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**Update: ACCME and
Regulatory Issues**
CACME Annual Conference
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 **Disclosure**

- No Direct Commercial Conflicts
- President, Global Education Group
- Past-President, NAAMECC
- Principal, AOE Consulting
- ACCME Accreditation Surveyor
- Views shared are personal and not organizational

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 **Agenda**

- ACCME 2009 Annual Report Analysis
- Pending ACCME Decisions
- Regulatory Update
- Sharing and Questions

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ACCME 2009 Annual Report

- Bad News ☹️
- Good News 😊
- Food for Thought

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CME in Decline?

Year	# CME Activities	# CME Hours
2007	113,000	741,000
2008	111,000	769,000
2009	95,000	689,000
Totals	-18,000	-52,000

Source: ACCME Annual Report Data, Published July 2010
 © Note: Virtually no change in total number of physician participants between 2008 and 2009

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Providers by the Number

Year	Nationally-Accredited Providers (ACCME)	State Medical Society-Accredited Providers
2007	736	1,663
2008	728	1,600
2009	707	1,518
Totals	-29 -3.9%	-145 -8.7%

Source: ACCME Annual Report Data, Published July 2010
 © Note: Not bad for a period of increased regulation and decreased funding

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◆ Pending ACCME Decisions

- Rapid Response to Non-Compliance
 - 2%, Now 5%, Future 10%
 - Immediate Improvement Plans
- Monitoring of CME Activities
- Calls for Comment

◆ ACCME Non-Compliance Findings

Criterion	% Non-Compliance
C7 (S2)	48%
C7 (S6)	46%
C11	33%
C2	30%
C8 (S3)	28%

◆ Call for Comment #1

- Transparency re: non-compliance
- ACCME complaint and non-compliance finding
- Organization identity confidential
- If accreditation status changed, public (but not reasons why status changed)
- ACCME aggregates/reports complaints data

Call for Comment #2

- Reincorporating “knowledge” into criteria
- A step back
- 2006 Criteria (1,3,11) require providers address “competency, performance, patient outcomes”
- Option 1: add “knowledge” to 1,3,11
- Option 2: “can present some activities that are designed to change knowledge” but must still meet 2006 criteria

Call for Comment #3

- Assessing state medical society accreditors
- Currently must go through “self study” process
- Proposal to simplify:
 - a) Submit evidence (activity file, etc.)
 - b) Achieve “equivalency” and be “compliant”
 - c) Equivalent, Probation, Non-recognition

Other Regulatory Issues

- Federal Healthcare Reform
 - Expansion
 - CME Exemption on Payments
 - States (CO) Adopts Federal

Other Regulatory Issues

- Massachusetts Gift Ban
- Backlash
 - Kate Atkinson, MD
 - www.policymed.com
 - *Chaos and Organization in Healthcare*

Other Regulatory Issues

- REMS
- *FDA Amendments Act 2007*
- Risk Evaluation and Mitigation Strategy
- Risk Profile
- Drug benefits outweigh risks
- Medication guide, communications plan, “elements to assure safe use”
- Sept. 30, 2009 FDA Guidance

Regulatory Transition

- ACCME move from “accreditor” to “regulator”
- Alignment of FDA, OIG, ACCME, Funders
- Congress
- Darwin

2009-2010: Regulators Gain Confidence

“The ACCME believes that the CME system’s internal controls provided by the ACCME Standards for Commercial Support and associated ACCME policies, support the development of independent continuing medical education that a) is free of commercial bias and b) does not result in an inclination by professionals to direct care that is unwarranted or unnecessary.”

March 2009 ACCME Board Summary

Good News from Bias Studies

Bias Study #1: Medscape Participants

- September 2009 American Journal of Medicine
- Study by Ellison, Hennekens, et al. reported the following:
- More than 1 million physicians responded to surveys via the Medscape online CME portal
- Respondents asked about possible bias in two categories of CME activities – those with commercial support and those without.

⦿ Bias Study #1: Medscape Participants

Results:

- Regarding the question of bias, 6% of respondents said they had “no opinion” on the matter.
- Regarding the question of bias, less than 1% of physicians indicated any bias in *either* activities that were underwritten with industry funds *or* those without industry funding.
- Regarding the question of bias, 93% of more than 1 million physician respondents affirmatively stated they perceived no bias in either type of CME activity.

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⦿ Bias Study #2: Cleveland Clinic

- Studied 346 CME activities; 95,429 participants
- Some were commercially supported; some not
- 98.4% stated the activities were free of bias
- When segmented by type of funding, results consistent:
 - None: 98% said no bias
 - Single source: 98.5% said no bias
 - Multiple source: 98.3% said no bias
- “No evidence that commercial support results in perceived bias . . .”

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⦿ Bias Study #2: Cleveland Clinic

- Study directly contradicts assertion by Cleveland Clinic physician
- “CME has become an insidious vehicle for the aggressive promotion of drugs and medical devices.”
(Chair of Cardiovascular Medicine)
- Evidence vs. Accusation

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The Future for CME?

- Simple economics
- 400,000 Medical Journal Articles Annually
- Physicians Want and Need Certified CME
- Drug makers have both right and responsibility to fund education about science and safety within therapeutic areas
- Funding declines in transition – ACCME 2009 Data
- If we demonstrate value, integrity, and compliance, CME increases likely

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Thank You!

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