



## Guidance on New Procedure for CME

These requirements only apply to providers doing new procedures and skills training.

### Requirements for designating new procedures and skills training for credit

This appendix will provide credit certificate language for all four levels of new procedures and skills training, and guide provider development of formal instruction (courses) and defined clinical preceptorships for this type of education. Ideally, providers will use both learning modalities and, further, arrange for post-course observation of the physician in his or her own practice setting as a means to evaluate both overall program effectiveness and the individual physician's mastery of the new skills.

Providers offering new procedures training will need to assess, at the activity's conclusion, the participant physician's level of achievement. The credit certificates for these four levels can be used by relevant credentialing bodies to determine physician eligibility for new or expanded clinical privileges that recognize this training.

### Formal courses

Formal courses designated for *AMA PRA Category 1 Credit™* in new procedure training must meet the following requirements:

#### Learning objectives

Each activity must meet the AMA definition of CME, include stated learning objectives that conform to accepted specialty or subspecialty practice, and be clearly designated for a specific level classification. The provider will define the skills to be taught beforehand and assess the physician's skill acquisition at the course's conclusion, prior to awarding a credit certificate.

#### Facilities

The site of the educational activity must be physically adequate to meet the program's stated objectives. Likewise, providers will ensure that participants work in facilities and with teaching materials appropriate to accomplishing the activity's learning objectives.

#### Faculty

The director and the faculty for the educational activity must:

- Know educational methodology and command the necessary clinical or laboratory expertise necessary to teach the course's subject matter.
- Present qualifications that meet specialty and subspecialty society specifications.
- Provide a ratio of clinical faculty to trainees small enough to satisfy course objectives, and to accurately document whether each participant physician achieves these objectives.
- Disclose to participants any prior or existing relationship with industry.

The faculty director alone, under the provider's guidance, must take responsibility for setting course objectives, developing the curriculum, overseeing faculty, and determining the criteria by which to evaluate trainees.

#### Qualifications of trainees

The trainees will be expected to demonstrate sufficient background knowledge, skills, and experience to successfully participate in the course. Physicians may be asked to document their qualifications or to complete a pretest to enroll in the course.

#### Curriculum

The providers will develop a written curriculum which lists the skills to be acquired, defines the skill levels, describes the incremental skill levels by which trainees will advance, and includes supplemental resources (reprints, citations, etc). These materials will be included in a syllabus given to all participants.

The activity must feature didactic instruction, supported by peer-reviewed data, in the following areas:

- Patient selection;
- Indications and contraindications;
- Instrumentation;
- Techniques and adjunctive techniques;
- Content validity;
- Cost considerations;
- Managing complications;
- Documenting methodology;

- Pre- and post-procedural care;
- Follow-up policies; and
- Outcome analysis.

To better frame the learning experience for the physician trainees, providers may want to address historical considerations and current research as topics for instruction.

Appropriate methodologies for teaching may include:

- Reading articles;
- Didactic sessions;
- Practice with inanimate models;
- Animate laboratory instruction and practice;
- Learning control and appropriate use of equipment;
- Video and computer instruction;
- Observing procedures;
- Simulated and virtual reality models;
- Interactive computer programs; and
- Self-assessment exercises.

#### Duration of training

The formal educational activity should allow enough time for the trainee to learn the skills, to demonstrate he or she has achieved the defined objectives, and to develop good working knowledge of the pathology that the procedure mediates.

#### Documentation

The director of the educational activity must provide each trainee with a written summary that verifies attendance and the physician's achievement of course objectives. This summary must detail how the physician's attainment of program objectives was evaluated. Providers will retain, for no less than six years, records for each physician and share these, as requested, with appropriate credentialing bodies.

#### Preceptorship in a clinical setting

##### Learning objectives

The clinical preceptorship must start with a program outline that states the learning objectives and details the tasks and skills to be covered during the training period.

##### Facilities

Preceptorship site facilities, and patient volume, must meet trainee learning needs. The preceptorship must be sponsored by an appropriately accredited (eg, JCAHO) health care organization, a Liaison Committee on Medical Education (LCME) accredited medical school or a recognized medical society accredited by the ACCME.

##### Preceptor

The physician preceptor must present appropriate credentials and verifiable clinical experience in the procedure to be taught. The preceptor sets objectives, develops the curriculum, oversees instruction and practice of skills, demonstrates technique and clinical procedures, and evaluates the trainee, all under the aegis of the accredited provider. In addition,

- The preceptor must disclose, in advance and directly to the trainee, any relationship with industry.
- The preceptor must exercise primary responsibility for patient care, not only supervising procedures in which the trainee participates but also overseeing the appropriate peri-procedure care.
- The provider must keep written evidence on file of patients' specific informed consent or an institutional review board's research approval, which allows trainee involvement in patient care.

##### Qualifications of the trainee

The trainee must command the background knowledge, skills and experience necessary to learn the assigned tasks. Trainees should be required to document their qualifications, including:

- A current and valid license to practice medicine or meet local requirements for waiver of licensure.
- Evidence of both current liability coverage and current clinical privileges in an accredited health care institution (unless this is impossible for legitimate reasons).
- Successful completion of an accredited residency training program or its equivalent as determined by the provider of the activity, or verifiable evidence of ABMS member board certification.

##### Curriculum

Providers must base preceptorship training on clinical experience, with both didactic and technical components. Of vital importance, the preceptorship needs to include an appropriate number of opportunities for the trainee to assist and serve as the primary operator in the procedure under instruction.

#### Duration of preceptorship

Training should be long enough for the trainee to develop and then demonstrate that he or she has achieved the program's defined objectives, including familiarity with the disease requiring the procedure.

#### Documentation

The preceptor must document qualitative and quantitative descriptions of the trainee's experiences. This documentation should detail the skills acquired and the number of procedures in which the trainee assisted or served as primary operator. Providers must document, for the trainee, that the procedures were satisfactorily performed. Upon the physician's written request, this information may be provided to the credentials committee of a health care organization. A log of activities kept by the trainee, and reviewed by the preceptor or credentialing body, can assist in the privileging process.

Providers must maintain permanent records of preceptees and make these available, on request, to appropriate credentialing bodies. If appropriate, providers may issue a continuing medical education credit certificate.

#### Indemnity

Both the preceptor and the trainee share responsibility for securing appropriate authorization from the host institution, and any necessary indemnity coverage.

#### Quality assurance

Health care institutions awarding new or expanded privileges to physicians on the basis of newly acquired skills should establish a program that continuously reviews physician performance as part of their overall quality assurance program.

#### Evaluations

To ensure their educational activity prepares qualified practitioners, providers should document their evaluations. For example, providers can request that the preceptee report the number of procedures performed and what the outcomes were. The assessment process must include the trainees' evaluation of the course and its faculty.

#### Overall program assessment

Every provider who certifies new skill and procedure educational activities for *AMA PRA Category 1 Credit™* must regularly evaluate whether their overall outcomes meet program goals. They must also report this data, on request, to appropriate organizations, such as the AMA or ACCME.

#### Assigning credits

The provider can designate the preceptorship for that number of *AMA PRA Category 1 Credits™* that represents their best and most reasonable estimate of those hours the preceptee will spend in meeting the activity's learning objectives.

#### PRA credit certificate language for new procedures

The AMA established a system of four levels of new procedure education, to reflect the level of training a physician has accomplished in an individual program. To verify the physician's level of achievement in the new procedure or skill, providers may use the following language for credit certificates issued to US licensed physicians. The physician can present this certificate to appropriate credentialing authorities as documentation of his or her education and training.

The four levels are:

#### Verification of attendance

The physician attended and completed the course.

The [name of provider] verifies that this physician has earned [number of credits] *AMA PRA Category 1 Credits™* by attending and completing the level 1 classification [name of course] course, in accordance with the AMA guidelines for Continuing Medical Education on New Procedures and Skills.

#### Verification of satisfactory completion of course objectives

The physician satisfactorily met all specified learning objectives.

The [name of provider] verifies that this physician has earned [number of credits] *AMA PRA Category 1 Credits™* by satisfactorily meeting all specified learning objectives for the level 2 classification [name of course] course, in accordance with the AMA guidelines for Continuing Medical Education on New Procedures and Skills.

#### Verification of proctor readiness

The physician is "proctor ready," which subsumes levels 1 and 2 and asserts the physician can successfully perform the procedure under proctor supervision.

The [name of provider] verifies that this physician has earned [number of credits] *AMA PRA Category 1 Credits™* by completing the level 3 classification [name of course] course and is able to perform the procedure under proctor supervision, in accordance with the AMA guidelines for Continuing Medical Education on New Procedures and Skills.

#### Verification of physician competence to perform the procedure

Competence asserts the physician can successfully perform the procedure without further supervision.

The [name of provider] verifies that this physician has earned [number of credits] *AMA PRA Category 1 Credits™* by completing the level 4 classification [name of course] course and is competent to perform the procedure without further supervision, in accordance with the AMA guidelines for Continuing Medical Education on New Procedures and Skills.