners as was done with the claims attachment transaction standards. We also recommend that CMS and industry stakeholders work to standardize commonly used terms such as "pilot testing" and "compliance testing" so that all entities can make decisions based on universally-accepted definitions.

Recommendation 3.1: HHS should develop a plan to work with the industry and the standards organizations to collect and analyze requirements related to testing (including defining the process of pilot testing), determine under what conditions pilots should be conducted, and when this testing should take place.

Recommendation 3.2: HHS should advocate the use of compliance testing services for software and/or applications that would demonstrate a covered entity's ability to create and receive compliant transactions.

Observation 4: Outreach to all stakeholders is critical.

The Subcommittee heard from stakeholders that the need is great for education and outreach regarding the adoption and implementation of Version 5010. Taking lessons learned from its

experience with the National Provider Identifier (NPI), testifiers reiterated the need to cast a wide net to better inform and educate all industry segments as to how Version 5010 will impact their workflows, operations and other aspects of their respective businesses, as well as critical implementation dates. Special initiatives, such as a joint CMS/SDO/stakeholder Version 5010 education summit, may be needed to target small software vendors and other hard-to-reach groups.

Testifiers proposed that HHS should undertake steps to collect and analyze data about the Version 5010 process, business impacts (both cost and benefit), return on investment and other information and make it available for dissemination. As this is the first update of HIPAA standards and NCVHS also has heard testimony in favor of streamlining the process to adopt modifications to the standards, possible changes to the modification process could be examined.

Recommendation 4.1: HHS should identify communication approaches and strategies to educate and inform interested constituencies by partnering with responsible persons and organizations.

Recommendation 4.2: HHS should develop materials to educate the industry regarding these standards, and in particular Version 5010, to enable industry and stakeholder implementation efforts.

Recommendation 4.3: HHS should consider a summit or other similar event for gathering input regarding the adoption of these standards. A "lessons learned" exercise at the conclusion of this implementation process is recommended to identify best practices as well as issues/concerns to be applied to future standards adoption efforts, which also could include ways to streamline the adoption process for modifications to the standards

The NCVHS appreciates the opportunity to provide these recommendations.

Sincerely,

/s/

Simon P. Cohn, M. D., M.P.H.
Chairman, National Committee
On Vital and Health Statistics

Cc: HHS Data Council Co-chairs