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Testimony of

Murray Kopelow, MD, MS (Comm.), FRCPC
Chief Executive
Accreditation Council for Continuing Medical Education (ACCME)

on

"Medical Research and Education: Higher Learning or Higher Earning?"

Before the
Special Committee on Aging
United States Senate

July 29, 2009

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INTRODUCTION

Good afternoon, Chairman Kohl, Ranking Member Martinez, and Members of the Committee. I am Dr. Murray Kopelow, the Chief Executive of the Accreditation Council for Continuing Medical Education, commonly known as the ACCME. In that role, I direct the executive and staff leadership functions of ACCME, including its relationships with medical education providers and other member organizations. I currently also serve as a special advisor to the White House Office of National Drug Control Policy.

By way of background, ACCME administers a voluntary self-regulated system for accrediting providers of continuing medical education (CME). This system of standards and credentialing is recognized, and often deferred to, by government entities including state medical licensing boards, the Food and Drug Administration and the Department of Health and Human Services Office of Inspector General.

At your invitation, we welcome the opportunity to address the current state of medical education including the quasi-regulatory standards of ACCME and extent of funding support by commercial interests. This written testimony is intended to supplement and update our Statement of June 2008 provided to the Committee in response to its continuing review of the relationship between drug and device manufacturers, and CME providers.

Specifically, at your request, our testimony will focus on: (1) the extent of industry support; (2) ACCME enforcement of its accreditation requirements and standards for commercial support; and (3) how the Council is implementing its commitment to become more transparent and responsive to its external constituencies.

A. Extent of Industry Support

1. Continuing Decrease in Commercial Support of CME

The relative proportion of CME supported by commercial entities continued a decline that began in 2003. For the first time in 2008, the absolute amount of commercial support also

decreased - by about $200 Million. As indicated below, in 2008, total commercial support of CME in the U.S. approached the levels reported by ACCME in 2003 and 2004.

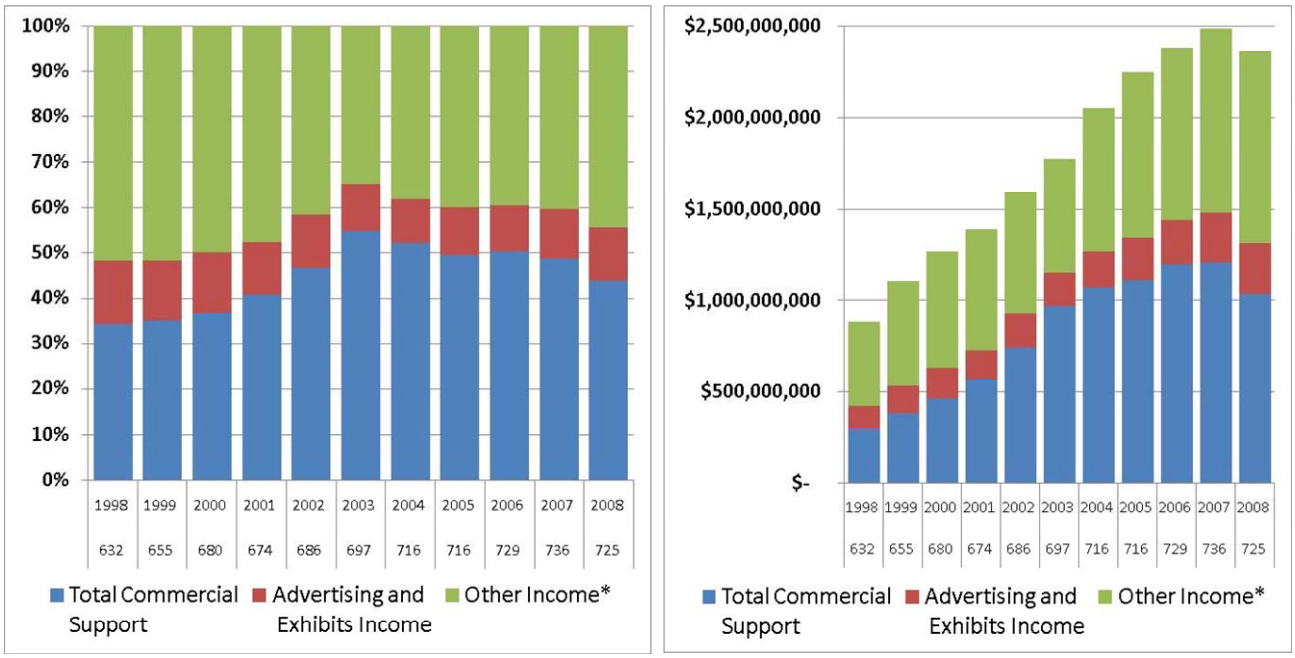

Figure 1: Percentage of Commercial Support of CME (1998-2008) and Amount of Commercial Support of CME (1998-2008)

	Count	Total Income	Total Commercial Support	Advertising and Exhibits Income	Other Income*	Total Expense
1998	632	$ 888,544,752	$ 301,949,112	$ 125,901,179	$ 457,694,461	$ 842,061,037
1999	655	$ 1,110,482,468	$ 387,619,740	$ 148,241,160	$ 574,621,568	$ 920,897,968
2000	680	$ 1,271,189,580	$ 466,971,749	$ 168,864,400	$ 635,353,431	$ 1,053,684,130
2001	674	$ 1,393,926,271	$ 568,767,299	$ 159,955,455	$ 665,203,517	$ 1,179,631,684
2002	686	$ 1,596,198,865	$ 746,015,426	$ 187,327,756	$ 662,855,683	$ 1,327,042,030
2003	697	$ 1,774,516,395	$ 971,100,098	$ 183,293,597	$ 620,122,700	$ 1,539,686,438
2004	716	$ 2,052,577,784	$ 1,071,064,979	$ 197,032,732	$ 784,480,073	$ 1,612,476,355
2005	716	$ 2,250,468,669	$ 1,115,597,071	$ 235,721,224	$ 899,150,373	$ 1,717,466,541
2006	729	$ 2,384,581,430	$ 1,199,405,519	$ 244,913,684	$ 940,262,229	$ 1,820,708,534
2007	736	$ 2,487,737,069	$ 1,211,345,204	$ 274,071,865	$ 1,002,319,998	$ 1,891,809,456
2008	725	$ 2,365,097,746	$ 1,035,942,134	$ 277,295,124	$ 1,051,860,486	$ 1,976,030,151

Table 1: Total Income for all providers (by source) and total expenses, for the period 1998 to 2008

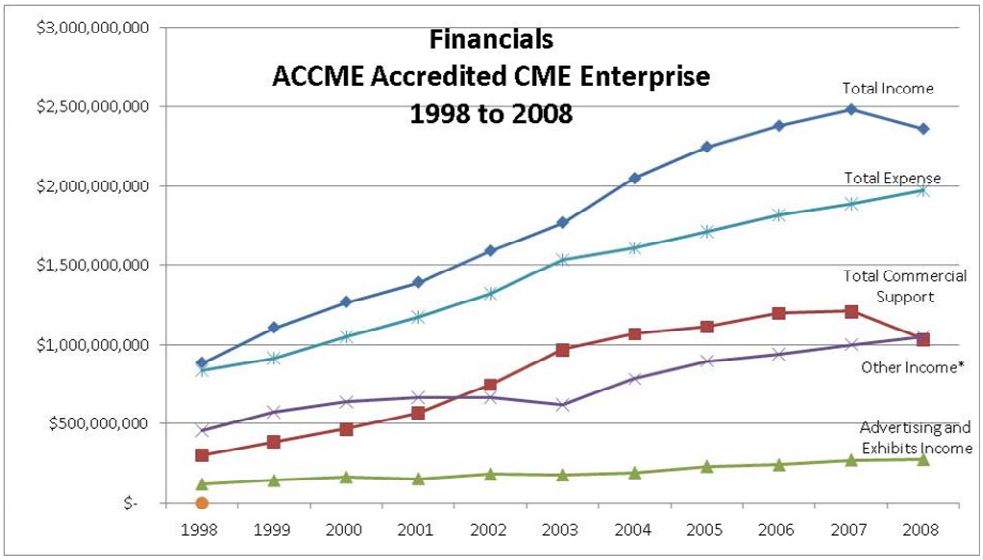

Figure 2: Total Income for all providers (by source) and total expenses, for the period 1998 to 2008 (same data as Table 1)

There was no associated contraction of CME made available to learners. (Note: most of the decrease in reported "activities" counts in 2008 was due to a change in reporting by Internet providers.)

Year	Activities	Hours of Instruction	Physician Participants	Non-Physician Participants
1998	48,092	574,069	3,662,701	1,544,664
1999	47,129	585,446	4,436,197	1,760,504
2000	49,451	551,739	5,093,595	1,883,811
2001	51,048	583,449	5,178,883	2,159,312
2002	55,967	624,824	5,415,945	2,692,971
2003	66,788	704,077	6,037,395	3,041,998
2004	71,564	692,673	6,516,564	3,235,562
2005	79,820	678,528	7,650,207	3,683,749
2006	93,582	712,163	8,255,017	4,577,078
2007	113,003	741,261	8,698,299	5,177,299
2008	100,898	769,439	10,665,514	6,559,564

Table 2: Size of the accredited CME enterprise.

Table 3 below, shows the impact of changes in amounts of commercial support across Provider groups. In addition to the absolute decrease in commercial support during this period, these changes can be attributed to attrition in providers as well as movement between provider groups.

	Commercial Support		
Provider Type	**2006**	**2008**	**% Change**
Government or Military	$4,191,416	$128,790	**-96.93%**
Hospital / Health Care Delivery System	$57,937,148	$39,473,400	**-31.87%**
Insurance Company / Managed Care Company	$262,200	$376,833	**43.72%**
Non-profit (Other)	$49,488,025	$86,637,092	**75.07%**
Non-profit (Physician Membership Organization)	$179,932,428	$202,541,623	**12.57%**
Not Classified	$27,878,144	$17,677,761	**-36.59%**
Publishing / Education Company	$620,657,409	$463,382,987	**-25.34%**
School of Medicine	$259,058,752	$225,723,643	**-12.87%**
Total	**$1,199,405,522**	**$1,035,942,126**	**-13.63%**

Table 3: 2006 and 2008 Comparison: Total Commercial Support, by Provider Type

There continues to be a non-uniform distribution of commercial support across accredited providers. There has been a small increase in number (to 140) and proportion (to 20%) of Providers that do **not** accept commercial support.

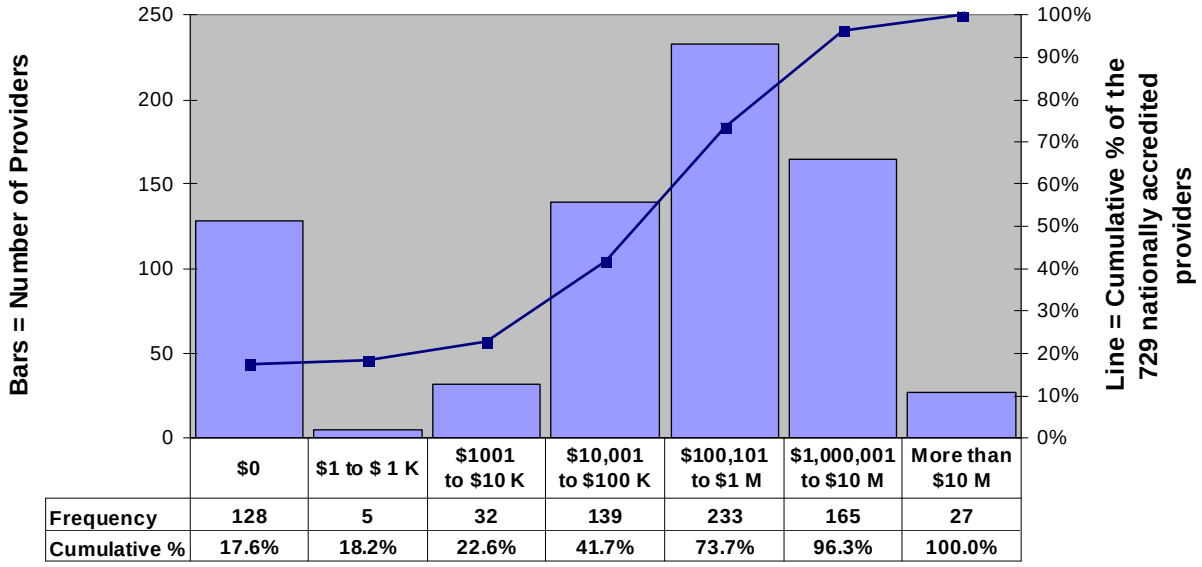

Figure 3; 2008 Distribution of Commercial Support by amount, across all accredited 725 providers

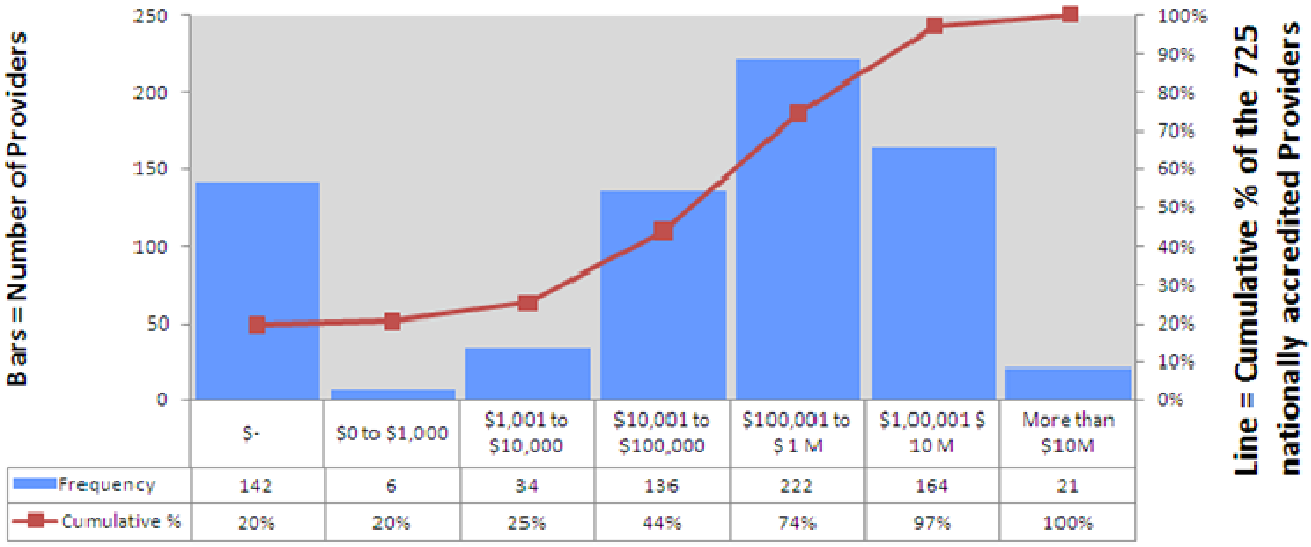

Figure 4: 2008 Distribution of Commercial Support by amount, across all accredited 725 providers

B. ACCME Enforcement of Accreditation Requirements

1. Initiation of Discussion over Policy Proposals

In January 2007, ACCME initiated a nation-wide discussion of whether commercial support of accredited CME should continue. We announced that we were considering taking action regarding the funding structure of continuing medical education. Ideas included in proposals for which comment was solicited included:

a. The *status quo* with commercial support of CME remaining an acceptable funding mechanism;

b. Complete elimination of commercial support;

c. Allowing commercial support only where it is in the public interest based on criteria including: (1) when educational needs are identified and verified by an organization free of commercial support; (2) if the CME addresses a gap in professional practice corroborated by *bona fide* performance measurements; (3) when CME content is from a curriculum specified by a *bona fide* organization; and (4) when the CME is verified as free from commercial bias;

d. Accredited providers must not receive communications from commercial interests related to specific content that would be preferred; including receiving internal criteria for providing commercial support;

e. Persons paid to create, or present promotional materials on behalf of commercial interests cannot control the content of accredited CME on that same content;

f. Use of designations like “Promotional Teacher and Author Free”™ where teachers or writers of any part of a CME program could not maintain financial relationships derived from marketing or promotional activities for commercial interests;

g. Use of designations like “Commercial Support-Free”™ where providers would not accept any commercial support including the use of advertising and promotion funds to underwrite the costs; and

h. Creation of a new entity independent of ACCME to pool unrestricted educational donations from commercial interests that would be available to ACCME accredited CME providers.

In March 2008, ACCME again expressed the belief that due consideration be given to the elimination of commercial support of CME. Many stakeholders inside and outside of CME enterprises responded with views on the subject. Based on that input, ACCME announced in its Executive Summary of the March 2009 Board Meeting that it “would not be taking any action to end the commercial support of accredited [CME].” In our June 2008 Statement to the Committee, we said that “…nothing would be worse than the deconstruction of a system without the identification of alternatives.” The proposals remain “on the table” even though ACCME has chosen not to act on them at this time.

The profession has become fully engaged in a discussion of the future relationship between industry and medical education as follows:

a. In July 2009, the Council on Ethical and Judicial Affairs of the American Medical Association (AMA) presented a report with recommendations for action on a new construct for classifying the ethics of the medical profession’s relationship with industry in CME.

b. In June 2009, the Committee on Conflict of Interest in Medical Research, Practice, and Education of the Institute of Medicine (IOM) identified the need for stakeholders to come together, in a consensus building process, to identify a future funding model for CME that ensures its independence from industry (IOM Recommendation 5.3).

c. During 2009 the Council on Medical Specialty Societies convened a Task Force on Professionalism and Conflict of Interest to *“develop and recommend a ‘Code of Conduct’ for specialty societies, to enhance professionalism and to disclose, manage and resolve conflicts of interest in relationships with industry.”*

d. Late in 2008, the Conjoint Committee for Continuing Medical Education, a group CME stakeholders convened by the Council of Medical Specialty Societies, identified a strategic imperative for itself to, *“[c]onvene a*

national conversation about a system of financing [CME] that responds to Recommendation 5.3…., to ensure that CME is free from the influence of commercial support."

e. In 2009, the American Boards of Medical Specialties approved Standards for its Maintenance of Certification program that include requirements that continuing professional development activities to be free of commercial bias, as regulated by ACCME and its Standards for Commercial Support. Issues of commercial support and potential bias will be topics for future discussion by that organization's Ethics and Professionalism Task Force.

f. In June 2009, the Association of American Medical Colleges convened a group to "Focus on Conflict of Interest in Academe" which included a half day discussion on the issues of conflict of interest in CME.

2. Definition of Commercial Interest

(1) In 2007, ACCME announced an expanded definition of a "commercial interest" to exclude from accreditation those organizations that market, re-sell, or distribute health care products or services used by, or on, patients. Accredited CME providers could also lose their accreditation if they joint ventured with a "commercial interest."

(2) ACCME has provided guidance concerning corporate models that would create independence between commonly owned commercial interests (e.g., marketing and advertising entities) and CME providers.

(3) Eligibility for continuing accreditation ends on August 31, 2009.

(4) Enforcement is being performed through enhanced screening for compliance within the accreditation eligibility process.

(5) ACCME has been conducting specific organizational reviews.

(6) Private CME providers have retained counsel to reorganize entities now designated as commercial interests under the new expanded definition, by separating affiliates seeking ACCME accreditation, or seeking to joint sponsor with accredited ACCME providers (e.g., creating "firewalls" to insure ACCME-defined independence).

(7) Reorganized accredited CME providers have sought the opinion of ACCME concerning the sufficiency of their "firewalls."

3. Enforcing Existing Policy on Independence

In 2009, ACCME continued to issue many clarifications concerning independence criteria in response to provider questions. For example, ACCME provided the following descriptions of appropriate roles and contributions that staff persons of commercial interests may make to accredited CME.[1]

[1] ACCME Standards for Commercial Support, Standard 1: Independence prohibits the circumstance that would allow the employee of the commercial interest to take the role of planner or teacher inside

NEW (03/2009)
PROVIDER QUESTION #8) Can employees of commercial interests serve as planners or speakers in our accredited CME activities?
ACCME RESPONSE: If the content of CME that the employee of the commercial interest controls relates to the business lines and products of its employer – **NO**. If the content of CME that the employee of the commercial interest controls DOES NOT relate to the business lines and products of its employer – **YES**.

NEW (03/2009)
PROVIDER QUESTION #9) Can we offer accredited CME activities on research that was controlled in some way by a commercial interest, either through funding, collaboration, or involvement of the commercial interests' staff in the research itself?
ACCME RESPONSE: Yes, as long as the CME activity complies with the ACCME's Accreditation Criteria, including the ACCME® Standards for Commercial Support℠. It is understood and accepted that industry conducts its own research and that industry partners, as funder or collaborator, in research projects. An important step in the translation of discovery to practice is the dissemination of the results of this research. There are several layers of internal and external controls already in place to manage the conduct of research (e.g., Institutional Review Boards, Government agencies) and the dissemination of results (e.g., editors, peer review, international standards.) The ACCME does not intend to interfere with these carefully managed phases. However, when an organization chooses to base its CME content on research the organization assumes responsibilities related to CME, including compliance with the ACCME® Standards for Commercial Support℠. The CME content (not the research that has already taken place or is taking place) cannot be controlled by a commercial interest. As an example, industry employees cannot deliver oral presentations and cannot author enduring materials that are accredited CME if the CME content relates to business lines or products of their employer.

NEW (03/2009)
PROVIDER QUESTION #10) One of our CME courses is an intensive hands-on course that trains physicians to perform vascular interventions in a laboratory setting. The training is primarily about newer medical devices

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accredited CME if the content of the CME is related to the business lines or products of the commercial interest. Standard 1 states:
SCS1.1 A CME provider must ensure that the following decisions were made free of the control of a commercial interest. (See www.accme.org for a definition of a 'commercial interest' and some exemptions.)

(a) Identification of CME needs;
(b) Determination of educational objectives;
(c) Selection and presentation of content;
(d) Selection of all persons and organizations that will be in a position to control the content of the CME,
(e) Selection of educational methods;
(f) Evaluation of the activity.

SCS1.2 A commercial interest cannot take the role of non-accredited partner in a joint sponsorship relationship.

and equipment, their use, and practical training in how to perform the procedures. The course director has asked a couple of companies to provide both training equipment/devices to use and company personnel to operate the equipment. We will track this loaned equipment as in-kind commercial support. The course director has independently designed the activity, determined the procedures to be taught, instructs the technologists on their roles, and is present to oversee and participate in the instruction. The course director verifies that the training and comments provided by the device technologists are technical only about the use of the equipment, and do not favor a commercial product or compare products. Is this situation allowed under the ACCME® Standards for Commercial Support?

ACCME RESPONSE: Education on devices is a special use-case in accredited CME. Some equipment contains "labeling requirements" set by the FDA that include the requirement for instruction prior to use. Each set of circumstances needs to be taken on a case-by-case basis as the conflicts of interest of industry employees are irreconcilable in CME, so they can never take the usual role as teacher or author in accredited CME. Industry employees can demonstrate the operational aspects of the use of a device under the umbrella of a provider's ACCME accreditation - but they must only demonstrate the operational aspects. They can do this without contributing in any way to any decision-making about the elements of SCS 1 of the ACCME® Standards for Commercial Support℠. It is also critical that the employees never expand their input into areas of clinical medicine while involved in accredited CME (e.g., never talk about indications for use, never talk about comparisons between competing products or comparisons between the device and/or invasive surgery and/or medical treatment). This special use-case, if it is going to remain compliant, requires careful supervision by the accredited provider's faculty and staff and proper professional behavior by industry staff.

4. Monitoring and Surveillance

ACCME maintains a ***Complaints and Inquiries Process*** (Attachment 1) whereby it can initiate formal inquiries into Providers' compliance with the ACCME requirements during their terms of accreditation.

Providers found in non-compliance with ACCME's requirements in the Complaints and Inquiries Process submit Notices of Correct Action where they describe, and provide verification of, their compliance with ACCME requirements.

In 2008 and 2009, ACCME completed and closed 17 Inquiries (*see* Attachment 2), 12 of which involved the Standards of Commercial Support (SCS). Five Inquiries ended with findings of non-compliance in at least one element of the SCS. Seven Inquires ended with findings of compliance. Twelve Inquiries relating to the SCS are still open.

a. ACCME Inquiry of Providers Receiving Commercial Support for CME Programs

In the July 2008 Statement to the Committee, ACCME wrote, "The ACCME has begun a process for looking into the practices of the approximately one hundred ACCME Providers that receive most of the commercial support."

Each provider surveyed was able to submit information descriptive of a mechanism and procedures in place to implement the ACCME SCS. This project did not produce useful diagnostic information because of the design and execution of the evaluation by the ACCME.

The Providers submitted a considerable amount of description and documentation of their mechanisms for compliance with the ACCME Standards of Commercial Support, exactly as requested.

We asked experienced ACCME surveyors and/or review committee members to review the submitted information and draw conclusions on items included in the Survey Instrument in Attachment 3.

An analysis of the results of the reviewers' analysis showed ACCME that there was considerable inter-rater variability which could not be explained on the basis of the descriptions submitted by Providers.

We discovered, after the fact, that the wording of our request for information consistently produced the delivery of an information set that was exactly aligned with our SCS but did not produce information for our evaluators to reliably make inferences about these areas of interest. ACCME could not draw conclusions. Upon analysis of the information that we got back, it appears that all the variability between providers was due to inter-rater variability as opposed to true differences between Providers.

We now consider the process a 'pilot' within a larger project in which we are looking for reliable, sensitive and specific ways to measure the outcomes of the implementation of the ACCME SCS. ACCME will be undertaking further analysis of the data and information submitted.

b. Monitoring by Direct Observation

In the July 2008 Statement to the Committee, ACCME wrote, “An additional system is being developed to directly monitor educational activities so as to establish the prevalence of commercial bias and to determine if there is any subsequent over use, or inappropriate use, of commercial products as a result of continuing medical education.”

ACCME developed a new activity database. CME Providers were required to provide information described in the announcement contained in Attachment 4. Creation and use of the new database was divided into three phases; (1) submission of additional information by CME Providers; (2) inclusion of monitoring information; and (3) inclusion of self-assessment data.

Phase 1 is just being completed. ACCME has developed a web-based database system to capture information descriptive of Providers’ CME activities as they are being planned and presented. This ACCME “activity database” has been built incorporating national standards and definitions so as to promote interoperability and communication between systems.

An example of the web pages for the Activity and Program Reporting System is included in Attachment 5.

c. Potential for Monitoring through Reporting Educational Impact on Strategy, Practice or Patient Outcomes

Since November 2008, ACCME has been measuring accredited Providers’ compliance with the 2006 Accreditation Criteria. In these Criteria, ACCME requires each Provider to measure the effectiveness of all educational activities in terms of changes in physician competence (strategy), performance-in-practice or patient outcomes.

It will now be possible for ACCME to ask Providers about the results of measurements of the changes in attitude, changes in strategies for use, changes in actual use and changes in patient outcomes with respect to outcomes of certain educational activities. Eventually, inferences will be able to be drawn about whether, or not, the direction of change is in a direction that will result in the learners’ inclination towards, or actual, use of a product or service that is more than is necessary.

5. Enforcement at Reaccreditation

a. Compliance Results- Standards for Commercial Support (2008-2009)

ACCME data shows that the non-compliance rate for elements of the SCS varies from 5% to 49% for recent decisions (Figure 5) and varies from 2% to 38% over the entire time period covered by the Updated Standards for Commercial Support (Figure 6).

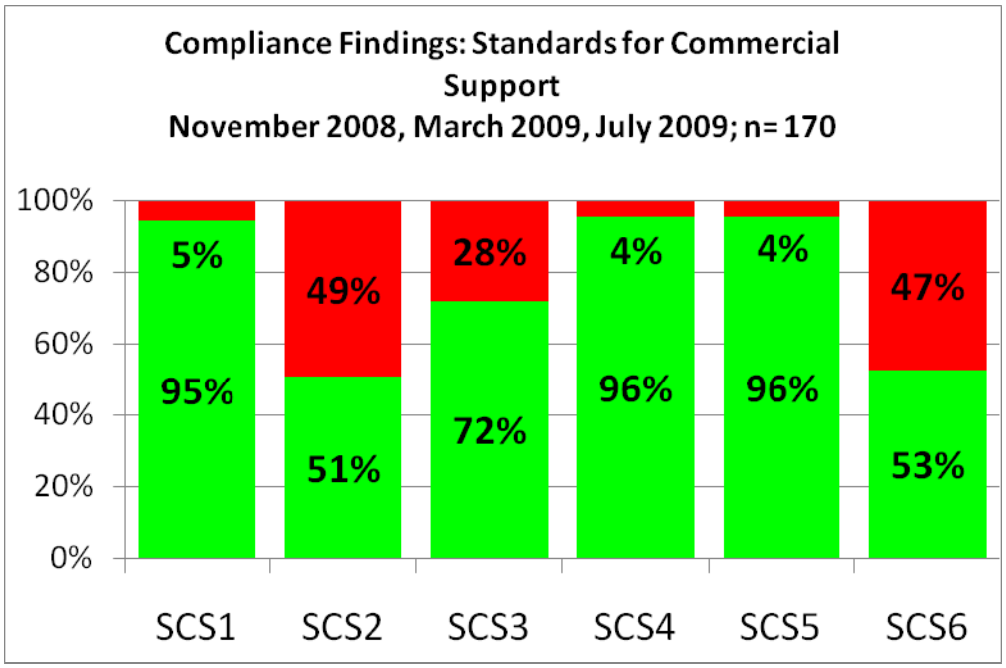


Figure 5: Recent Accreditation Decision

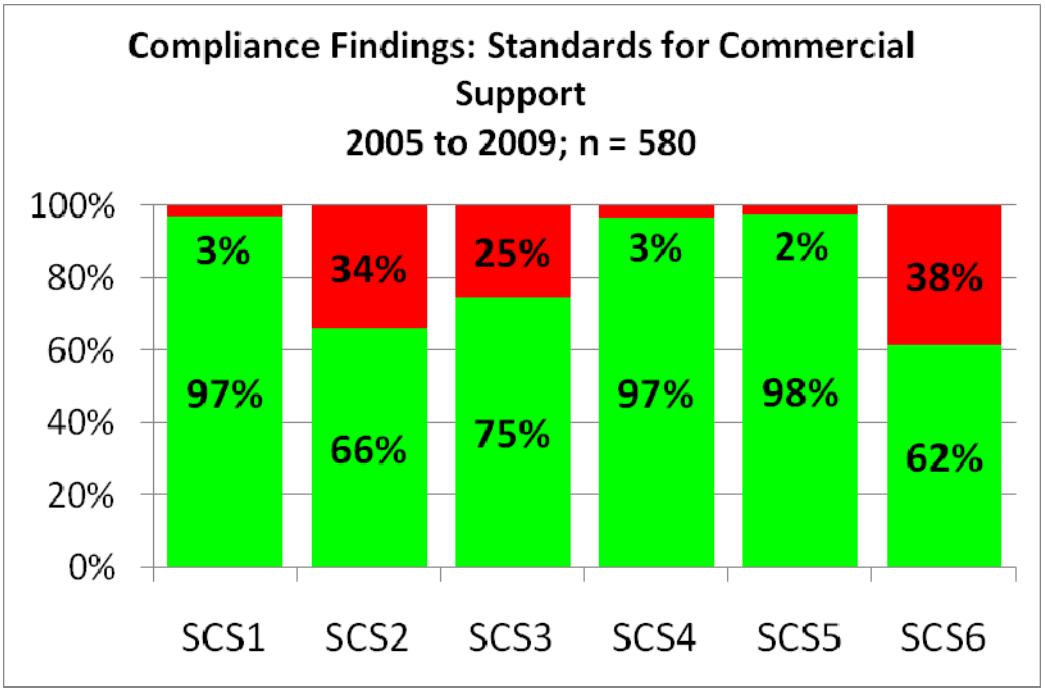


Figure 6: Accreditation findings since 2005

Figure 7 represents the “ACCME Compliance Grid” containing the accreditation findings for the 170 Providers evaluated under both the 2006 Accreditation Criteria and the 2004 SCS.

A **row** represents findings for an individual provider.

The **columns** represent the 22 Criterion, in groups. Criteria 7 to 10 (indicated with the blue box) are the SCS.

b. Accreditation Results Since November 2008

- Two Providers received **NON ACCREDITATION** for failure to come into compliance with Criteria through the Progress Report process.

- Fourteen of the 22 Initial Applicants for accreditation received decisions of **NON ACCREDITATION** for failure to demonstrate compliance in all ACCME accreditation elements. All, but one, was found in non compliance with the SCS.

- Fifteen Providers were placed on **PROBATION** for: **a)** a failure to demonstrate any implementation of the 2006 educational accreditation criteria; or **b)** recidivism with respect to compliance with the ACCME SCS. (This represents some providers that were found in non-compliance with the SCS four years previously, demonstrated correction with a Progress Report and then were found in non-compliance with the SCS during this re-accreditation review.); or **c)** failure to address some components of the ACCME Standards for Commercial Support.

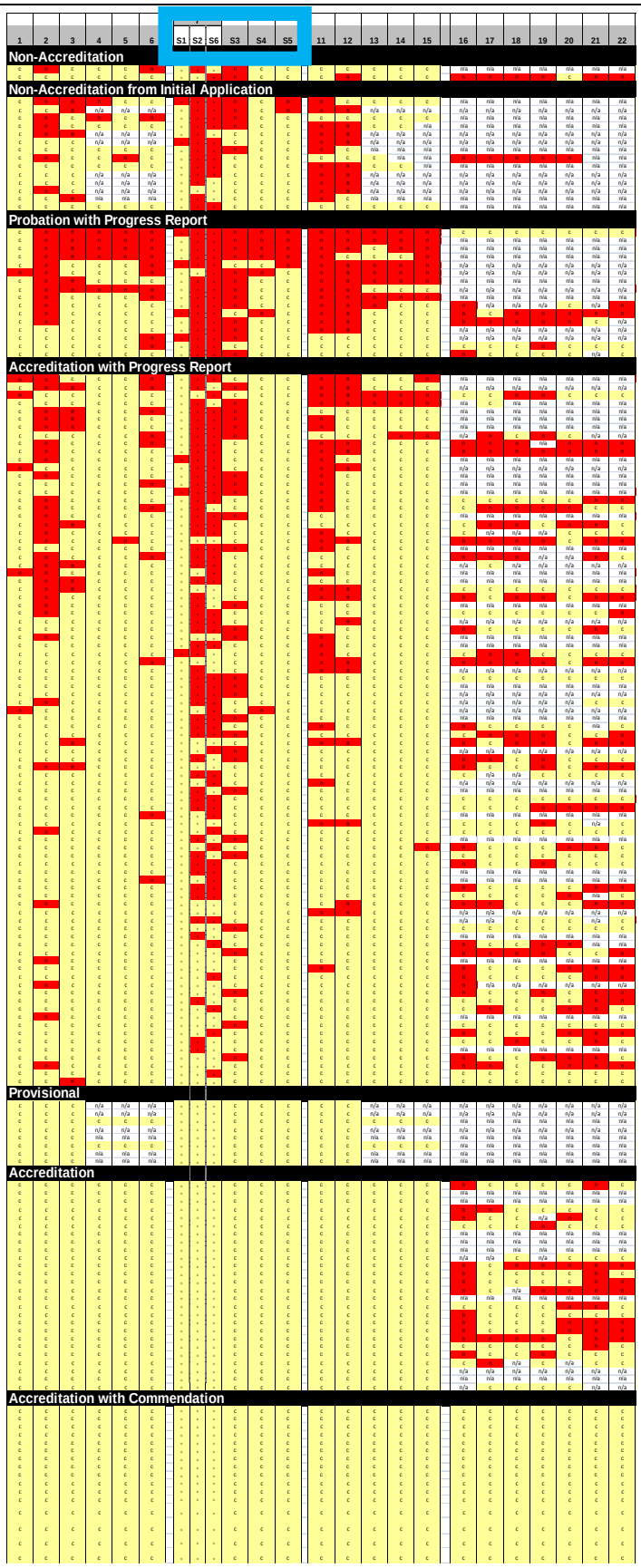
- Eighty-eight providers were awarded **ACCREDITATION** with a Progress Report. These providers are being required to submit a Progress Report in order to demonstrate compliance in all elements of the ACCME requirements. Seventy one included non compliance findings in the SCS.

- Fifty Providers were found in compliance with all their required accreditation elements. Of these:

    - Eight received **PROVISIONAL (INITIAL) ACCREDITATION.**

    - Twenty six received **ACCREDITATION.**

    - Sixteen received **ACCREDITATION WITH COMMENDATION.**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Non-Accreditation
Non-Accreditation from Initial Application
Probation with Progress Report
Accreditation with Progress Report
Provisional
Accreditation
Accreditation with Commendation

Figure 7

Figure 8 shows that for 170 Providers, 81% received **ACCREDITATION**, 9% received **PROBATION** and 10% received **NON ACCREDITATION**.

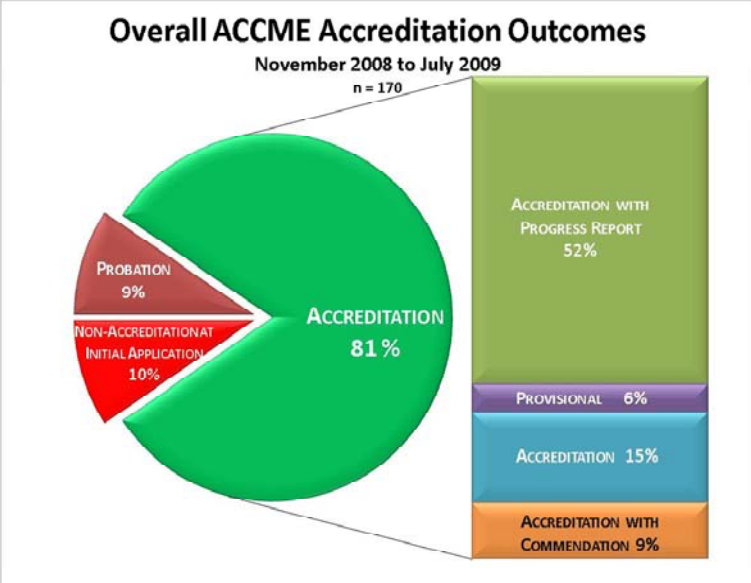


Figure 8: Combined Accreditation Outcomes November 2008, March 2009 and July 2009. n=170

In August 2008, ACCME contacted accredited Providers and informed them that information would be required more quickly when non-compliance findings were made and that ACCME verification would be more rigorous and timely. This new process requires Providers to establish improvement plans (immediately after receipt of the accreditation decision) followed by the submission of verification of improvements within one year. This two-step improvement process is intended as a mechanism for assisting and encouraging providers to identify solutions to deficiencies and remediate them more quickly. The process is designed to assist Providers by providing fair notice and opportunity to modify existing practices, as well as to ensure that learners are receiving the highest quality CME.

ACCME's accreditation system is a careful and deliberate process in which serious and systemic issues that place providers and their learners at risk can be identified. We have learned over the years that an accreditation status of "**Probation**" sends a clear message that significant changes need to be made. ACCME has also observed that the vast majority of providers make the necessary changes immediately, leading to sustained compliance, and in a number of instances, Accreditation with Commend-ation.

In order to increase Provider compliance with new and increasingly rigorous requirements, ACCME has placed more accredited Providers on **Probation** - especially those found in Non Compliance with the most important elements of the ACCME Standards for Commercial Support.[SM] The current rate of **Probation** has

increased to about 10% of Providers seeking Reaccreditation from about 1% prior to 2008.

c. Path to Compliance or Non Accreditation

The enforcement outcomes of a finding, or findings, of non compliance in the SCS are,

1. An alteration to the Provider's accreditation status to Probation; ***and/or***
2. An ACCME Progress Report that requires the Provider to: a) submit an improvement plan (new in last year) descriptive of intended corrective action; and b) submit documentary evidence that verifies compliance.

Provider's accreditation status is changed to **PROBATION** at REACCREDITATION if the Provider demonstrates recurrence of non-compliance in the SCS between terms of accreditation (new in last year), failure to implement elements of the ACCME Standards for Commercial Support, or a general failure to meet ACCME requirements as demonstrated through multiple non-compliance findings. **PROBATION** will also occur in the presence of persistent non- compliance after submission of a first Progress Report that is submitted at 9 months; decision rendered at 12-15 months. (As of November 2009, Progress Reports will be considered by ACCME at 4, 8 or 12 months which will require submission at 2, 6 or 10 months (new in last year.)

Providers can remain on **PROBATION** for up to 24 months. If Providers cannot demonstrate compliance through adequate Progress Reports, their accreditation status will be changed to **NON ACCREDITATION**.

Providers also receive decisions of **NON ACCREDITATION** if, at Initial Accreditation, applicants are in non-compliance with any element of ACCME's standards. In the 3 cohorts evaluated using the 2006 Criteria, 59% of initial applicants received a decision of **NON ACCREDITATION.**

d. Enforcement of Requirements through Progress Report Process

It is rare that Providers fail to demonstrate improvement and compliance through the Progress Report process. In the period from 2007 to 2009, ACCME's enforcement policies and procedures are projected to produce an overall compliance rate of 96% with the SCS.

Figure 9,below, shows that for every 100 providers seeking reaccreditation, 52 will be found in compliance with all elements of the SCS at initial review. Eighty-nine will be in compliance after a single Progress Report, and 96 will be in compliance after a second Progress Report. This compliance rate equates to 96%. The 4 that remain in non-compliance will withdraw, go to non-accreditation, or come into compliance with a third Progress Report.

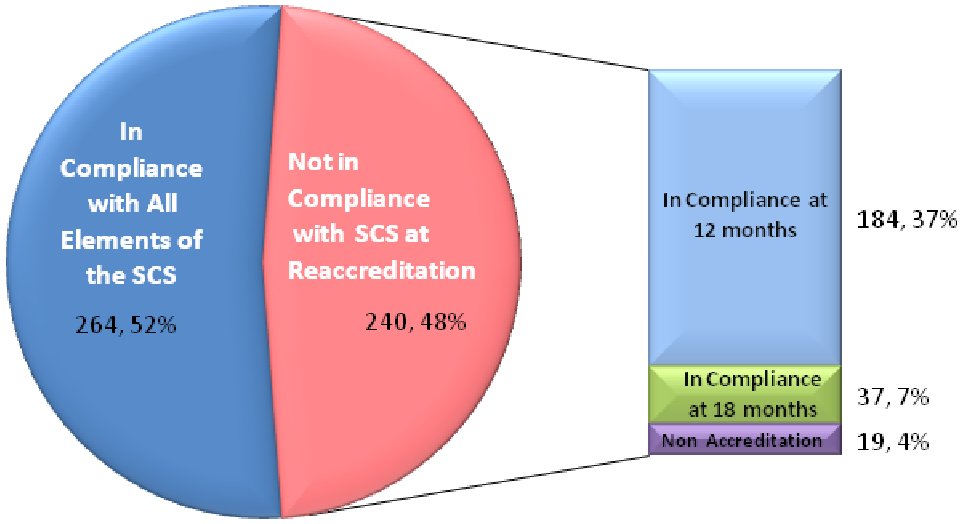
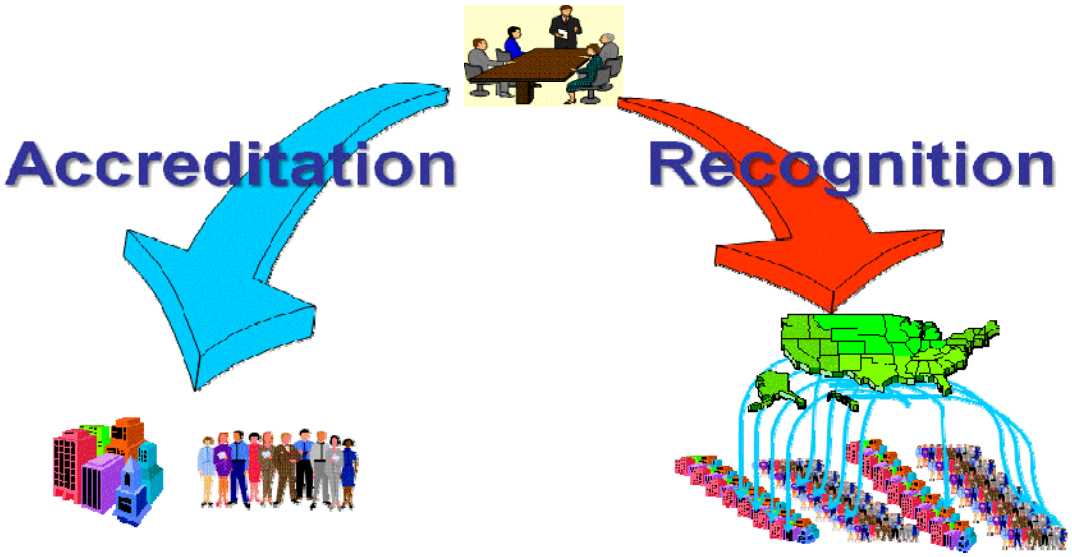


Figure 9: Outcomes as a Result of Compliance with the ACCME Standards for Commercial Support at Accreditation and on Progress Reports 2007 - 2009 (projected)

6. Enforcement by Equivalency between Accreditors

a. Equivalency within ACCME System

ACCME accredits 725 providers directly. In addition, there are about 1,600 state-based accredited providers that enjoy all the rights and privileges of an ACCME accredited Provider resulting from their accreditation by a state medical society, or equivalent. These Providers are not directly accountable to ACCME. The 46 organizations that accredit them, however, are accountable to ACCME through the ACCME process of RECOGNITION.



This process of RECOGNITION by ACCME has relevance to medical licensure, and CME in general. The policy of the Physician's Recognition Award of the AMA states that, "organizations accredited by the ACCME or a Recognized state medical society may designate CME activities for AMA PRA Category 1 Credit.[TM] "

Until 2009, ACCME RECOGNITION was achieved through the enforcement of a set of process-based requirements. ACCME required that a Recognized state medical society adopt and use the ACCME SCS as part of their own accreditation process. ACCME did not verify if the SMS applied the SCS in the same manner as ACCME.

Starting in 2009, the SMSs are now required to demonstrate that: **a)** each SMS' processes and accreditation rules and accreditation standards are the same as ACCME's decision-making rules and standards; **b)** that the SMS interprets provider practices with respect to compliance in the same manner as ACCME; and **c)** that their accreditation outcomes (e.g., accreditation status award) are appropriate to the accreditation findings and the same as the other ACCME-system accreditors.

Because of ACCME's new 2008 ***ACCME Markers of* Equivalency** (Attachment 6), starting in 2009, all accredited Providers within the ACCME system, regardless of where an accredited provider is reviewed, their performance will be interpreted the same, and their accreditation outcome will be the same --- and neither will be a manifestation of decision-making that is less than the national standard. These accreditation standards include the ACCME SCS.

RECOGNITION and the 2008 ACCME ***Markers of Equivalency*** require that the SMS's produce equivalent interpretations and accreditation outcomes – equivalent to ACCME, and equivalent to each of the other SMSs.

b. Enforcement by Equivalency between Continuing Professional Education Systems

The ACCME Standards for Commercial Support[SM], and associated ACCME definitions and interpretations, are moving closer to becoming a common national standard to manage the issues surrounding commercial interests and commercial support in continuing professional education (CPE).

Three accrediting bodies – all of which are currently incorporating accreditation standards concerning commercial support in their accreditation programs - have indicated their intent to voluntarily agree to adopt the ACCME Standards for Commercial Support,[SM] along with the ACCME definitions, interpretations and clarifications. They have committed to use these ACCME Standards for Commercial Support[SM] in the same manner as ACCME does in making accreditation decisions. ACCME is drawing up documents currently for formal consideration and execution by three accreditors.

When agreeing to use the ACCME Standards for Commercial Support[SM] in this manner, ACCME will each organization to agree to:

1. Adopt the ACCME SCS and all of the policies published on www.accme.org related to the ACCME Standards in their entirety;

2. Accredit continuing education using the ACCME SCS and the definitions, interpretations and clarifications that ACCME has established and has published on www.accme.org;
3. Maintain an accreditation system that determines compliance with the ACCME SCS;
4. Display and use the licensed service mark and copyrighted document in accordance with the format established by ACCME;
5. Share sufficient information with ACCME so that ACCME can make a fair determination about the colleague organization's fulfillment of 1 to 4, above; and
6. Indemnify ACCME against damages, claims and expenses incurred by ACCME by reason of a third party claim relating to the use of the licensed mark, or document, by the colleague organization.

ACCME will, in turn, offer to implement a simple, non- intrusive no-cost system, to determine that the colleague organization is, in fact, fulfilling these expectations.

ACCME will offer to attest publicly that the colleague organization does indeed use and apply the ACCME SCS to the level specified in the agreement.

Under these circumstances, continuing professional education accreditation will use the ACCME SCS as the national and inter-professional standard.

C. Transparency and Responsiveness to External Constituencies

1. Transparency Regarding Personal Financial Relationships with Commercial Interests of Teachers and Authors

Since 1992, ACCME has required teachers, authors and providers to disclose relevant financial relationships to learners before the start of a CME activity. Since 2005, ACCME has required teachers, authors and planners to disclose financial relationships that cause conflict of interest in CME to the CME provider during the process of activity planning so that Providers can implement mechanisms to identify and resolve any conflicts of interests prior to presentation of the activity to learners.

2. Transparency Regarding Commercial Support of CME

Since 1992, ACCME has required Providers to disclose to learners whether or not the CME Provider has received any funds, including in-kind support, from commercial interests. This disclosure must include the identity of the firm supplying the funds.

3. Transparency Regarding ACCME Accredited Providers

In 2009 ACCME announced:

> "In the spirit of transparency, the ACCME believes that additional data and information about the accreditation system and the accredited CME enterprise will allow all stakeholders of our system – including physician learners, licensing and certification bodies, and the public – to assess the accredited continuing medical education in the United States for themselves."

ACCME now includes the following information in each Provider's record on our public list of accredited Providers contained on www.accme.org:

- The provider's current accreditation status;
- # of activities reported in the last year;
- # of contact hours reported in the last year;
- # of physician participants reported in the last year;
- # of non physician participants reported in the last year;
- Accepts commercial support (Y/N);
- Accepts advertising and exhibit revenue (Y/N);
- Reported participating in joint sponsorship (Y/N);
- Produces courses (Y/N);
- Produces performance-improvement CME (Y/N);
- Produces Internet live or enduring materials CME (Y/N);
- Produces other enduring materials (Y/N);
- Produces Internet searching and learning activities (Y/N); and
- Produces other types of activities (Y/N).

4. Transparency Regarding ACCME Decision-Making

Beginning with the results of the July 2009 ACCME meetings, ACCME is publishing the ACCME's Accreditation Grid depicting the compliance findings for each Provider and the array of findings associated with accreditation status decisions. In this way, ACCME will make public its compliance data by element and compliance data by Provider, and by accreditation outcome (see Figure 5, Figure 6: Accreditation findings since 2005, Figure 7).

5. Feasibility of Implementation

In June 2008, we announced the following expansion to operational elements of the ACCME in order to fulfill the strategic imperatives identified by the Board (e.g., monitoring, education communication, enforcement):

"Since its inception in 1981, the ACCME has always been run on a tight budget with little allowance for growth or development. For most of the last decade, a small staff has administered the ACCME oversight processes for close to 50 recognized state-accreditors and nearly 2,500 providers of CME. The ACCME has taken pride in its efficiencies and controlled growth. However, during the same period, ACCME's sister accrediting bodies have doubled or tripled their operations. The ACCME now finds that it requires greater support to meet the needs of the CME system.

For decades, the ACCME has emphasized value-based, professional self-monitoring to ensure propriety in continuing medical education. As called for by elements within and outside the ACCME, the system now needs more emphasis on monitoring and measuring. Some have called for more 'enforcement.'

The majority of Accredited Providers are accredited by ACCME Recognized State Medical Societies that voluntarily participate in this process, donating their operational and educational resources to ensure that there is regional access within the local communities of practice to high quality continuing medical education. These entities have asked for, and are receiving, additional educational, administrative and operational support from the ACCME.

The ACCME is willing to add additional layers of monitoring, surveillance, and support to the systems it oversees. The ACCME is acting quickly so that it will be ready and able to implement on its expanded mandate in the coming months. Taken together, the following substantive actions will ensure that the ACCME can contribute vibrantly to the impact of the CME system on US healthcare.

ACCME enhancements approved for implementation over 2008 and 2009:

- An enhanced monitoring and surveillance system.
- Expanded educational supports -especially for State Medical Society Accredited Providers and Accreditors.
- Expanded operational and educational supports for the accreditation decision-making processes within State Medical Societies.
- An Information Technology/Knowledge Management development plan that includes enhancements to web services and a restructuring of ACCME electronic systems.

- Updated online accreditation surveyor report tools
- Operational plans for development of a provider-maintained database of CME activities and learner participation
- Expansion of Chicago office space by 100% to improve services and resources provided to Providers, Recognized Accreditors, volunteers, leadership, and staff.
- Twenty percent increase in ACCME staff (2008 to 2010)."

The 2009 ACCME budget, and its new 2009 – 2012 fee schedule, supports a 50% increase in operational expenses and revenue (over 2006 levels). In this period ACCME will have gone from $3.5 Million in annual expenses to $5.26 Million with a growth in staff complement from 15 to 24.

Attachment 1

ACCME's Process for Handling Complaints/Inquiries Regarding ACCME Accredited Providers

1. Complaints/inquires are written notifications to the ACCME by a third party which claim that an ACCME accredited provider is not in compliance with ACCME Essential Areas, their elements, or accreditation policies with regard to one or more of its activities.
2. To receive status as a complaint/inquiry the written complaint must confirm the name, USPS address and contact information of the person making the submission.
3. Complaints/inquires may a) refer to single activities / series or b) the provider's entire program of CME.
4. The statute of limitation of the length of time during which an accredited provider must be accountable for any complaints/inquiries received by the ACCME is twelve months from the date of a live activity, or in the case of a series, twelve months from the date of the session which is in question. Providers are accountable for an Enduring Material during the period of time it is being offered for CME.
5. The confidentiality of the complaining/inquiring party shall be protected, except as may be required by legal process.
6. ACCME may initiate a complaint or inquiry about an accredited provider.

Procedure for review, analysis, compliance determination and reporting regarding complaints and inquiries

7. ACCME will review the complaint/inquiry to determine whether it relates to the manner in which the provider complies with Essential Areas, their elements, or accreditation policies.
8. The person initiating the complaint will be notified of the planned course of action by the ACCME.
9. ACCME may or may not need to ask the provider for additional information[i]. If, during the course of addressing the complaint inquiry, additional information is needed from the provider then the provider's response must be accompanied, where possible, by supporting documentation.
10. All responses from the provider to a Letter of Inquiry must be received by the ACCME within thirty days after the provider receives the request for information/response from the ACCME. If a provider fails to respond to any request for information, the ACCME may change the provider's accreditation status to **Probation** or **Non Accreditation** [vi].

When ACCME determines that the information submitted is adequate upon which to base a finding

11. The provider may be found in Compliance or Not in Compliance for that activity[ii].
12. The provider will be notified of the finding. If the finding is Not in Compliance, the non-compliance will be explained in a **Notice of Non-Compliance** to the provider[iii].

Next steps

13. The ACCME may require the provider to submit **documentation of corrective action**[iv] within thirty days of receipt of the Notice of Non-Compliance.
14. The ACCME may require the provider to submit a **Monitoring Progress Report**[v] at a time determined by the ACCME.

Outcomes

15. If a provider fails to respond to a request for information, the ACCME will change the provider's accreditation status to **Probation** or **Non-Accreditation**[vi].
16. If a provider fails to convert **Non-Compliance** to **Compliance**, the ACCME reserves the right to change the provider's accreditation status to **Probation** or **Non-Accreditation** [vi].
17. At any point in the complaint/inquiry process the ACCME reserves the right to require an immediate full or focused accreditation survey, including a full or focused self-study report and interview[vii].
18. ACCME reserves the right to make public some information about the ACCME Complaints and Inquiries Process which may include but is not limited to the facts and circumstances involved in the complaint or inquiry, the name of the accredited provider involved, the names of commercial supporters, the names of non accredited joint sponsors and the ACCME's findings.

[i] If, during the course of addressing the complaint inquiry, additional information is needed from the provider then ACCME will send a written communication (Letter of Inquiry) that confirms receipt (e.g., email, USPS certified mail, FEDEX-type courier) to the provider describing the nature of the complaint/inquiry. The Letter of Inquiry will request a response in which the provider can offer its interpretation of how it complies with ACCME Essential Areas, their elements, or accreditation policies. Upon receipt of the provider's response, the ACCME shall determine whether additional information is necessary and may request such information from the provider.

[ii] If a finding of 'Not in Compliance' results from a complaint of inquiry then the ACCME Letter of Inquiry, the provider's response, any documentation of corrective action and any Monitoring Progress Report will be placed in the provider's file and will be made available to the survey team and the ARC reviewer at the next review. The activity will be included in the files reviewed by ACCME for re-accreditation.

[iii] ACCME will send a Notice of Non-Compliance (that confirms receipt e.g., email, USPS certified mail, FEDEX-type courier) to the Provider describing the nature of the non compliance.

[iv] When asked for 'documentation of corrective action' the provider will be asked to provide documentation of corrective action to the ACCME within thirty days of receipt of the Notice of Non-Compliance, and will be notified that failure to correct the deficiencies may result in an immediate resurvey which may affect the provider's accreditation status.

[v] If the Monitoring Report adequately describes and documents Compliance it will be accepted. If the Monitoring Report does not adequately describe and/or document Compliance it will NOT be accepted.

[vi] **Regarding Letters of Inquiry:** Change of status to **Probation** will automatically occur at 45 days from the time the provider receives a request for information/response from the ACCME, if the provider has failed to respond to a request for information. **Regarding Documentation of Corrective Action**: Change of status to **Probation** will automatically occur at 15 days after the due date for the notice set by the ACCME, if the provider has failed to submit the required documentation of corrective action. **Regarding Monitoring Progress Report**: Change of status to **Probation** will automatically occur at 15 days after the due date for the Monitoring Progress Report set by the ACCME, if the provider has failed to submit the required Monitoring Progress Report. Change of status to **Non-Accreditation** will occur at 15 days from the date a provider was placed on Probation for failure to submit information, documentation of corrective action or a monitoring Progress Report if the provider has still failed to submit the required information. Change of status to **Probation** or **Non-Accreditation** for 'failure to submit' does not require Board action.

ACCME will send a notice to the provider of this change of status in a manner that confirms receipt (e.g., email, USPS certified mail, FEDEX-type courier). In the communication the provider will be informed that a change of status to Non Accreditation will occur if the provider has failed to respond to the request for information in the manner stipulated by ACCME.

[vii] A provider's compliance must be reviewed by the ARC/DC in order to either a) change the provider's accreditation status to Probation or Non Accreditation or b) proceed with a full or focused accreditation survey, including a full or focused self-study report and interview.

History of Complaints and Inquiries Received and Processed
(2008-June 2009)

1. The **complainant** was ACCME.
   The **complained-against** organization was a Publishing/Education Company.
   The **activity** was a Enduring Material.
   The **finding** was **not in compliance** with SCS 4.5 because the accredited provider used a commercial interest as the agent providing a CME activity to learners.
   The **finding** was **compliance** with SCS 1 (Independence); **compliance** with SCS 1 Conflict of Interest) and **compliance** with SCS 5 (Bias).

2. The **complainant** was the ACCME's Accreditation Review Committee.
   The **complained-against** organization was a Nonprofit (Physician Membership Organization).
   The **activity** was a Journal-based activity.
   The **finding** was **not in compliance** with SCS 2 in that the provider failed to identify a *relevant* financial relationship from the disclosure information provided by an author. In addition, the accredited provider's accreditation statement did not appear in the on-line version of the activity and the **finding** was also **not in compliance** with SCS 6 because although the conflict was disclosed to the provider, the provider failed to the relevant financial relationship to the learners.

3. The **complainant** was another accredited provider.
   The **complained-against** organization was a Publication/Education Company that was acting as a joint sponsor with a non-accredited provider.
   The **activity** was a live activity.
   The **finding** was **not in compliance** with SCS 1 (Independence) because five speakers were employees of commercial interests and the provider presented no documentation of who authored materials for the activity or who participated in the planning group so ACCME was unable to determine what role if any these five speakers played; **not in compliance** with SCS 2.3 (Resolution of Personal Conflicts of Interest) in allowing these five employees of commercial interest to speak during the activity but to resolve the conflict by not to awarding CME credit for their presentations; **not in compliance** with SCS 4.2 (Appropriate Management of Associated Commercial Promotion) because the provider allowed product promotion to occur in and during a CME activity.

4. The **complainant** was a non-accredited joint sponsor.
   The **complained-against** organization was a Publishing/Education Company.
   The **activity** was an online-activity.
   The **finding** was **not in compliance** with ACCME's policy of requiring separation between education and promotion because email advertisements of commercial interests were sent from the domain and using the logo of the accredited provider.

5. The **complainant** was a newsletter.
   The **complained-against** organization was a Nonprofit (Physician Membership Organization).
   The **activity** was a Journal-based activity.
   The **finding** was **not in compliance** with SCS 2 in that the provider failed to identify a *relevant* financial relationship from the disclosure information provided by an author. In addition, the accredited provider's accreditation statement did not appear in the on-line version of the activity.
   The **finding** was also **not in compliance** with SCS 6 because although the conflict was disclosed to the provider, the provider failed to the relevant financial relationship to the learners.

Figure 1: Compliance findings for five Inquiries with at least one element of the SCS in Non Compliance

Twelve Inquiries relating to the SCS are still open.

1. The **complainant** is the ACCME based on an article by an on-line media company.
The **complained-against** organization is a School of Medicine.
The **activities** were on line materials, enduring materials, and live programs.
The **issues raised are** that the activities were not planned independent of commercial interests (C-7 (SCS 1,2,6)) the activities promoted a commercial interest (C-10)(SCS 5)) and these activities violated ACCME Policy on Content Validation. The accredited provider's response in the form of a Notice of Corrective Action is under review.

2. The **complainant** is a learner.
The **complained-against** organization is a Publishing/Educational Company
The **issues raised are** whether two activities that were part of a multi-year single subject initiative were planned independent of commercial interests (C-7) whether the activities promoted a commercial interest (C-10) and whether these activities violated ACCME Policy on Content Validation.

3. The **complainant** is a learner.
The **complained-against** organization is a Publishing /Education Company.
The **activity** was an enduring material.
The **issues raised are** that the activity violated SCS 1 relating to planning of activities free of commercial interests and SCS 5 relating to delivery of content and format free of commercial bias.

4. The **complainant** is an author.
The **complained-against** organization is a Publishing/ Education Company.
The **activity** was an enduring material.
The **issues raised are** is that the accredited provider did not adhere to its own policies governing its business obligations and commitments namely the payment of honoraria.

5. The **complainant** is a commercial interest.
The **complained-against** organization is a Publishing/Educational Company.
The **issues raised are** whether three separate activities related a single medical condition were planned independent of commercial interests (C-7) whether the activities promoted a commercial interest (C-10) and whether these activities violated ACCME Policy on Content Validation because the medical writer for the joint sponsor had previously worked for the commercial supporter. The ACCME is currently looking at the additional question of whether these activities were planned in accordance with Criterion 7 and 10 relating to other planners and faculty.

6. The **complainant** is a publisher of a blog.
The **complained-against** organization is a Publishing /Education Company.
The **activity** was an on-line activity/enduring material.
The **ACCME has found** the activity **violated** SCS 5 relating to delivery of content and format free of commercial bias and that the accredited provider violated ACCME's Policy on Content Validation. The accredited provider's response in the form of a Notice of Corrective Action is under review.

7. The **complainant** is a physician.
The **complained-against** organization is a Publishing/Educational Company
The **issue raised is whether** an on-line activity was planned independent of commercial interests (C-7) whether the activity promoted a commercial interest (C10) and whether the activity violated ACCME Policy on Content Validation.

8. The **complainant** is The ACCME based on an article by an media publisher.
The **complained-against** organization is a School of Medicine.
The **activities** were an on line activity, and two live programs.
The **issues raised are** that the activities were not planned independent of commercial interests (C-7 (SCS 1, 2,6)) the activities promoted a commercial interest (C-10)(SCS 5)) and these activities violated ACCME Policy on Content Validation. The accredited provider's response in the form of a Notice of Corrective Action is under review.

9. The **complainant** is a physician.
The **complained-against** organization is a Publishing/Education Company.
The **activities** were two enduring materials.
The **issues raised are** are that the activities were not planned independent of commercial interests (C-7 (SCS 1, 2,6)) the activities promoted a commercial interest (C-10)(SCS 5)) and these activities violated ACCME Policy on Content Validation.
The accredited provider's response in the form of a Notice of Corrective Action is under review.

10. The **complainant** is ACCME based on a letter from a commercial interest.
The **complained-against** organization is a Publishing/Education Company.
The **issue** involves the commercial interest's decision to no longer fund any of the accredited provider's activities.
The **issues are** not known at this time because ACCME has not yet received the information that led to the commercial interest's decision.

11. The **complainant** is special interest group.
The **complained-against** organization is a Non-Profit (Physician Membership Organization).
The **activity** is an online enduring material.
The **issues raised are** that the accredited provider did not ensure the validity of the joint sponsor's content in violation of (C-10)(SCS 5)) and ACCME's Policy on Content Validation.

12. The **complainant** is a learner.
The **complained-against** organization is a Non-Profit (Physician Membership Organization).
The **activity** was an enduring material.
The **issues raised are** that the activity violated SCS 1, 2, 6 relating to planning of activities free of commercial interests.

2008 SCS **Inquiry** Initial Review Tool

Reviewer Questions

1. The provider determines the content/scope of commercially-supported CME activities in the following way(s):
   a) According to ACCME Criterion 2
   b) According to educational needs/goals as stated by a commercial interest (e.g., within a Request for Proposal [RFP], posted on a grant submission website, communicated during a meeting)
   c) According to a standing commitment or expectation of support for a legacy/continuing event, program, or initiative (e.g., annual conference, consortium)
   d) As a result of an agreement stemming from personal relationships between persons that work with or for the accredited provider and commercial supporters (e.g., joint sponsor, consultant)
   e) As a result of an ongoing relationship between a commercial supporter and a provider (e.g., trusted vendor)
   f) Other Scenarios Described (optional):
2. The provider determines the format of commercially-supported CME activities in the following way(s):
   a) According to the provider's mission, desired results of their CME program (e.g., changes in competence, performance, patient outcomes), practice-based needs and gaps, and environment of the learners
   b) According to the interests of learners (e.g., via survey)
   c) Because of the area of business expertise/experience of the provider
   d) According to guidance or direction from a commercial supporter, as stated in a RFP, website announcement, or meeting
   e) Because of a commitment to a legacy/continuing event, program, or initiative (e.g., live symposium at an annual meeting)
   f) Other Scenarios Described (optional)
3. The provider uses the following safeguard(s) as processes to develop commercially-supported CME activities that are content-valid and free of bias:
   a) A checklist or process tool that follows the ACCME Standards for Commercial Support
   b) Internal review by planners and authors
   c) External review with independent reviewers (e.g., committee, peers)
   d) Self-attestation by planners and authors that content is valid and free of bias
   e) External review by a joint sponsor or consultant
   f) External review by agents of a commercial supporter(s)
   g) Other Scenarios Described (optional):
4. The provider determines who will plan, author, present, and/or deliver a commercially-supported CME activity in the following way(s):
   a) By determining what person(s) would have the best knowledge, skills, and insight to make the CME activity effective in reaching its desired results
   b) By using internal staff and/or faculty that are broadly involved in content development for numerous activities within the providers program of CME (e.g., retained writers/teachers)

c) By recommendations or suggestions from partners and collaborators (e.g., joint sponsors, speaker's bureau)

d) By soliciting recommendations from commercial interests

e) Other Scenarios Described (optional)

5. The provider measures the effectiveness of its processes for ensuring validity and the absence of bias during the planning, execution, and evaluation of CME activities in the following way(s):

   a) By screening or measuring for bias during the planning of a CME activity

   b) By surveying activity participants (learners) on their perceptions of the validity and bias of the CME activity

   c) Through external, independent review at an activity level (e.g., monitors)

   d) Through measurement of validity/bias at a program level (e.g., annual review of activities

   e) By external review at an activity or program level by a joint sponsor or outside consultant

   f) By external review at an activity or program level by the agent(s) of a commercial supporter

   g) Other Scenarios Described (optional)

6. The provider evaluates the effectiveness of commercially-supported CME activities in the following way(s):

   a) By the provider's own (internal) analysis in keeping with ACCME Criteria 11-12

   b) Through provider-led collaboration with external resources (e.g., CME committee, peers)

   c) By a third party vendor (e.g., joint sponsor, consultant, "outcomes" company)

   d) By external review involving agents of a commercial supporter(s)

Attachment 4

NEW ACTIVITY DATABASE, NEW SOURCES OF INFORMATION

The ACCME's maintenance of an accurate and complete database of CME activities and participants is critical to ACCME's ability to provide additional, direct oversight of activities in real-time.

Phase 1: All Accredited Providers will be required to transmit to the ACCME an enhanced data set of information descriptive of each of CME activity. Transmission of data to ACCME will be through a web-based portal or direct transmission of appropriately formatted spreadsheets. Maintenance of accreditation will depend on ACCME's receipt of complete information in a timely fashion.

Phase 1 Data Points

- Activity Title
- Date and Location
- Direct or Joint Sponsorship
- Type of Activity Format
- # of Hours
- # of MD's
- # of non-MD's
- The amount and source(s) of commercial support.
- Content of CME
- The nature, scope, and value of financial relationships of persons
- Information on the prevalence of CME on products in the pipeline or use that is off-label
- If designed to change Competence?
- If changes in Competence measured?
- If designed to change Performance?
- If changes in Performance measured?
- If designed to change patient outcomes?

Phase 2: The ACCME will expand the database of activity information to include data derived directly from ACCME 'monitors' present at activities. This will include information from learners and from other special ACCME observers. It may also be expanded to include lists of participants.

Phase 3: The ACCME database will be expanded to include self-assessment data that is reported to ACCME by Accredited Providers about their programs of CME. The ACCME will be requiring that Accredited Providers measure for commercial bias and content validity and report their results in real-time through a web portal. A Providers analysis of these data and their response to the findings will contribute to their compliance with Criteria 12 and 13. There will be transparency and disclosure of compliance information. **What the ACCME knows about provider compliance will be published publicly to www.accme.org.**

Detailed specifications will be announced shortly by ACCME and will be consistent with national data standards being developed.

Activity and Program Reporting System

Homepage of Activity and Program Reporting System:

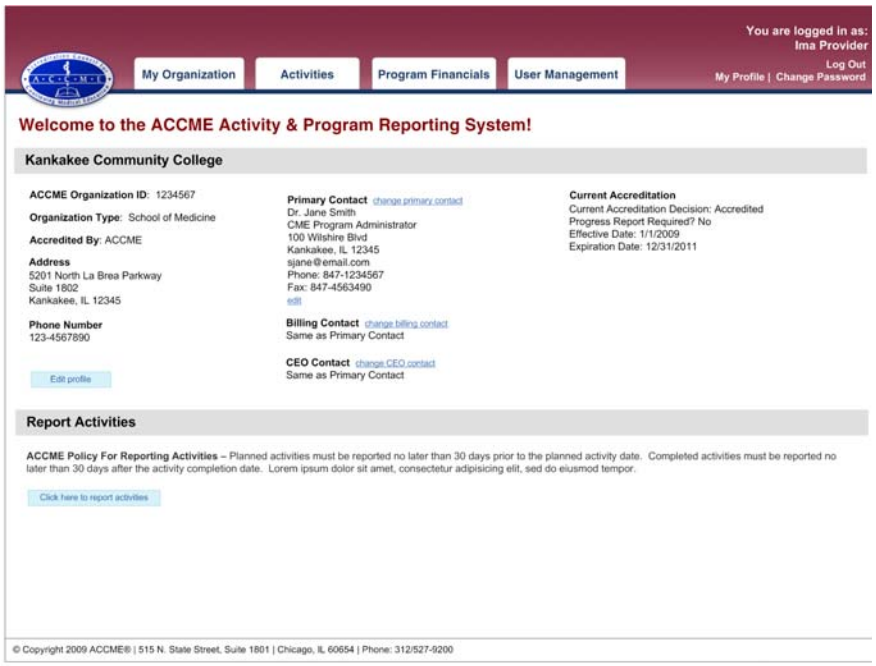


Figure 1

The presence of this database system will create an impact at several levels. It will streamline the accreditation process by making activity information available more easily for calculations of the Annual Report, activity lists at reaccreditation and sources of sampling information for documentation review and verification of performance in practice. It will also act as the platform from which ACCME will launch its monitoring and surveillance system (new this year).

A completed activity record will contain information about the amount of commercial support received, the name of the commercial supporter(s), the education content in standardized format[1] as well as an indication of how educational effectiveness is being measured (e.g., in terms of physician competence(strategy), performance-in-practice or patient outcomes.

[1] http://www.nlm.nih.gov/mesh/MBrowser.html

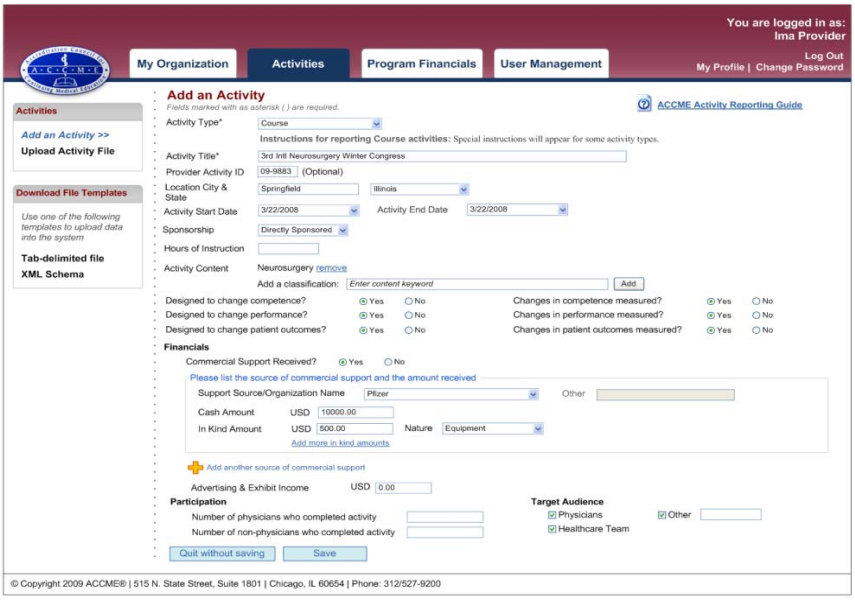


Figure 2

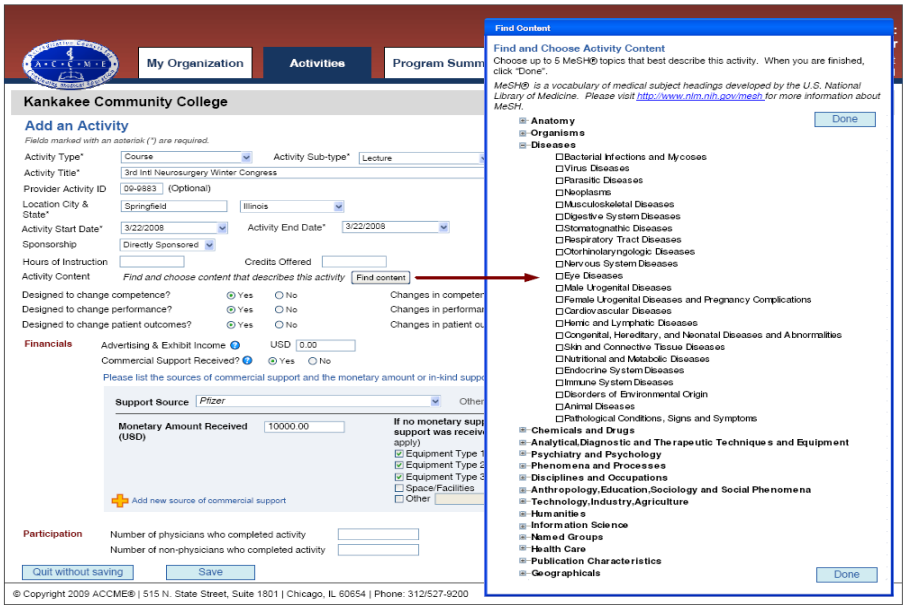


Figure 3

The intent is to monitor for commercial bias and content validity by the direct observation of qualified observers.

It is ACCME's intention to recruit observers from among the learner and expert community. (Experience in this type of monitoring reported by the American Academy of Family Physicians shows that in some case only content experts can detect commercial bias in CME activities.)

With the assistance of outside experts, ACCME data gathering instruments will be developed and observers will be recruited and trained so that direct monitoring can commence in 2010. The database development is virtually

completed and deployment is planned for the fourth quarter of 2009 to allow data entry beginning in 2010.

Attachment 6

ACCME'S **NEW** RECOGNITION REQUIREMENTS
MARKERS OF EQUIVALENCY

1. **Equivalency of Rules**
2. **Equivalency of Process**
3. **Equivalency of Interpretation**
4. **Equivalency of Accreditation Outcome**
5. **Equivalency of Evolution/Process Improvement**

Critical Features have been identified for each Marker of Equivalency. In order for an Intrastate Accreditor to achieve and maintain Recognition by the ACCME, the Accreditor must demonstrate Equivalency with each Marker. Equivalency will be demonstrated by meeting the Critical Features associated with each Marker.

The ACCME has also identified and provided definitions and policies to make explicit its expectations for meeting the Critical Features and demonstrating Equivalency.

1: EQUIVALENCY OF RULES

The Recognized Accreditor must:

1. Use the ACCME's Accreditation Requirements* that are applicable at the time ("accreditation requirements") as the basis for each accreditation decision.

2. Incorporate all the formats of CME activities into the accreditation review process consistent with national standards established by the ACCME*.

2: EQUIVALENCY OF PROCESS

Regarding the development of accreditation decisions, the Recognized Accreditor must,

1. Implement a mechanism to communicate to its accredited providers and perspective applicants all applicable "accreditation requirements" and processes.

2. Implement an accreditation process that requires providers to describe and verify compliance in all applicable "accreditation requirements".

3. Implement an accreditation process that makes accreditation decisions using data and information,

    a. descriptive of compliance in each applicable "accreditation requirement".

    b. from a provider's self study report **and** a provider's performance in practice **and** an interview with representatives of the provider.

    c. from all the types of CME activities offered by the provider.

    d. from all years of a provider's term of accreditation.

4. Utilize its accreditation decision-making body to verify and adopt accreditation findings and outcomes before communicating findings and outcomes to the provider.

5. Report to the Provider in writing the Provider's compliance or non compliance,

    a. with each applicable "accreditation requirement".

    b. of an accreditation decision being made that is consistent with national standards established by the ACCME*.

Regarding the operations of an accreditation system the Recognized Accreditor must,

6. Implement procedures to resolve conflicts of interest within the accreditation decision making process consistent with national standards established by the ACCME*.

7. Maintain accurate accreditation records that are updated in a timely fashion by,

    a. making an accreditation decision or granting an extension before a provider's term expires. If an extension is granted the extension must be consistent with national standards established by the ACCME*.

    b. making all accreditation decisions by conducting a provider's survey interview consistent with national standards established by the ACCME*.

    c. updating the provider's accreditation information through the ACCME Online System consistent with national standards established by the ACCME*.

8. Communicate in writing to the provider and the ACCME the new accreditation expiration date when an extension was granted.

9. Implement mechanism(s) to collect, store, and retrieve the following documents and information used in administering the accreditation process for each provider (Documents and information that must be maintained for each provider should be retained by the accreditor for its current term of ACCME Recognition).

    a. Completed self study report/application from the provider that the accreditor reviewed in the process for making the most recent accreditation decision on the provider.

    b. One complete activity file that was reviewed in the process for making the most recent accreditation decision on the provider.

    c. All completed surveyor forms (e.g., surveyor report form, documentation review forms, activity review forms, etc) used in the process for making the most recent accreditation on the provider.

    d. Correspondence between the accrediting body and the provider during the accreditation process (from notification to decision) and throughout the provider's term of accreditation.

    e. Written actions taken by the accreditation body which outline the term and status awarded to the provider.

    f. Follow-up reports (e.g., progress reports) generated by the CME provider, if required.

10. Ensure that Annual Report data from each accredited provider, consistent with national standards established by the ACCME, is submitted via the national reporting system in keeping with ACCME-designated expectations and deadlines*.

11. Have, and use when necessary, written policy and procedure on Reconsideration and Appeals on adverse accreditation decisions.

12. Have, and use when necessary, written policy and procedure on Complaints and Inquiries on its accredited providers.

3: EQUIVALENCY OF INTERPRETATION

The Recognized Accreditor must:

1. Must base its compliance findings and decisions solely on the integration of data collected from the three sources during the accreditation process.

2. Develop compliance findings for each accreditation requirement that are,

    a. Supported by data and information from 3 sources.

    b. Consistent with national standards established by the ACCME* **and**,

    c. Appropriate to the performance of the provider.

4: EQUIVALENCY OF OUTCOMES

The Recognized Accreditor must:

1. Translate accreditation findings into accreditation outcomes (accreditation term; accreditation status, progress reports) that are

    a. Appropriate for the accreditation findings and

    b. Consistent with national standards established by the ACCME*.

2. Require the demonstration of improved performance (a Progress Report) for each finding of NON COMPLIANCE within a timeframe, consistent with national standards established by the ACCME*.

3. Require that a Progress Report contain both a review of a provider's performance in practice and descriptions of procedures and practices, in order to determine if the provider has improved.

4. Hold a provider accountable, through second Progress Reports or a change in accreditation status (Probation or Non Accreditation), when a provider fails to demonstrate improved performance within a timeframe and in a manner, consistent with national standards established by the ACCME*.

5: EQUIVALENCY OF EVOLUTION/PROCESS IMPROVEMENT

The Recognized Accreditor must:

1. Integrate new accreditation requirements and new national standards established by the ACCME into its accreditation processes and/or the CME programs of its providers.

2. Provide access to training for accreditation staff, surveyors and decision makers to ensure that these individuals attain and maintain adequate knowledge and competence in the accreditation of CME providers in a manner that supports equivalency in the national accreditation system.

ACCME Definitions and Policies that Support the *New* Recognition Requirements

Critical Feature of Markers of Equivalency		Link to current ACCME policy/practice
1.1	Use the ACCME's Accreditation Requirements that are applicable at the time ("accreditation requirements") as the basis for each accreditation decision.	ACCME's Essential Areas, Elements, Updated Accreditation Criteria and Policies (including 2004 Standards for Commercial Support) as noted on website: http://accme.org
1.2	Incorporate all the formats of CME activities into the accreditation review process consistent with national standards established by the ACCME*.	Formats of CME as defined on website under Annual Report Definitions: http://accme.org/annualreports
2.5b.	Report to the Provider in writing the Provider's compliance or non compliance…of an accreditation decision being made that is consistent with *national standards established by the ACCME.	Accreditor must inform provider of accreditation decision within 4 weeks of decision.
2.6	Implement procedures to resolve conflicts of interest within the accreditation decision making process consistent with national standards established by the ACCME*.	Individuals with conflicts of interest must recuse themselves from the decision making process.
2.7	Maintain accurate accreditation records that are updated in a timely fashion by…	
a.	…making an accreditation decision or granting an extension before a provider's term expires. If an extension is granted the extension must be consistent with national standards established by the ACCME*.	Extensions may not exceed 8 months.
b.	…making all accreditation decisions by conducting a provider's survey interview consistent with national standards established by the ACCME*.	Accreditation decision must be made within 6 months of conducting a provider's survey interview.
c.	…updating the provider's accreditation information through the ACCME Online System consistent with national standards established by the ACCME*.	Accreditor must update provider's accreditation information within 4 weeks of making an accreditation decision.
2.10	Ensure that Annual Report data from each accredited provider, consistent with national standards established by the ACCME*, is submitted via the national reporting system in keeping with ACCME-designated expectations and deadlines.	Accreditors are required to facilitate the annual report data collection of its providers within the designated deadlines. Failure to meet ACCME administrative deadlines by providers or recognized entities could result in (a) an immediate change of status to Probation, and (b) a subsequent change of status to Nonaccreditation or Nonrecognition.

3.2b	Develop compliance findings for each accreditation requirement that are…consistent with national standards established by the ACCME*.	ACCME's Decision Making Pathways as described on website: http://accme.org
4.1b	Translate accreditation findings into accreditation outcomes (accreditation term; accreditation status, progress reports) that are…consistent with national standards established by the ACCME*.	Accreditation Status and Terms must allow for: Accreditation with Commendation with 6 years; Accreditation; Provisional Accreditation; Probation with 2 year maximum.
4.2	Require the demonstration of improved performance (a Progress Report) for each finding of NON COMPLIANCE within a timeframe, consistent with national standards established by the ACCME.	Providers seeking re-accreditation that receive Non-Compliance in one or more of the ACCME's Criteria including the Standards for Commercial Support will be required to submit a Progress Report. *Applicants seeking provisional accreditation that receive one or more Non-Compliance findings in the ACCME's Criteria automatically receive a decision of Non-Accreditation.* The usual due date for a Progress Report is one year from the date of the original finding.
4.4	Hold a provider accountable, through second Progress Reports or a change in accreditation status (Probation or Non Accreditation), when a provider fails to demonstrate improved performance within a timeframe and in a manner, consistent with national standards established by the ACCME.	Progress reports rejected when performance doesn't meet criteria. Repeated failure to demonstrate compliance through progress reports = change in status. Providers on probation must demonstrate all NC findings converted to compliance within 2 years or status change to non-accreditation.