Final Report:
Evaluation of a Code Set Being Proposed for HIPAA Transactions:
Alternative Billing Concepts (ABC) Codes

Executive Summary:

In January 2003, former Secretary Thompson approved a test demonstration project to assess the use of a new code set in the electronic transactions that have been adopted under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This demonstration was approved under 45 C.F.R. §162.940 of the Transactions Rule, which permits an exception to the use of a standard to test a proposed modification to that standard, when approved by the Secretary. The exception was approved for a two-year period in order to determine whether the Alternative Billing Concepts (ABC) code set should be adopted as a mandatory standard code set for use by all covered entities when conducting HIPAA transactions. ABC codes are maintained by Alternative Link, Inc. (Alternative Link), based in New Mexico. The code set represents Complementary and Alternative Medicine (CAM) services, which range from acupuncture and body manipulation to homeopathy preparations and vitamins.

The Secretary's January 2003 approval letter included the ten criteria specified in the rule, and provided general guidance on the type of data or evidence that would be expected in the report.

The study officially began on October 16, 2003, with 10,000 registered participants, and was expected to last through October 2005. On October 16, 2004, Alternative Link submitted a final report to the Secretary citing its contents as the background and supporting materials demonstrating the appropriateness of ABC codes in HIPAA transactions.

After Alternative Link completed its pilot project to test a proposed modification, the company also submitted a legal analysis to the Office of the Secretary, in which it contended that HCPCS could adopt, as part of code set "maintenance," the entire ABC code set, without testing and reporting under 45 C.F.R. §162.940 and without a Notice of Proposed Rule Making (NPRM). One of Alternative Link's stated reasons for submitting their final report and cost-benefit evaluation before the end of the allotted two-year period was to expedite review of their rationale for establishing ABC codes as HCPCS Level IV codes through maintenance.

In January 2005, the Office of HIPAA Standards convened a review committee to evaluate Alternative Link's report against the requirements of 45 C.F.R. §162.940. The review committee was comprised of individuals with subject matter expertise in HIPAA, code sets, standard setting, complementary and alternative medicine, finance and economics. The attached report is the summary of the committee's findings.

The committee members were:

Name	Title	Agency/Affiliation
Vivian Auld	Senior Specialist for Health Data Standards	National Information Center on Health Services Research and Health Care Technology (NICHSR), National Library of Medicine, NIH
Suzie Burke-Bebee, MS, RN	Senior Health Informatician	Office of the Secretary, Office of the Assistant Secretary for Planning and Evaluation (ASPE)
Carol Blackford	Deputy Director	Division of Community Post Acute Care, Chronic Care Policy Group (CCPG),Center for Medicare Management (CMM), CMS
Jim Bowman, MD	Medical Officer	Chronic Care Policy Group (CCPG), Center for Medicare Management (CMM), CMS
Cynthia Hake	HCPCS Panel Chairperson	Division of Community Post Acute Care, Chronic Care Policy Group (CCPG), Center for Medicare Management (CMM), CMS
Jim Mays	Actuarial consultant	Office of the Actuary (OA), CMS
Richard Nahin, Ph.D, MPH	Senior Advisor for Scientific Coordination and Outreach	National Center for Complementary and Alternative Medicine, NIH
Michael Pepper	Policy Analyst	Office of the Secretary/Office of the Assistant Secretary for Planning and Evaluation (ASPE)
Chester Robinson	Director	Division of Community Post Acute Care, Chronic Care Policy Group (CCPG), Center for Medicare Management (CMM), CMS
Lorraine Tunis Doo	Senior Policy Advisor	Office of HIPAA Standards (OHS), CMS
Gladys Wheeler	Policy Specialist	Office of HIPAA Standards (OHS), CMS

The Report on
Alternative Billing Concepts (ABC) Codes

This is the formal evaluation of the demonstration project to test a proposed modification to the HIPAA standards conducted by Alternative Link, Inc. (Alternative Link) from October 2003 through October 2004. As stated in the Executive Summary, the HIPAA transactions and code sets standards regulations, at 45 C.F.R. §162.940, require proposed modifications to HIPAA standards to meet ten criteria in order to be considered for adoption. The results of this committee's evaluation of the information and data provided in Alternative Link's report titled: "The Commercial Use and Cost-Benefit of ABC Codes in HIPAA Transactions and the NHII" are summarized in the table below:

Criteria	Evaluation Results: (Met, Partially Met, Not met)
162.940(a)(1)(i) Improve the efficiency and effectiveness of the health care system by leading to cost reductions for, or improvements in benefits from, electronic health care transactions.	Not Met
162.940(a)(1)(ii) Meet the needs of the health data standards user community, particularly health care providers, health plans, and health care clearinghouses.	Not Met
162.940(a)(1)(iii) Be uniform and consistent with the other adopted standards, and as appropriate, with other private and public sector health data standards.	Met
162.940(a)(1)(iv) Have low additional development and implementation costs relative to the benefits of using the standard.	Not Met
162.940(a)(1)(v) Be supported by an ANSI-accredited SSO or other private or public organization that would maintain the standard over time.	Met
162.940(a)(1)(vi) Have timely development, testing, implementation, and updating procedures to achieve administrative simplification benefits faster.	Met
162.940(a)(1)(vii) Be technologically independent of computer platforms and transmission protocols used in electronic health transactions, unless they are explicitly part of the standard.	Met
162.940(a)(1)(viii) Be precise, unambiguous, and as simple as possible.	Partially Met
162.940(a)(1)(ix) Result in minimum data collection and paperwork burdens on users.	Partially Met
162.940(a)(1)(x) Incorporate flexibility to adapt more easily to changes in the healthcare infrastructure (such as new services, organizations, and provider types) and information technology.	Met

General Overview of Complementary and Alternative Medicine in the United States

Complementary and alternative medicine (CAM) therapies have existed since the early ages. According to a recent report from the Institute of Medicine (2005)[1], the rising use of CAM in the United States requires a better understanding of the effects of these treatments from the perspective of personal and public health. Serious, rigorous research on the subject began in the 1990s. In 1992, the U.S. Congress established the Office of Alternative Medicine (OAM) within the National Institutes of Health (NIH) to develop a baseline of information on CAM use in the United States. In 1999, the OAM was elevated to the National Center for Complementary and Alternative Medicine (NCCAM), and by 2003, there were 19 institutes and centers within NIH, all with a focus on CAM-related research and activities.

Based on a 1990 survey, Americans made an estimated 425 million visits to providers of complementary care, which exceeds the number of visits to primary care physicians (388 million). Expenditures for CAM are estimated to be nearly $14 billion, three-quarters of which was paid out of pocket ($10 billion). Of the out-of-pocket dollars spent on CAM, $8 billion are estimated to be for herbal products and high-dose vitamins.

At present, health plans offer limited coverage for a narrow category of CAM therapies, primarily by providing access to a credentialed network of chiropractors, acupuncturists and massage therapists who accept a discounted fee-for-service, or by offering added benefit contracts or insurance riders, as requested by employers or groups. Hospitals, too, are increasingly offering access to on-site wellness programs with similar CAM services, and the principal form of payment is self-pay (out-of-pocket).

Thus, increased use by consumers, and growing acceptance of some CAM therapies by the health care industry, supports the need to study these treatment modalities with scientific rigor and research. Experts in the field agree that optimal integration of CAM services will take time. Evidence-based research is needed to support the assimilation, use and promotion of CAM before further decisions can be made about its safety, efficacy, acceptance as a standard benefit covered by health plans, and appropriate tools and methods for coding and tracking the myriad services offered or used.

Committee Recommendation Regarding Adoption of the ABC Code Set for HIPAA Transactions

Based on a thorough and comprehensive assessment of the data and narrative submitted in the report from Alternative Link, the committee determined that the ABC code set does not qualify to be recommended for adoption as a HIPAA standard or as a modification to an adopted HIPAA code set standard. Some criteria were supported by the information provided, while others were either partially met or not met. The net

[1] Institute of Medicine, Committee on the Use of Complementary and Alternative Medicine by the American Public, Complementary and Alternative Medicine (CAM) in the United States, (Washington, D.C.: National Academies Press, 2005).

result is that the project did not prove that the ABC code set should be recommended to the Secretary as a standard or standard modification that should be adopted as a mandatory code set for HIPAA transactions - either as a new Level IV under HCPCS, or as a stand-alone, independent code set.

The committee agreed to reconvene at such time as substantive data from an appropriate sample of demonstration pilot registrants becomes available, should Alternative Link wish to continue the demonstration and secure new supporting data.

The committee identified the following:

1. The financial and economic statements, as well as the cost benefit analysis in the report were not supported by empirical data
   - There was insufficient utilization data from the registered participants – it is possible that concluding the study after one year may have been premature and did not allow sufficient time for testing, implementation, production and data capture.

2. The examples were principally limited to services for which codes do exist within CPT or HCPCS, rather than a diverse representation of other therapies believed to be underrepresented in existing code sets
   - The report lacks evidence to demonstrate the need for greater granularity in codes used in the standard HIPAA transactions.

3. A large number of the examples in the report were for entities and transactions not covered by HIPAA, such as automotive and workers compensation claims.

Finally, HHS has not received direct inquiries, correspondence or formal requests from health plans or covered health care providers to add the full ABC code set to the roster of code set standards under HIPAA.

A copy of the full report from Alternative Link, as well as additional documentation to support the findings in this report, are available from the Office of e-Health Standards and Services upon request. The additional information available from the committee includes the following items:

A. Combined summary of the Financial and Economic Analysis
B. Back up documentation for 45 C.F.R. §162.640(a)(1)(ii)
C. Secretary's January 2003 approval letter and guidelines
D. HCPCS code request process
E. CPT code request process
F. ABC code set request process and forms
G. Executive Summary from the Alternative Link report

EVALUATION OF THE REQUIRED CRITERIA UNDER 45 C.F.R. §162.940

I. Requirement §162.940(a)(1)(i): Improve the efficiency and effectiveness of the health care system by leading to cost reductions for, or improvements in benefits from, electronic health care transactions. **Not met.**

Secretary's expectation: Provide three to five specific examples comparing ABC codes with other adopted standard codes in terms of cost savings or benefit improvement.

Summary of review:

The text here represents the committee's consensus findings.

While Alternative Link provided four hypothetical examples in response to this requirement, these examples were based on a set of assumptions that have not been validated. The examples did not use actual data from pilot registrants, and therefore the figures presented cannot be verified. There is no empirical data from the registrants themselves that demonstrated a cost/benefit scenario.

For example in Table 48 of the report, these assumptions are made without supporting citations or data:

> *"RNs earn $35/hour; MDs earn 105/hr; 85% of nurse encounters are insurer paid; 95% of these visits are MD supervised; 25% of these require direct communication totaling 6 minutes; 75% of these communications could have been avoided through the use of ABC codes."*

The study's participants should have provided supporting data (e.g., comparing the percent of communications required pre- and post-study, to result in a finding that 75% of communications could have been avoided through the use of ABC codes). Without actual data from the participants, cost savings or improved benefits using ABC codes cannot be objectively demonstrated.

The report claims that use of the ABC code set would increase the use of EDI for health care transactions, and that the financial benefits accrued to covered entities would be a result of using the ABC code set. However, the overarching impact of HIPAA has been to increase the use of EDI for certain health care transactions. The use of the ABC code set (or any other adopted code set mandated by the regulations) cannot be credited alone for increasing EDI.

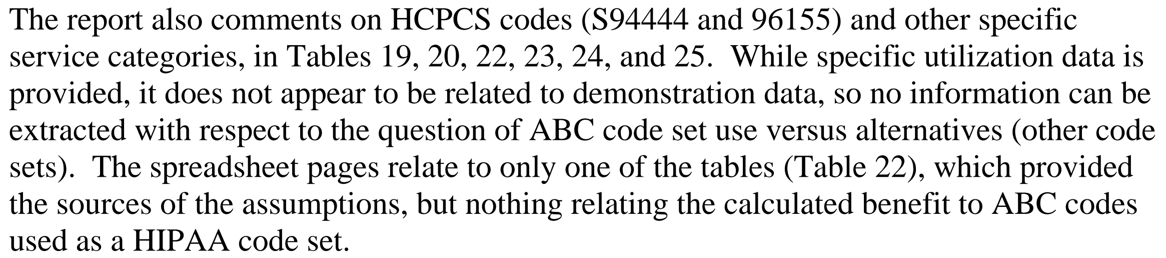
The 4 hypothetical examples provided by Alternative Link are not supported by data derived from the demonstrations.

- Managing advanced nursing practice – Table 53 in the report works a hypothetical calculation, but makes no reference to any data supporting the claim that making ABC codes a HIPAA code set would lead to any of the calculated benefit. The support page in the detailed spreadsheet "DemoReportQuantCalc-040915-31dp.xls" shows sources of assumptions regarding national statistics, but no data relating the calculated benefit to ABC codes used as a HIPAA code set. Similarly, Table 55 makes no reference to any data supporting the implicit claim that making ABC codes a HIPAA code set would lead to any of the benefits, and there is no corresponding support page in the detailed spreadsheet.

- Savings from reduced MD/OD oversight of advanced nurses – Tables 48, 49, and 60. No reference to any data supporting the implicit claim that making ABC codes a HIPAA code set would lead to this result, beyond what will occur under current payment arrangements, is provided. The support page for Table 48 in the detailed spreadsheet shows sources of assumptions regarding national statistics, but no data was provided that relates the calculated benefit to the use of ABC codes as a HIPAA code set. The support page for Table 49 shows sources of assumptions regarding national statistics. It also gives the source for the origin of the claimed $7,200 savings per practitioner associated with HIPAA code sets, which is predicated on savings for practitioners who use the current code sets. The question of what such a number might be for Integrative Health Care practitioners (IHCP), and how much of that would be likely to occur even without adopting the new ABC code set, is not addressed.

- Avoiding overpayments due to finer granularity of the codes – Table 54 presents a hypothetical calculation showing that lower payments by health plans would be possible if payment is based on more precise codes. No reference to any data supporting the implicit claim that making ABC codes a HIPAA code set would lead to this result, beyond what will occur under current payment arrangements, is provided. The support page in the detailed spreadsheet shows sources of assumptions regarding national statistics, but no data relating the calculated benefit to ABC codes used as a HIPAA code set.

- Increased covered benefits and expanded care example – reference to Exhibit W, a letter from Aetna Health Plan, a large insurer. The letter, dated June 2004, reiterates Aetna's intention to continue exploring strategic opportunities to deploy ABC codes, RVUs and other coding solutions, and to discuss their plans with high level contacts within the public and private sectors, particularly OPM. The letter expresses interest in getting access to the codes as soon as possible. However, there is no subsequent reference to any data supporting the implicit claim that making ABC codes a HIPAA code set would lead to greater efficiency or effectiveness for Aetna's programs.



The report also comments on HCPCS codes (S94444 and 96155) and other specific service categories, in Tables 19, 20, 22, 23, 24, and 25. While specific utilization data is provided, it does not appear to be related to demonstration data, so no information can be extracted with respect to the question of ABC code set use versus alternatives (other code sets). The spreadsheet pages relate to only one of the tables (Table 22), which provided the sources of the assumptions, but nothing relating the calculated benefit to ABC codes used as a HIPAA code set.

II. Requirement §162.940(a)(1)(ii): Meet the needs of the health data standards user community, particularly health care providers, health plans, and health care clearinghouses. **Not Met.**

Secretary's expectation: Include providers, health plans and, if possible, at least one health care clearinghouse in the study. The evaluation should document the volume of transactions, and specifically the volume of electronic transactions conducted, which transactions were used, and any problems encountered.

Summary of review:

The report includes several experiences with providers, health plans (payers) and vendors/clearinghouses. None of the examples effectively demonstrate how the ABC code set met the needs of each user community, because almost no specific HIPAA transaction data is provided. We describe those examples in the first few paragraphs, and then follow these with a formal economic and financial review. Committee members provided a comprehensive analysis of the documentation provided for this requirement. That detailed documentation is available upon request from the Office of e-Health Standards and Services. Some examples are provided below:

Example: According to the report, the American Healthcare Alliance (AHA) coalition of preferred provider organizations issued a letter of intent stating that its "initial strategy is to promote the use of the ABC Codes to our participating …[PPOs]" and … additionally, "Stage two of our approach is to encourage both our … [PPOs] and our participating Payers to consider using the ABC Codes…." However, no actual demonstration has been completed with these providers.

Example: A provider experience involved a partnership between Lovelace Sandia Health System and Bridges in Medicine PPO. Their use of ABC codes for reporting and billing simply demonstrates the feasibility of operational use of this code set. However, the report is incomplete in that a number of important details are missing regarding transaction volumes and the extent to which these alternative health care services are actually covered and paid for. Further, no comparisons are made to a control group of providers without access to the ABC codes. Hence, a specific comparable advantage over existing code sets is not supported by any report of experiential data from the results of an actual comparison demonstration with providers under contract.

Example: The health plan experience with Alaska Medicaid using a small set of ABC codes to support coding gaps in its behavioral health program failed to document the relative magnitude of the total claims volume processed and did not report experiential data from the results of an actual comparison demonstration with providers under contract. The report also did not demonstrate that the use of the ABC codes was necessary in all cases presented to address coding gaps created by the removal of the local codes. Specifically, it did not demonstrate that Alaska Medicaid could not have used existing HCPCS behavioral health codes in some or all of the cases in which the ABC codes were used. We also do not know, and the report does not indicate, whether Alaska Medicaid participated in the CMS local code replacement project that took place

to help States replace their local codes and comply with HIPAA, and, if so, whether it was unsuccessful in having its needs met through that process. These facts would have been useful in helping to put together a complete picture of the code set issues pertinent to the State's implementation of HIPAA. The report does not document any benefits achieved by using the ABC codes for behavioral health services as opposed to available HCPCS codes.

Example: Several hypothetical projections of cost savings are presented for health plans based on "clean" electronic data interchange (EDI) claims submission instead of paper claims. Such "what-if" scenarios comparing claims processing transaction costs of electronic with paper claims are not new to third party payers and are not code set - dependent. All HIPAA-compliant code sets are designed to be compatible with EDI claims processing. The purported hypothetical cost savings are not supported by any report of the results of actual experience of a completed demonstration with payer claims transactions, providers under contract, and paid benefits for covered members.

Example: Of the three clearinghouse-type vendors included, one reported finding no HIPAA transactions with ABC codes in its database, another limits its business focus to automotive injury claims and utilization beyond the scope of the health care delivery system, and a third is actually a web-based information exchange of provider utilization data. None of these three clearinghouses reported experiential data from the results of an actual comparison demonstration using claims and utilization information.

In short, no documentation of an actual demonstration was submitted to support the possible need of the user community of providers, health plans, and/or third-party payers and clearinghouses for adoption of the ABC code set for HIPAA-compliant purposes.

Furthermore, HHS has not received any requests from covered health care providers or health plans indicating a need to, or requesting the ability to, use the ABC codes specifically. The HCPCS code set maintainer has not received any requests for new codes to accommodate complementary and alternative medicine. The CPT code set maintainer did add several codes in 2005 that could be considered CAM-related, including acupuncture, vitamins, and end-of-life counseling.

Financial and Economic Review for 45 C.F.R. §162.940(a)(1)(ii). The report provides information related to 3 sets of providers.

- With respect to the American Healthcare Alliance, Tables 45 and 46, the hypothetical examples were discussed under (i) above.

- For the "small PPO," Table 50, the report gives claims counts from a demonstration site, but savings are not based on the demonstration. The report says use of ABC codes converts inherently complex claims into "clean claims[2],"

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[2] The term "clean claim" has a legal meaning under various laws. However, for purposes of this document, we are using the term as it is used and described in the Alternative Link report – to indicate a claim that does not require additional information in order to be processed. Assuming the same logic, we understand

and that "comparing NaviMedix data to the literature and reports of other demonstration sites" implies clean claims cost $5 each and complex claims cost $23 each, so $18 is saved on each conversion. No support is provided in the report, and the spreadsheet support page on EDI versus paper claims shows the $5 and $23 values as "NaviMedix claim information, July 2004." More importantly, irrespective of the average costs for clean versus complex claims, the costs which are germane to this savings estimate are the costs for using ABC codes for these specific claim types versus the available alternatives – using ABC codes in attachments, or adding specific codes to existing code sets.

- Preferred Health Systems (PHS) – credentialing savings – the savings are based on hypothetical current costs and are not supported by demonstration experience.

The report provides information related to 3 sets of health plans.

- A national payer – Table 43 – calculations are largely hypothetical, rather than reflecting demonstration experience. Spreadsheet support page shows savings per claim tie back to NaviMedix averages, not data related to specific services examined in demonstration, and with no claim processing costs derived from demonstration.

- Preferred Health Systems – addressed above.

- Ardent Lovelace Sandia Medicare Advantage (HMO) – the example shows the feasibility of using the code set, but does not address the satisfaction of data needs.

The report provides information related to 3 clearinghouses. The data generally supports feasibility, only NaviMedix suggested savings, which were discussed above in terms of clean versus complex claims.

The report also provides letters from participants commenting on various aspects of ABC code use. It is unclear what informational value these have in the absence of data from the associated demonstrations. (If a demonstration site did produce data showing costs and benefits associated with use of ABC codes versus the alternatives, then the opinions of the participating entities could be of use in extrapolation).

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the term "complex claims" is intended to mean claims which require additional information in order to be processed.

III. Requirement §162.940(a)(1)(iii): Be uniform and consistent with the other adopted standards, and as appropriate, with other private and public sector health data standards. **Met.**

Secretary's expectation: None provided.

Summary of review:

In order to be adopted as a HIPAA code set, any new code set would have to meet certain criteria, listed below, with the other standards that have been adopted. These include:

1. Minimizing disruption due to adoption of the code set (for example, because the code set adopted is in widespread use among hospitals, physician offices, other ambulatory facilities, pharmacies, and similar health care locations) (65 FR 50325 and 50362). **This criterion was applied when the initial code set standards were adopted, and may not make sense in the context of a modification to an existing standard code set, insofar as the adopted standards preclude use of the proposed code set. Accordingly, we do not apply this criterion in determining whether the above requirement is met. However, we note that, if the adoption of the ABC code set were considered to be the adoption of a new standard (as opposed to a modification, as Alternative Link has characterized its proposal), this criterion would not be met, based on the evidence provided by the Report.**
2. The development process must offer open and public access (45 C.F.R. §162.910). **Access to the development of the ABC code set has been consistent with other proprietary code sets such as CPT and the ADA/CDT codes.**
3. Expedited process to address content needs identified within the industry (45 C.F.R. §162.910). **The report discusses Alternative Link's routine and annual updates for ABC codes, and states that it does have a "Just-in-Time" (JIT) code gap filling process, though it is not explicit about the actual expedited process for JIT.**
4. Efficient low cost mechanism for distribution (42 U.S.C. 1320d-2(c)(2); 65 FR 50324). **The CD-ROM version of the ABC Coding Manual for Integrative Healthcare is available for $59.95 and the print version is available for $79.95. These costs are comparable to the CPT manual ($49.95) and the Dental Code Manual ($39.95)**
5. An appeals process for the requestor and/or a DSMO if the requester is dissatisfied with the outcome of a ruling on a proposed code (45 C.F.R. §162.910). **There is a process for appealing a decision by the code set maintainer.**

While not a requirement for this study, several committee members did feel it important to reference a previous assessment of the ABC code set done for a different purpose, but relevant here. The earlier study sheds light on some of the difficulties the industry has had, and could have, with the ABC code set as a mandate. In 2002-2003, the National

Committee on Vital and Health Statistics (NCVHS) conducted an analysis related to the adoption of uniform data standards for patient medical record information (PMRI). The analysis concentrated on identifying a core set of terminology standards for clinical use so that recommendations could be made to the Secretary of Health and Human Services in November of 2003. The report, titled **Patient Medical Record Information Terminology Analysis Reports**, is available at http://www.ncvhs.hhs.gov/031105rpt.pdf. The methodology for the study included distributing a comprehensive questionnaire, which consisted of 100 questions (found within the report referenced above). Public hearings were conducted with vocabulary experts to assist in the questionnaire's development and to identify the appropriate stakeholders for inclusion in the study. Alternative Link, Inc. was one of the 46 stakeholders sent the questionnaire by NCVHS and was one of the 42 respondents. All terminology developers submitted feedback on the evaluation of their terminologies with that feedback incorporated into the final report.

The final analysis concluded that ABC codes did not meet a sufficient number of criteria used in the analysis, and thus the code set was not included in the final recommendations for standard PMRI terminologies to the Secretary.

The ABC codes did not meet the essential technical criteria. The study criteria had 3 sets of features:

1. **Essential technical features: *concept orientation*, *concept permanence*, *non-ambiguity*, *and explicit version identification*.**
2. Desired technical features: meaningless identifiers; multiple hierarchies; non-redundancy; formal concept definitions; infrastructure tools for collaborative terminology development; change sets; and mapping to other terminologies.
3. Desired organizational and process features: intellectual property and licensing terms; governance structure; funding mechanism and developmental activities; and policies and processes for maintenance.

The first set of features (the essential technical criteria) was applied to all 42 terminologies submitted, including the ABC codes. The initial analysis identified ten terminologies which met the essential technical criteria. Scoring for this part was determined by applying a score to each of the four (features) components within the essential technical criteria: concept orientation, concept permanence, non-ambiguity and explicit version identification. The following rating scale was used: 1 = met; 0 = not met; and ? = could not be ascertained.

ABC codes scored as:

- **(?)** concept orientation;
- (**0**) concept permanence;
- (**1**) non-ambiguity;
- (**1**) explicit version identification.

The two items on which the ABC codes scored low, are defined below:

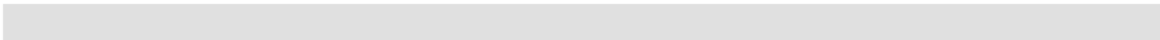
Concept orientation: Elements of the terminology are coded concepts, with possibly multiple synonymous text representations, and hierarchical or definitional relationships to other coded concepts.

> Concept permanence: The meaning of each coded concept in a terminology remains forever unchanged. If the meaning of a concept needs to be changed or refined, a new coded concept is introduced. No retired codes are deleted or re-used.

The ten terminologies that fully met the essential technical criteria proceeded for further analysis at the second and third levels (desired technical and desired organizational and process features). While the ABC code set met the standard for non-ambiguity by both groups, it was ultimately not selected to go forward for the PMRI, and this is consistent with the findings of this HIPAA evaluation committee.

The NCVHS report additionally identified "important related terminologies" for necessary mappings with importance to administrative and clinical processes. Although ABC codes were not specifically identified in this group of terminologies, NCVHS suggested exploring the incorporation of content from terminologies other than those selected for the core set of PMRI terminologies, e.g., the International Classification of Functioning, Disability and Health (ICF) and Complementary and Alternative Medicine.

While the committee was not required to use this information for the review, it did provide important balance to the documentation that was provided in the Alternative Link report.



IV. Requirement §162.940(a)(1)(iv): Have low additional development and implementation costs relative to the benefits of using the standard. Not Met.

Secretary's expectation: The pilot participants should include covered entities that have not previously used the ABC codes, as well as entities that have already adopted them. The evaluation should study the implementation costs of these two groups separately.

Summary of review:

The majority of information provided to support this criterion is anecdotal. In the report, Alternative Link has outlined how they developed the ABC codes, including their intended functionality. While the strategy is sound, they have not provided any evidence from users of the codes to demonstrate that the intent was realized.

ABC codes are five characters in length as are CPT and HCPCS, the difference is that ABC codes are alphabetic, CPT codes are numeric, and HCPCS II codes use one alphabetic character at the beginning of the code followed by four numeric characters. The all alpha format of the ABC codes may be problematic for the industry if the system modifications needed to accommodate it are significant, such as re-programming individual legacy systems. On page 64 of the report, there is acknowledgement that some software may need to be reprogrammed to eliminate system checks for illegal codes, but only CPT is mentioned. The report states that, "In no case did a demonstration site report needing to make architectural changes to use ABC codes." We have received varying responses from system engineers at the federal and state levels, and from the private sector, regarding the system impacts for using an all alpha character code set. It is still uncertain as to the extent of the business and technical impacts adoption that an all alpha character code set would have on the industry. The reviewers could not ascertain if this potential issue was assessed with the entire pilot group, a large subset, or a smaller subset. Given the potential for high costs, this is an important issue to understand.

A full assessment of the costs associated with initially loading ABC codes as well as the costs associated with updates of ABC codes is missing. Further, because ABC codes were designed to be used with HCPCS, it stands to reason that anyone who will use ABC codes has already loaded HCPCS and CPT and is processing annual updates for these code sets. The report does not discuss beyond anecdotally how the update process for ABC codes relates to that of HCPCS and CPT codes. The figures provided are based on assumptions rather than actual figures from the pilot participants. There were a number of open questions for which the committee could not find answers in the report, such as: will the addition of an extra code set add to the cost (both in terms of money, staff, and computer space) associated with annual updates or reduce the costs? Can the processes be merged or do they need to be done separately? Based on the experience of the pilot participants, what update schedule would fit best with the pre-existing update schedules of HCPCS and CPT?

Financial and Economic Assessment:

Alternative Link estimates that deployment and maintenance of ABC codes will cost the nation $1.1 billion in year one and $225 million annually thereafter. Alternative Link identifies the following costs:

- Initial data acquisition will cost the industry $117.2 million.
- Initial data deployment will cost the industry $32.4 million.
- Initial training will cost $917.7 million.
- Annual training will cost $91.8 million.
- Annual updates and maintenance will cost the industry $133.4 million. (Page 21)

Loading Costs:

In Table 31, Alternative Link estimates that "loading" the codes for plans and clearinghouses will cost half of the acquisition or $32.4 million ($7.4 million for data plans, and $25 million for Health Care IT). There is no explanation of why the plan loading costs are 50% of acquisition costs. Apparently there will be no "loading" costs for practitioners but there is no explanation for the lack of practitioner loading costs or information as to whether this accounts for the 50% of acquisition costs. Alternative Link offers examples of the use of codes in the Alaska Medicaid system and at Bridges of Medicine. But in neither example, does Alternative Link account for the costs or the effort required to implement the codes for the health plans.

Alternative Link states on page 53 that a plan may load the expanded definitions of the codes into its current system or print out the definitions. However, there is no statement of the costs entailed in either operation.

Training Costs:

Alternative Link states that it used the Rand study as its model for estimating training costs. On page 66, Alternative Link lists several reasons for lower training costs than RAND estimated for the implementation of ICD-10. Yet on page 68, Alternative Link concludes that the cost of training will be twice as much and states its belief that more robust initial training will reduce implementation problems. Table 32, which identifies the cost factors, does not present an analysis of the cause for the higher costs. There are no data from the RAND estimate to compare to Alternative Link's estimate of training costs and therefore it is impossible to determine the cause of the higher costs.

Costs of Updating Data:

Comparing Tables 35 and 36 presents a complicated picture of the costs to update the financial projections. Table 35 presents the costs for license renewals with the only change in costs for loading of 25% of licensing costs compared to 50% displayed in Table 31. Table 36 presents an example of redeployment costs from the Medicare Advantage demonstration participant. The initial cost of acquiring and loading the data appear to be $42,500 with redeployments in subsequent years dropping to $5,800 the next year and $1,800 the year after that. These redeployment costs do not appear to include

license renewal fees; but the lack of adequate labels makes it difficult to determine if the two tables are comparable. Thus, it is not clear what the redeployment or update costs would be.

The report gives calculations for a national implementation cost of $1.1 billion, of which $0.9 billion would be initial training. The support spreadsheet provides the sources for the assumptions, but no data derived from the demonstration sites appears to have been used. Partitions of costs were assumption-driven, rather than based on demonstration data. Since there were no substantive results derived from demonstration data, it was not inappropriate that no splits of results were provided on a pre- versus post-October 2003 basis. Some costs elements were shown for Sloans Lake HMO/PPO and for Mitchell Medical, but neither was apparently used in the national estimate. Table 36 shows redeployment costs for an MA plan, but those also were not reflected in the national estimate.

Table 36 also addresses cost-benefit calculations, but the benefit side was assumption-driven, rather than reflecting data obtained in the demonstration. The analysis also does not address what the calculated benefit would have been with available alternatives to ABC – either using ABC for claims attachments, or using other attachment data. Details in the support spreadsheet note who made each assumption, but do not offer any connection between the assumptions and the demonstration experience.

V. Requirement §162.940(a)(1)(v): Be supported by an ANSI-accredited SSO or other private or public organization that would maintain the standard over time. **Met.**

Secretary's expectation: None provided.

Summary of review:

ABC codes are managed and maintained by Alternative Link, Inc., and the Foundation for Integrative Health Care. All necessary materials and communications about the code set are conducted by Alternative Link and the Foundation. Consequently, the code set is supported by a private or public organization (or an ANSI SDO) that would maintain the standard over time, as required. Alternative Link is a private corporation, and the Foundation is a 501(c)(3) corporation. The codes are also part of the NIH U.S. National Library of Medicine's Unified Medical Language System (UMLS).

The report states that the ABC code set has an annual update process which is discussed on pages 146-147. We would expect that if ABC codes were an adopted standard, the code set maintainer would follow an update release schedule that would be compatible with the release schedule of the other adopted code sets. The industry has already informed HHS that the different timing of updates for CPT and ICD-9-CM is problematic. Several groups have indicated an interest in resolving the issue, including the NCVHS, NLM and WEDI, the latter of which is creating a white paper for the industry.

Alternative Link is able to accommodate requests for new codes and to add these codes to its code set on a timely basis, which fits in with their update schedule. An example is provided in Table 97 on page 140, where it references a request for Christian Science codes that was completed in about 30 days, though the nature and number of codes requested are not referenced. The report further states that Alternative Link's technical personnel can complete terminology crosswalks and validate code assignments within approximately 40 days of receipt of the request.

ABC codes are supported (named as an external code set) in the ASC X12N 4050 Implementation Guides for claims and remittance advice, with the caveat that they are not an adopted HIPAA code set, but can be used in other commercial transactions, or as part of a demonstration approved by the Secretary. Also, HHS has not adopted any new versions of the X12N implementation guides, thus version 4010-A1 must still be used by covered entities. Nonetheless, should HHS adopt new versions of the X12N implementation guides, and the ABC codes be permissible for health care transactions, either as an adopted code set or continuation of the demonstration project, the guides will be able to accommodate those codes and the transaction would be considered compliant.

The report states that because ABC codes are designed to support not only HIPAA requirements, but also the consumer-centric and interoperable NHII to improve research, management and commerce, the codes will be supported by a broader range of SSOs. There is no documentation to support this remark/opinion, and no indication of who the

SSOs are, when they will support ABC codes, in what capacity they will support ABC codes, and the level of support. Furthermore, the NHII is out of the scope of this project.

Alternative Link has an extensive history in securing support of other ANSI organizations. Throughout the period that the Transaction Rule was being finalized, Alternative Link did attempt to have the ABC code set named as a standard, including working through the DSMO change request process. In January 2001, Change Request #137 was submitted through the DSMO Change Request Process. The original request was denied with a suggestion that the Alternative Link re-submit the request with additional information regarding code set description, examples of code set values, process for updating the code set, and a listing of payers/health plans that support the code set. A second DSMO Change Request #493, was submitted by Alternative Link in September 2001. Alternative Link responded to the DSMO requests for additional information and answered issues raised with the original change request. Request #493 specifically requested that ABC codes become a standard code set in any updates to the HIPAA standard and be listed in any revised notice of proposed rule making concerning administrative transactions or code sets. The resulting action was that the ABC codes are supported in the ASC X12N 4050 claims and remittance advice transaction implementation guides, in consideration of possible future use, and use by other non-covered entities that use the X12 transactions standards.

VI. Requirement §162.940(a)(1)(vi): Have timely development, testing, implementation, and updating procedures to achieve administrative simplification benefits faster. **Met.**

Secretary's expectation: Provide a description of how the code set update process worked throughout the pilot.

Summary of review:

The report provided a solid overview of how the codes are developed, tested, implemented and updated, and the process is consistent with that of other code sets currently adopted under HIPAA.

The benefits of administrative simplification include:

1. Establishing standards and requirements to enable the electronic exchange of certain health care information.
2. Improving the Medicare and Medicaid programs and other Federal health programs as well as the private sector.
3. Improving the efficiency and effectiveness of the health care industry in general.
4. Simplifying the administration of the health care system.

The ABC code set appears to have timely development, testing, implementation, and updating procedures which can be considered to support administrative simplification. The code set maintainer, Alternative Link, has an infrastructure, similar to the infrastructure established for CPT and HCPCS, which has dedicated staff to manage the code design, development, testing and implementation procedures. If the code set were to be approved, or if certain codes were submitted to HCPCS or CPT for consideration, efficiencies are possible through Alternative Link's "concept crosswalk" with HCPCS II and CPT code sets. The crosswalk was intended to avoid the creation of duplicate or partially overlapping codes and definitions, thereby leading to potential administrative simplification through new efficiencies.

Alternative Link stated that if its code set were adopted under HIPAA, more IHC practitioners would move to using electronic transactions when billing health plans. What is unknown and undocumented, is the extent to which health plans in fact cover a significant number of CAM interventions, and how they are currently billed and paid for (i.e., which code set is used on the claims and remittance advice documents). There is growing coverage for some CAM interventions such as acupuncture, chiropractic care and some massage therapy, which do have codes in CPT and HCPCS, and which practitioners are accustomed to using for billing purposes. When these services are covered and paid for as a plan benefit, providers bill using existing compliant codes. Data reflecting provider billing of these services using ABC codes -- for example, between several of the participating project registrants -- would have been informative for the study.

The example described in Table 92 to support having met the criteria in section 162.940(a)(1)(iv), is also useful here. In this example, a West Coast health system states that it is planning to deploy ABC codes in its IHC business unit in order to develop fees for CAM interventions, and to track the cost-effectiveness of this care. While no details are provided, this initiative has the opportunity to improve a private sector program, as well as offer data to Medicare and Medicaid for their consideration (related to coverage). Since the project is in the planning phase, there is no data available to demonstrate an impact on administrative simplification.

VII. Requirement §162.940(a)(1)(vii): Be technologically independent of computer platforms and transmission protocols used in electronic health transactions, unless they are explicitly part of the standard. **Met.**

Secretary's expectation: The evaluation should demonstrate that ABC codes can work on different computer platforms.

Summary of review:

ABC codes work on different computer platforms and are not tied to any specific platform or transmission protocol. The ABC code set is available in ASCII format and can be read in EBCDIC or in any software that supports HIPAA transactions. The 2005 *ABC Codes and Terminology: ASCII Data File* contains 4,327 5-character ABC codes, corresponding 28-character, short, and full-length code descriptions, as well as expanded definitions. The ASCII data file CD-ROM includes a list of 2-character practitioner identifiers that can be used as code modifiers. The information was sufficient to prove that the code set is technologically independent of computer platforms.

Additionally, Alternative Link successfully submitted its code set to the Standard Development Organization (SDO) ANSI ASC X12 for the ABC codes to be added as an external code set into transaction sets such as Remittance Advice (835) and Claims or Equivalent Encounter Information (837). The external code set function within the X12 transactions gives users the ability to choose the ABC code set to meet specific business needs although in a version not yet recognized by a HIPAA mandate.

VIII. Requirement: §162.940(a)(1)(viii): Be precise, unambiguous, and as simple as possible. (Page 144 of final report). **Partially Met.**

Secretary's expectation: Provide sample instructions that participants used to train coders, as well as data regarding the time needed to train coders on ABC use, error rates, etc.

Summary of Review:

The anecdotal information Alternative Link provides in the report does not demonstrate that they have met this requirement in full, but the intent for the design of the code set is clear, and warrants a "partially meets" for this requirement. There is no documentation definitively demonstrating how these features of precision, unambiguousness and simplicity are experienced in the field by participating users.

Training information was provided to the Department as part of the original demonstration application, and is still on file. The materials provided were within the realm of training for other code sets.

<u>Precision:</u> The codes are precise and very specific about the service, procedure, time and provider taxonomy and certification. For example, the report states that the ABC codes include 35 codes for chiropractic adjustments and related treatments, versus the 4 chiropractic codes available in the CPT code set. The 35 codes provide detail about body regions, tissue type, joint adjustment techniques and mobility treatments.

However, having a large number of codes does not necessarily equate to precision, nor prove need or demand. It would be important to understand why the 35 codes were developed for this treatment paradigm, and the administrative, financial and even clinical benefit derived from this added granularity for each segment of the industry, particularly health plans and health care providers. While the granularity and specificity of the ABC codes with respect to specialty, provider type, and service details do meet the precision standard, the need for such granularity is not explicitly explained in terms of market demand or administrative and financial value.

<u>Unambiguous and Simple</u>: The report states that each of the ABC codes has specific meaning, and provides a number of illustrated examples. However, there were no examples of how these detailed codes are simple and easy to use in the field. There is no demonstration that this meaning aids the use of the codes or is easily understood by those using the codes. Evidence that this functionality is useful to both provider and health plan/payer pilot participants should have been provided.

As further evidence that the ABC code set is used for its ease and simplicity, the report states that the ChiroCode Institute includes the ABC codes in their ChiroCode DeskBook "because the codes are precise, unambiguous and simple." The committee visited the

ChiroCode website and found the description of its DeskBook. It is promoted as follows: "The 2005 ChiroCode DeskBook – The Coding, Reimbursement and Compliance MultiBook. This 13th annual edition is updated throughout with 2005 CPT®, ICD-9, HCPCS and ABC codes. Significant updates for 2005 include new and revised codes for Acupuncture, Ultrasound, and Tests & Measurements." There are a number of bullets highlighting the contents of the DeskBook, which are listed below. It is true that the ABC codes are included in this resource, but the purpose and value they provide to the Chiropractors are not exactly as stated in the report. This is the text from the website:

The contents of the DeskBook are:

1. INSURANCE / CLAIMS guidelines for billing all insurance types. Shows how to properly bill with CMS-1500 forms. Learn to file clean claims for maximum, lawful, and timely reimbursement. Includes helps for denied claims.
2. Essential ICD-9-CM DIAGNOSIS codes for Chiropractic listed in three simplified formats (Anatomic, Numeric, and Alphabetic) for quick and easy code finding.
3. Essential CPT & HCPCS PROCEDURE codes for Chiropractic: E/M, Lab, X-ray, Musculoskeletal, and Physical Medicine, with National Correct Coding Initiative (CCI) Edits. ABC codes also included.
4. Essential HCPCS SUPPLY codes for Chiropractic. Using specific supply codes from HCPCS could increase your income and expedite payments. ABC codes are also included.
5. Critical COMPLIANCE alerts for HIPAA entities and for non-HIPAA entities. Fraud alerts and CCI edits. Also, directories of NACA attorneys, state associations, state boards, national organizations, and more.

IX. Requirement §162.940(a)(1)(ix): Result in minimum data collection and paperwork burdens on users. (Page 145 of final report). **Partially Met.**

Secretary's expectation: The CAM and Nursing Coding Manual includes a number of undefined codes. Please provide an explanation of how the undefined codes are tracked and from 1-3 sample reports of ABC code use during your testing that demonstrate reduction in data collection and paperwork burdens.

Summary of Review:

The report states that "The ABC codes are so granular that they could preclude the need for attachment documentation that is often required of a claim for CAM" (and many other services). This assumes, then, that such services are paid for under a plan of health benefits as a covered service that might require pre-adjudicated review (before payment can be made). It also assumes that CAM providers use electronic commerce for their billing transactions. Further, it assumes that the codes alone will change medical review policies.

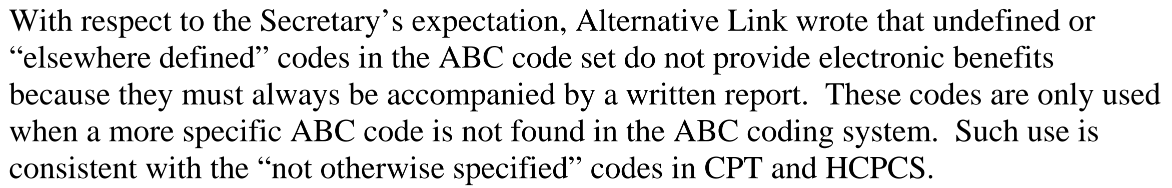
The hypothetical examples provided by Alternative Link are based on assumptions, rather than actual data collected during the pilot testing of the ABC Codes. For instance Table 46 makes the assumption that: "all direct bill IHC are complex; 75% of direct bill IHC claims require attachments; 3 billion practitioner claims are processed in the US per year; and 789.6 million claims per year are from direct bill IHCPs." No data or citations are provided to support these assumptions and no data or citations are provided that these assumptions reflect actual use of the ABC codes by Alternative Link's partners. Empirical evidence is required to understand the real costs of processing claims, both in terms of data collection and paperwork burden, prior to implementation of the ABC codes and real cost saving obtained after implementation of the codes. Without such data, Alternative Link cannot clearly demonstrate actual reduction in data collection and paperwork burden.

The report claims that the need for certain business functions would be reduced, such as -

1. General communications among providers and payers
2. Inquiries regarding claim payments, claims status, credentialing status, eligibility and benefits, fee schedules, precertifications and referrals
3. Maintenance of provider data
4. Requests for overpayment recovery and remittance
5. Sending of benefits rosters, capitated lists, and credentialing decision letters
6. Verification of the legality, clinical necessity and cost-effectiveness of care.

While some elements of these necessary business functions might be reduced over time, as the industry becomes accustomed to using the code set, and data gaps were filled as a result, there is no data to support this assumption, even given the current use of the mandated code sets between covered entities. In spite of ongoing efforts towards

standardization, many of the benefits listed above will not be realized for several years to come, and the adoption of one code set will not resolve problems of such long standing.



With respect to the Secretary's expectation, Alternative Link wrote that undefined or "elsewhere defined" codes in the ABC code set do not provide electronic benefits because they must always be accompanied by a written report. These codes are only used when a more specific ABC code is not found in the ABC coding system. Such use is consistent with the "not otherwise specified" codes in CPT and HCPCS.

X. Requirement §162.940(a)(1)(x): Incorporate flexibility to adapt more easily to changes in the healthcare infrastructure (such as new services, organizations, and provider types) and information technology. **Met.**

Secretary's expectation: None provided.

Summary of Review:

The report provided by Alternative Link does provide examples of how various organizations plan to begin using ABC codes and the benefits these organizations hope to achieve. Lacking is specific evidence resulting from the pilot study demonstrating that the anticipated benefits have been realized.

The report states that ABC codes were designed to identify a broad range of interventions that are currently recognized, as well as interventions that may exist in the future. On page 115, they state "With a hierarchic structure and a greater number of potential code combinations than the purely numeric or mixed alphanumeric HCPCS CPT and HCPCS Level II codes, ABC codes can be used to describe over 11 million health interventions." The codes are designed to support the growing acceptance and demand for alternative medicine; however, they have not demonstrated beyond anecdotally that this demand exists or that the ABC codes provide useful granularity beyond that provided by HCPCS and CPT. Examples demonstrating where this added granularity resolves specific problems encountered by those reporting information under HIPAA are needed. Also, there is a blurring of distinction between what would actually be needed for accurate billing of services, and their claim that implementation of EDI rests on adoption of their code set. These are two very different issues that need to be addressed separately.

The code set was structured to enable specific labeling of provider types by use of a 2-character modifier. The report does not acknowledge that HIPAA has been implemented to collect this information through the use of the taxonomy code, and ultimately, the national provider ID. Examples demonstrating that use of the taxonomy codes and/or provider identifiers are not sufficient and that the 2-character modifiers found in ABC codes provide greater functionality are needed. The issue is discussed on page 125 of the report but it lacks specifics. There is additional value for the 2-character modifier however, in that it differentiates practitioner licensing and practice allowances by State.

The update process for ABC codes is discussed on pages 146 – 147 of the report. It states that ABC codes "…are not subjected to conventional medical technology assessments in the manner described by CPT and HCPCS II code developers. This reduces the time for terminology and code request to code assignments." Again, specific examples resulting from the pilot study demonstrating this point are needed, but the described process meets the criteria.

On page 117, the report states "ABC codes offer the benefit not only of filling gaps in the CPT and HCPCS II codes, but also of representing many retiring HCPCS III and other local codes." CMS worked closely with the industry, particularly at the state level, to resolve potential issues resulting from the elimination of local codes, as described

earlier in this report (the State local code conversion project). Alternative Link's report only discusses this issue anecdotally. Empirical data could have been provided demonstrating the issues that remain and how ABC codes are being used to resolve these issues: not how they might be used, but rather how they are being used.

Final Committee Conclusion

Overall, the report makes a good effort to outline certain relevant health, financial and business issues, and to present an hypothesis about the potential benefits of the ABC codes. Nonetheless, the report does not have sufficient empirical evidence to support the theories and meet the required criteria. As a result, the committee is unable to recommend that the ABC code set be proposed as a modification to an adopted code set for covered entities conducting HIPAA transactions.

END OF REPORT.
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