GUIDELINES FOR MEDICAL SPECIALTY SOCIETIES' CODING AND NOMENCLATURE COMMITTEES

Issued: March 15, 2012 by the CPT Editorial Panel

The success of the Current Procedural Terminology (CPT®) code set, and the processes by which codes are established by the CPT Editorial Panel, depend upon policies and procedures that assure fairness, evidence-based objectivity and integrity for all stakeholders. Medical specialty societies and non-physician healthcare professional societies ("Societies"), their coding and nomenclature committees or their equivalents ("CONCs") that develop and review proposed changes to the CPT code set, and their CPT/HCPAC Advisors are central to the CPT process. As such, Societies' practices, policies and procedures pertaining to the CPT process must be recognized by all stakeholders as fair and objective.

The American Medical Association ("AMA") and the CPT Editorial Panel recommends the following guidelines, which are believed to represent "best practices." The CPT Editorial Panel encourages full compliance.

Documented Procedures and Confidentiality

Societies should have well-documented policies and procedures for their CONCs which do not conflict with the CPT process. Information about CONCs and their policies and procedures should be readily available to interested parties. Fairness and integrity should be hallmarks of a Society's CONC policies and procedures. Policies and procedures should (1) explain the process for development or assessment of code change proposals by CONCs; (2) disclose the degree of confidentiality accorded to the activities and deliberations of CONCs, including disclosure (or not) of identity of persons serving on CONCs and the outcome of CONC deliberations; (3) provide for the protection of the confidentiality of sensitive information, such as trade secrets, submitted by industry and others; and (4) explain limitations on lobbying or other communications directed at or with members of CONCs or the Society with respect to code change proposals.

The AMA has available documents regarding confidentiality, conflict of interest policies and lobbying restrictions that may assist CONCs in developing or revising their policies and procedures.

Adherence to CPT Criteria

Development of codes and evaluation of codes must focus on objective, evidence-based application of the criteria for Category I and Category III codes, as appropriate, as established by the CPT Editorial Panel (see Appendix A). Support for, or opposition to, a proposed new code or revised code cannot be based on factors other than the established CPT criteria. The potential economic impact on physicians related to a new procedure, service or technology, or related to possible changes in valuation and reimbursement of existing codes, cannot be a factor in determining a society's support for, or opposition to, a proposed code change. These requirements apply regardless of who is proposing the new or revised code.
Conflicts of Interest

Societies should adopt a conflict of interest policy applicable to all persons who evaluate or comment upon matters being addressed by CONCs, including code change proposals. A conflict of interest policy should clearly identify interests that must be disclosed and interests that warrant recusal from participation. The policy should be accessible to persons participating in discussions related to code change proposals. Societies are expected to share with AMA's CPT staff their conflict of interest policies if requested.

CPT/HCPAC Advisors ("CPT Advisors")

Societies should select their CPT Advisors on the basis of knowledge of the CPT process, medical coding expertise and commitment to objectivity. Societies should provide or arrange for adequate training for CPT Advisors and alternates, such as attending the CPT Advisor orientation and the annual CPT Advisors meeting hosted by the AMA. CPT Advisors are expected to review and be familiar with the CPT Advisors Guidelines.

CPT Advisors’ comments on code change proposals must be submitted in accordance to the published CPT/RUC scheduled deadlines and should in all cases address directly and specifically whether a code change proposal does or does not meet the stated criteria for a Category I or Category III code (depending upon which code is sought by the applicant). As set forth in the Guidance for CPT Advisors-Preparing, Reviewing and Commenting on Proposals, Educating Your Society and Coordinating with Your Society RUC Advisor with respect to Category I code change proposals:

CPT Advisors should evaluate an application strictly on the basis of whether the application does or does not satisfy the Category I criteria. CPT Advisor comments should address whether the criteria have been satisfied and include a brief statement of the basis for the Advisor's position. It is inappropriate for a CPT Advisor to base evaluation and comments on factors other than the stated Category I criteria, such as potential financial impact on members of the CPT Advisor's specialty society or other economic considerations, or to simply defer to the judgment of another CPT Advisor.

While CPT Advisors are encouraged to access expertise needed to properly comment on code change proposals, which may include consultation with other CPT Advisors, members of the specialty with special expertise, outside experts and/or industry, a CPT Advisor's comments must be based upon the exercise of independent, professional judgment and should be submitted independently of any other Advisor's comments.

CPT Advisors are required to comply with the CPT Editorial Panel Conflict of Interest policies applicable to CPT Advisors.

Engagement with Industry and Other Parties

Societies are not required to assist code change applicants or prospective applicants, including industry or other commercial interests, in the development or review of code change proposals. Nor are Societies expected to endure “lobbying” that is prohibited by the
Lobbying Statement adopted by the CPT Editorial Panel. However, Societies are encouraged to assist applicants and prospective applicants, including those from industry, to assure that code change requests are complete, coherent and consistent with current medical practice and coding conventions.

In dealing with industry and other parties:

- Societies should follow and, where appropriate, urge industry and other parties to follow the CPT Editorial Panel’s policy on lobbying (see Statement on Lobbying www.ama-assn.org/go/cpt-lobbying), and direct applicants and others to CPT staff for guidance on compliance with this policy.

- Societies should explain their CONC procedures clearly so that applicants and prospective applicants will have an accurate understanding at the outset of the level of assistance that may be available and the timetable for such assistance.

- Societies should respond in a timely manner to inquiries.

- Societies must not demand that applicants submit literature demonstrating clinical efficacy that exceeds the threshold level of evidence established by the CPT Editorial Panel. (See Appendix B)

- Societies’ conflict of interest policies should apply.

- If a Society engages with industry or other parties with respect to a code change proposal sought by industry, and if the Society determines not to support the code set revisions proposed in the application, the Society should, in a timely fashion, explain the reasons for non-support, citing specifically which of the stated criteria for Category I and Category III codes (as appropriate) have not been met.

Societies should apply these principles consistently regardless of the identity of the applicant or the potential economic impact to the Societies’ members from the code proposal.

**Compliance with Laws**

Societies, their CONCs and their participants, and related processes, must comply at all times with all legal requirements and should never be used to effectuate an agreement or understanding among competitors to restrain trade, engage in or facilitate unfair competition, fix prices or fees, allocate markets, or otherwise to suppress competition.

These guidelines will be posted on the public portion of the American Medical Association’s CPT web site. The CPT Editorial Panel reserves the right to adjust these guidelines from time to time. Questions should be addressed to the Director of CPT, 515 N. State Street, Chicago, IL 60654, or to marie.mindeman@ama-assn.org.

Submittal of comments by a CPT Advisor on code change proposals are deemed to be the comments of that Advisor’s Society and constitute an affirmation by the Society that it is in compliance with these guidelines.
APPENDIX A

CRITERIA FOR CATEGORY I AND CATEGORY III CODES

Criteria for Category I Codes

A proposal for a new or revised Category I code must satisfy all of the following criteria:

- All devices and drugs necessary for performance of the procedure or service have received FDA clearance or approval when such is required for performance of the procedure or service.
- The procedure or service is performed by many physicians or other qualified health care professionals across the United States.
- The procedure or service is performed with frequency consistent with the intended clinical use (i.e., a service for a common condition should have high volume, whereas a service commonly performed for a rare condition may have low volume).
- The procedure or service is consistent with current medical practice.
- The clinical efficacy of the procedure or service is documented in literature that meets the requirements set forth in the CPT code change application.

Criteria for Category III Codes

The following criteria are used by the CPT/HCPAC Advisory Committee and the CPT Editorial Panel for evaluating Category III code applications:

- The procedure or service is currently or recently performed in humans; **AND**

At least one of the following additional criteria has been met:

- The application is supported by at least one CPT or HCPAC advisor representing practitioners who would use this procedure or service; **OR**
- The actual or potential clinical efficacy of the specific procedure or service is supported by peer reviewed literature which is available in English for examination by the Editorial Panel; **OR**
- There is a) at least one Institutional Review Board approved protocol of a study of the procedure or service being performed, b) a description of a current and ongoing United States trial outlining the efficacy of the procedure or service, or c) other evidence of evolving clinical utilization.
APPENDIX B

THE FOLLOWING EXCERPTS ARE FROM THE CPT CODE CHANGE APPLICATION (pages 13 and 14)

General Guidelines for inclusion of the articles are noted in the following:

1. Abstracts are allowed to supplement application but will not be accepted in substitution of full length journal articles.

2. Foreign journals will be permitted if published in the English language.

3. List up to 5 references, of which at least 3 report the procedure/service in a U.S. patient population. Of these, at least 2 articles must report different patient populations or have different authors (no overlapping patient populations or no overlapping authors).

4. At least 1 of the publications meets or exceeds the criteria for evidence level III (i.e. obtained from well-designed, non-experimental descriptive studies such as comparative studies, correlation studies, and case control studies). However, Code Change Applications requesting editorial changes to existing Category I codes and applications for bundled codes to describe unchanged existing Category I services (when provided together) need not meet this requirement.

Level of Evidence Table – LOE

<table>
<thead>
<tr>
<th>Level</th>
<th>Type of evidence (based on AHCPR 1992)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ia</td>
<td>Evidence obtained from meta-analysis of randomized controlled trials</td>
</tr>
<tr>
<td>Ib</td>
<td>Evidence obtained from at least one randomized controlled trial</td>
</tr>
<tr>
<td>Ila</td>
<td>Evidence obtained from at least one well-designed controlled study without randomization</td>
</tr>
<tr>
<td>Ilb</td>
<td>Evidence obtained from at least one other type of well-designed quasi-experimental study</td>
</tr>
<tr>
<td>III</td>
<td>Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case control studies</td>
</tr>
<tr>
<td>IV</td>
<td>Evidence obtained from case reports or case series</td>
</tr>
<tr>
<td>V</td>
<td>Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities</td>
</tr>
</tbody>
</table>