Healthcare Under President Obama

Changing Landscape of Continuing Medical Education

Brad Bednarz
Association of Medical Media Meeting
Nov. 20, 2008
Visible Productions develops professional and patient education programs utilizing visual technology (animations, 3d rotatable/dissectable models, morphing technology) to enhance the learning experience. Our customers are pharmaceutical companies, hospital groups, medical associations, web healthsites, insurers, government, & others.
Healthcare Reform Under Obama

• Broad-based stimulus package favored by Democrats
  – Includes additional federal Medicaid funds for states
  – Unlikely to pass during lame-duck session due to Republican opposition

• Strong pressure for healthcare reform
  – Core Obama campaign promise
  – Business Roundtable, Nat’l Federation of Independent Businesses, AARP & Service Employees International Union with $M PR campaign
  – Pushing reform in first 100 days

• Washington Post
  – “Thinking is universal coverage will lower health care costs, make companies more willing to hire…create new health care jobs“

• Obama & Democrats beginning to frame healthcare proposals
Obama’s Plan

• Obama Plan
  – Extend health coverage by expanding existing private & public programs with federal subsidies & mandates
  – Employers, except small businesses, provide health insurance or contribute to the cost
  – Require all children to have health insurance
  – Expand Medicaid & State Children's Health Insurance Program (SCHIP)
  – Create *National Health Insurance Exchange* to pool risk & offer choice of competing private or public health plans

• Claim: Lower average family's health premiums by $2,500/year

• Reforms modeled on Massachusetts
  – Enacted universal healthcare legislation in ‘06
  – Was most costly healthcare state
  – Now nation's lowest uninsured rate
Cost & Timing

• Tax Policy Center (nonpartisan tax analysis group)
  “Plan would reduce the number of uninsured Americans from projected 67M to 33M over decade at $1.6 trillion cost”

• PriceWaterhouseCoopers
  "Plan would cost $75 billion & cover 2/3 of uninsured”

• How Obama will pay for it:
  – Roll back Bush tax cuts on people making over $250,000/yr.
  – Keep estate tax at ‘09 levels
  – Plus other tax reforms

• No timetable for Obama’s proposed reforms

• Medicare reform…bigger challenge
  – Failed under Clinton
  – Need bi-partisan support this time
Other Healthcare Proposals

- Senate Finance Committee Chair Baucus (D-MT) proposal
  - Expand health insurance to all U.S. residents
  - Employers provide coverage or pay into federal insurance fund
  - Individuals purchasing insurance in private market given tax credit
  - Similar to Obama NHIE
  - Expand Medicare coverage to ages 55 to 64
  - Enroll people with income below federal poverty line into Medicaid

- House Ways & Means Chair Rangel (D-NY), Health Subcommittee Chair Stark (D-CA), & Kennedy (D-MA)
  - “Baucus plan supports a number of principles we have pursued over time”
Republican Reaction & Democrat’s Priorities

• Finance Committee, Grassley (R-IA)
  "Dramatically expanding government spending & putting additional pressure on employers already struggling to create jobs ...repercussions that need to be carefully considered"

• House Ways & Means Health Subcommittee, Chairman Pete Stark (D-CA)
  – Democrat Priorities
  – Passing measures vetoed by Pres. Bush
  – SCHIP for children
  – Rebasing Medicare physician payment system to eliminate need for annual fixes
  – Adoption of health information technology

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Health and Human Services (HHS)

• Obama Transition Team
  – Named William Corr, Exec. Dir, Campaign for Tobacco Free Kids
  – Dr. Nicole Lurie, RAND public health & health care disparities expert
  – Team leaders to manage transition at HHS

• New Head of HHS
  – Democratic National Committee Chair. Howard Dean
  – Physician & former Vermont governor
  – Expanded healthcare in Vermont
  – Not from inside the Beltway
• John Dingell (D-MI) plans to introduce early next year the Food & Drug Globalization Act
  – Enhance FDA's authority & increase funding
  – For inspections worldwide & compliance programs
  – Fee on imported drugs & foods

• New FDA Commissioner?
  – Dr. Steven Nissen, controversial Cleveland Clinic cardiologist as possible choice
  – Former Deputy FDA Commissioner Mike Taylor
  – Duke University researcher Robert Califf
  – Industry Consultant Mary Pendergast
  – CDER Director Janet Woodcock
Political Issues Impacting Pharmaceutical Marketing

- Inquiries into Pharma Marketing Practices
  - Vioxx controversy & others
  - Driving litigation & scrutiny of marketing practices
  - At federal & state levels
  - Corporate Integrity Agreements

- Gifts to Physicians
  - Grassley: National Physician Payment list

- Greater Transparency
  - Lily, Merck, others disclosing physician payments

- Issues provide politicians with powerful PR
- New PhRMA Code, effective Jan. 1, 2009

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New Legal Cases

- Impact of Litigation
  - Lilly’s recent $62M settlement
  - Alleged improper marketing of Zyprexa
  - Sweeping mandates for:
    - Promotional practices
    - Dissemination of medical information
    - Funding of CME
    - Disclosure of clinical trials
  - Cephalon $425M settlement for “off-label” issues
  - Abbott Labs $28M drug pricing settlement with Texas
    - False reporting of drug prices to Medicaid
  - Wyeth Supreme Court case
    - Preemptive legislation
Medicare Changes

- MedPAC Medicare Payment Advisory Committee
  - Impacts Medicare & gov’t reg’s
  - Congress listens to recommendations
  - Tough new disclosure law
  - Report financial relationships w/physicians, institutions, medical schools, CME providers
  - National database on physician financial relationships
  - $100 threshold
  - Preempts state laws
Who’s Driving the Ship?

Government Committees
Senators Grassley & Kohl
Revising Version of
Physicians Payment Sunshine Act

Players for Universal Healthcare Coverage
Obama, Kennedy, Stark, Rangel, Baucus, Grassley, Dingell, Clinton (Chair of Health, Education, Labor?), Wyden (D-Ore.)

State Attorneys General Filling FDA Void

Marketing Practices Being Dictated by Litigation & Legislation
We now accept the fact that learning is a lifelong process of keeping abreast of change. And the most pressing task is to teach people how to learn.

Peter Drucker
CME Issues

- Under assault from various groups
  - Gov’t, medical associations, media (professional, consumer, blogs), health care institutions, physicians, others
- Perception being promoted…pharmaceutical funding “taints” Certified CME
- Funding introduces bias
- Certified CME lumped in with marketing
  - Lack of understanding between promotional education & Independent Certified CME
- Drive to eliminate pharmaceutical funding
- Congress & states focusing on CME activities

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CME Issues

- Independence of CME providers from companies being questioned
- Institutions banning pharmaceutical funding of Certified CME
- Societies banning gifts
  - Wisconsin Society, others
- States banning gifts to physicians (MA, etc.)
  - Honoraria lumped with payments to physicians
- IOM Report and recommendations
- Erosion of support for CME within Pharma
Government Focus on CME

☑ Baucus/Grassley Committee
  - Investigating use of CME to influence prescribing
    • Control program content & influence physicians
    • Increase gov’t. spending on drugs
  - Published report “Use of Educational Grants by Pharmaceutical Manufacturers”
  - Requested info from ACCME
  - ACCME response was vague & unclear
  - Continue to investigate CME

☑ FDA
  - Tom Abrams supportive
  - Will this help?
CME Confusion

• Confusion Around Education
  – No difference
  – Certified CME same as Non-Certified Education (within labeling)

• Confusion Around Terminology
  • Terms used incorrectly reinforces confusion
  • I.e. Grantor vs. Sponsor; Provider is accredited, activity is certified.
What Can Be Done?

- Reassert Certified CME as “independent activity”
  - Separate from within-label education
- Educational Challenges
  - In ‘97, FDA defined CME as “scientifically rigorous, balanced, independent and objective”
  - Educate key stakeholders on value of pharma funding
- Emphasize industry reforms
  - Current system is working
- Avoid governmental regulation of CME
Pfizer Policy Change

July 2, 2008
Effective immediately, Pfizer is eliminating all direct funding for physician continuing medical education (CME) programs provided by medical education and communication companies (MECCs)

Pfizer Press Release, July 2, 2009
We understand that even the appearance of conflicts in CME is damaging and we are determined to take actions that are in the best interests of patients and physicians.

Dr. Joseph M. Feczko, Chief Medical Officer, Pfizer Inc.
Industry Reaction

- Strong industry reaction against decision
- Position of CHC & Others
  “Honest but misguided attempt to blunt public criticism of commercial support”
- CHC Issued
  Statement on the Value of Independent Commercial Providers of CME
  Coalition Web Site: www.cohealthcom.org

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Problems with Decision

✓ Didn’t accomplish objective
✓ Commercial providers have highest compliancy rate
✓ No objective evidence supporting position
✓ Reduces competition
✓ Other providers less equipped to deal with transparency/compliance issues
✓ Pfizer *more* at risk, $ to direct customers (anti-kickback issues)
✓ Becoming a non-issue (only Zimmer)

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ACCME Changes
A **Commercial Interest** is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

Effective 8/07. Updated 2004 Definition

- Providers of clinical services directly to patients aren’t commercial interests (i.e. hospitals) & are therefore exempt
ACCME Changes

✓ Providers fix non-compliance more quickly
✓ Increased monitoring, surveillance & enforcement
✓ Increased accreditation fees
  - Added new category:
    • Evaluation of *non-accredited joint sponsors* to insure compliance ($4K)
    • No guidance on procedures
✓ New database of CME activities
  - Include $ amounts to presenters
Soliciting input & comments on *Three Key Areas*

1. End commercial funding of CME
2. Eliminate RFPs & communication from commercial supporters
3. Ban writers and faculty who work on promotional programs from CME

Being discussed at Nov. 20th, Board Meeting
• CHC Responded to all three areas

  *Plus*

✓ Reform how ACCME formulates policy
  • Greater transparency
  • Follow due process in enforcement against providers
  • Failure could have legal ramifications
1. Eliminate Communication
   - No evidence it introduced bias
   - Increases costs
   - Defining areas of interest doesn’t impact independence of content

2. End Commercial Funding
   - No evidence to support it
   - Replace 50% of funding?
   - Current Commercial Standards control bias
   - New proposed paradigm won’t work
   - Old practices long gone
3. Ban Writers & Faculty

- Eliminates top CME faculty
- Unenforceable
- Current standards control bias
- Delay dissemination of new findings
CHC Response Survey

- Complied Responses
- Press Release on Nov. 19, 2008
- Full report at: cohealthcom.org

**Issue # 1:**
- Communication from Commercial Interest
  - 104 responses
  - A. Communications such as RFP's
    - 79% disagreed, 21 % agreed
  - B. Communications on "internal criteria"
    - 67% disagreed, 33% agreed
Responses

• Issue # 2:
  – Ban Commercial Funding
    • 594 responses
    • 93% disagreed, 5% agreed, & 1% neutral

• Issue # 3:
  – Ban Writers & Faculty
    • 263 responses
    • 76% disagreed, 12% agreed, & 11% neutral
Publishing Challenges
Future of CME

- Decreased Pharma CME funding (?)
  - Tied to drug approvals
  - CME’s role in overall mix
- Joint sponsorships with academic partners
  - Impact on margins
  - Make-up of partnership…”Win-Win” situation
- Multiple companies funding programs
  - Increased difficulty to get funding
- New CME Educational Paradigm
  - Focus on outcomes, quality improvements, & professional practice gaps
  - Practice-based learning
CME Issues Facing Publishers

- New reg’s driving change & rules unclear
- MECCs as separate organizations
  - No commonality between groups within publishing company
- Old selling strategies out
- New Hurtles:
  - No access to CME decision makers (i.e. no capabilities pitches)
  - No feedback on non-approvals
  - Too many $ from company – your out
  - Commissioned sales people – your out
New Paradigm for Publishers

• Changes Needed
  – Support new business model
  – Impact non-advertising revenue
    • Supplements, classified ads, reprints, Web sites, conferences
• Leverage your relationship with physicians
• Integrate value of journals into CME equation
  – Journals most important source of information (ACNeilsen)
  – Reach physicians with new info (clinical trial data, new treatments)
  – Careful positioning
    • Maintain credibility & avoid compromising reputation
Separate CME Company

• Separate MECCs
  – *Changes in place by Aug. ’09*
  – Independent separate legal entity
  – Reporting into “holding company”
  – Holding company board’s status (?)
    • Who is in charge, can’t be the same
  – No overlap of staffs (exemptions?)
  – Personal conflicts of interest (editors, publishers, sales people)
Publishing Questions to ACCME
Questions to ACCME

- Questions pertinent to publishers
- Submitted on 11/6 to:
  - Dr. Murray Kopelow, Chief Executive ACCME
- Response:
  - From Dr. Murray Kopelow on 11/19
  - Letter available: bbednarz@visiblep.com
Questions to ACCME

• Question #1
  Although ACCME has defined that publishers are exempt, there is still confusion around personnel conflicts of interest.

• Answer:
  “Publishers” are not ‘exempt’ from any rules or regulations of ACCME.
Questions to ACCME

- Question #2
  An editor writes a non-CME supplement funded by a pharmaceutical company. Is that individual now considered to be involved with a "marketing" program that establishes a "relevant financial relationship?"

- Answer:
  Two issues involved here.

  #1 – **Personal Conflict of Interest** - Yes, based on the facts and circumstances provided, under current ACCME policy that person has a financial relationship with industry that could be relevant in CME, depending on the content of the piece being written and the scope of products of the pharmaceutical company.

  #2 – **Definition of a Commercial Interest**: Based on the facts and circumstances provided, the firm the Editor works for could be involved in marketing - depending on the content of the piece being written and the scope of products of the pharmaceutical company. When promotional products are being created for industry by a firm then the firm would be considered an ACCME-defined commercial interest.

  ACCME-defined commercial interests cannot control the content of accredited CME.
Questions to ACCME

• Question #3
Can that individual then work on a CME program (i.e. developing content)?

• Answer:
By virtue of being an ACCME-defined commercial interest the firm cannot control the content of accredited CME – so the Editor while working for the firm would not be controlling the content of accredited CME because the firm would not be producing accredited CME.

In CME activities outside the firm that person would have a relevant financial relationship that would need to be managed through SCS 2 and 6 of the ACCME Standards for Commercial SupportSM.
Questions to ACCME

• Question #4
  Can an ad space sales rep be involved in seeking funding for accredited CME supplements for journals?

• Answer:
  Yes
• Question #5

Many publishers do stand-alone conferences, non-accredited supplements, web sites sponsored by pharmaceutical companies. How do these other non-traditional publishing ventures impact both the publisher and its staff's status?

• Answer:

Participation in the development of promotional activities, or materials, by a firm for a commercial interest causes that firm to become an ACCME-defined commercial interest.
Questions to ACCME

• Question #6
How long does it take for ACCME to evaluate a corporate structure?

• Answer:
ACCME is preparing information on this for release.
Questions to ACCME

• Question #7
For a non-accredited provider seeking evaluation as a joint-sponsor, what is the process? Nothing has been released except the $4,000 evaluation fee.

• Answer:
ACCME is preparing information on this for release.
Questions to ACCME

• Question #8
Will an accredited provider be required to have a non-accredited joint-sponsor's structure approved by ACCME to work with them?

• Answer:
No
Questions to ACCME

• Question #8, Part B
  Can they do their own evaluation?
• Answer:
  Yes
Questions to ACCME

• Question #9

Are academic institutions (i.e. their non-accredited groups) exempted from any requirements in this area, even if they have financial relationships with a commercial interest?

• Answer:

The business of delivering healthcare does not cause an entity to become an ACCME-defined commercial interest.
Questions to ACCME

• Question #10

There is confusion around moving an accredited provider into a holding company to separate it. Can a board member of the holding company be an executive from one of the other companies doing business with commercial entities?

• Answer:

ACCME is preparing information on this for release.
Questions to ACCME

• Question #11

Publishers use physicians for research and advisory groups to get feedback on editorial and their business practices, much of which is designed to help them grow their revenue (i.e. get more income from commercial entities). If a publisher pays a clinician for consulting services, does he now have a "relevant financial interest" that can preclude him from working on accredited CME programs developed by the publisher?
Questions to ACCME

• Question #11 (Cont.)
Answer:
A financial relationship is only relevant in CME if that relationship is with a commercial interest. If the publisher is an ACCME-defined commercial interest then this relationship could be relevant in CME – depending on the CME content being controlled by that clinician.

The conflict of interest in CME created by relevant financial relationships are managed under SCS 2 and 6 of the ACCME Standards for Commercial Support™

Persons with relevant financial relationships are not precluded from working on accredited CME programs.
What Do You Do?

• Decisions
  – Drink the Kool Aid?
    • Move out of CME or shift to promotional ed
      – Brings new competition & new skill sets
  – Place you bet on both sides?
    • Promotional & CME
  – Take the plunge & make the long term commitment?
    • Revisit revenue projections & margins
  – Look for CME niches
    • Biotech, oncology, etc.
  – Expand customer base
    • Gov’t, insurers, hospital groups, etc.
What Do You Do?

• Decisions (cont.)
  – Invest in new learning continuums
    • *Same old* doesn’t work anymore
  – Adult learning models
    • Talk to adult learning experts
  – Shift sales strategy from relationship selling
  – Leverage assets of journals
  – Position to take advantage of Web 2.0
    • Sermo, others
• Next Steps
  – Make your decisions now
    • Transition plans, Teams, Positioning
  – Dec. 1st, new grants are being submitted
    • CME programs take time to execute
    • Budgets open up Jan. 1st
  – Restructuring completed by Aug. ‘09

• There will be funding for ’09 and beyond

• With change there are always opportunities
Thank You!

Questions & Answers?

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