NIH-116
1100-G-8a
WHCCAMP Committee Records

01 -- Access and Delivery P 21-22 Feb *2002*
02 -- Seattle Testimony and Talking Points *30-31 Oct 2002*
03 -- 1992 Break-out Session Transcript *1992*
04 -- Articles WNCCAMP *2001*
05 -- Report Definition CAM *2001*
06 -- Council for Responsible Nutrition *2001*
07 -- F[ederation of] S[tate] M[edical] B[oards] *2001*
08 -- Integrated Health Care Forum 10/31-11/3/01
09 -- Information Wellness Issue *Mar 2001*
10 -- Issue: Information Development and Dissemination, Wellness *Mar 2001*
11 -- Issue: Reimbursement *2001*
12 -- Research II Issue *May 2001*
13 -- WHCCAMP Merting October 4-6, 2001
14 -- Issues *Aug 2001*
15 -- Coordination of Research "A", G. Pollen *Sept-Oct 2001*
16 -- Information Development and Dissemination "B", C Axelrod *Aug-Oct 2001*
17 -- Access and Deliver "C", M. Chang *Aug 2001 - Jan 2002*
18 -- Coverage and Rimbursement "D", M. Millerq *Aug 2001*
19 -- Educating and Training "E", J. Kaczmarczyk *Aug - Oct 2001*
20 -- CAM Centralizing and Corodinating Efforts "F", J. Kaczmaczyk *Sept-Nov 2001*
21 -- Wellness "G", C. Axelrod *Aug - Sept 2001*
22 -- Definition and Principles "H", J. Swyers *2001*
23 -- Oklahoma *2001*
24 -- Rhode Island Legislation (proposed) *2001*
25 -- Treaury Dept 11/15/01
26 -- Comissioner Meeting *Jun 2001*
27 -- Secretary - WHCCAMP OS/DHHS Report 8/27/01
28 -- Should Government Cover Trasitional Indian Medicine *6-8 Sep 2001*
29 -- Sampson Wallace, MD *2000-2001*
30 -- CAM Principles *c. 2000*
31 -- Dietary Supplements *2001*
32 -- CAM Articles *2000-2001*

Groft, Stephen (NCCAM)

To: Commissioners E-mail
: WHCCAMP Staff
ubject: Access and delivery Section

We have heard from several commission members that Monday, March 4 from 2:15 -4:30 EST may be the best time to hold a telephone conference on the Revised Access and Delivery Section. Dr. Max Heirich, Maureen Miller, and Corinne Axelrod have been involved with this re-write. It will be sent out later this afternoon..

To connect to the Telephone Conference Please Call 1-877-717-7252 and then dial in the Participant code of 371886 at any time during the conference time schedule. It would be helpful after reading the document and if you have questions about the content, to send the comments out to the other Commission Members

Discussion of Access and Delivery Section

Dr. Max Heirich is preparing a revised version of this section. We hope to have a document available for your review by either late Thursday night or Friday morning. Max has been incorporating the December text, the revised Recommendations and Actions from last week, and the expanded information discussed at the meeting. **Please send me the times when you are available on Monday (preferable) or Tuesday (before noon EST if possible) to participate in a telephone conference to discuss this section**. If you have comments on the revised section and are willing to share them with the Commission prior to the teleconference, it would help to focus the discussion on potential problem areas or areas of disagreement.

Timeline for Report

Please note we plan to have all documents go into a copying stage by Tuesday night March 5 to prepare the Final Report to be delivered to the Secretary on March 7. We will send you a copy of the Final report via FedEx overnight delivery at the ıme time it is delivered to the Secretary. After the transmittal letters are signed by the Secretary we will complete the ublishing and Printing of the document for distribution by the Government Printing Office. The document will also be placed on our website that will be maintained by NCCAM.

If you have any questions on these issues, please give me a call on 301-435-6199

Steve Groft

MAX

A memorandum to Jim Gordon (and members of the White House Commission on Complementary and Alternative Medicine Policy):

Jim, I'm glad you found my earlier critique of the draft report helpful. You asked me to comment more specifically chapter by chapter. I have only a short time available this evening, but shall at least give it a try.

As noted earlier, the report has so many recommendations that one loses track of them. I think the Commission should prioritize the ones they most want to emphasize. Perhaps each of us should mark recommendations and action steps that seem the most critical to keep in the report. This memorandum will not attempt that. Instead it will share my overall reactions, chapter by chapter...

As you will see, I will be suggesting a different strategy for presenting the content of chapters four and six. My recommendations re: the kind of policy stance most likely to bring wide agreement with these chapters grows out of my own experience beginning in 1993. For four years I chaired a National Task Force of seventeen organizations that were attempting to write certification, training and performance guidelines for workplace health promotion. We faced similar issues to those confronting CAM policy advisers now, and my own first drafts were in many ways similar to the stance I see in WHC chapter drafts four and six. I learned the hard way that this approach can lose important support, and can splinter earlier effective coalitions. We regrouped, chose a slightly different strategy, and were eventually able to get national endorsement from a portion of the original coalition, after we had adopted an approach closer to the one I propose here. That experience colors my response to these chapters and the advice about that that I offer.

I hope these chapter-by-chapter summaries, taken from the notes I wrote in the margins as I read the draft, are useful. Best wishes to all, and congratulations on the progress made thus far. I think this can shape into a document that can have some real impact.

Now for the notes:

A missing ingredient that is much needed: An Executive Summary of no more than three to five pages.

Introduction and Chapter Two: The writing works fairly well, but the whole document will have more impact if it gets set in the context of larger public policy issues for which CAM developments could be relevant. (As discussed in my earlier note.) This could come either in the Introduction or in Chapter Two at the end. (Discussions in each later chapter then could point to their relevance for the policy issues identified early on in the Report.)

Chapter Three: This is a strong chapter. As I sketched out its argument and recommendation in my notes I wrote five comments in the margins:
"Recommendation 1, that federal agencies should receive increased funding for clinical, basic and health service CAM research, ignores what tax cuts have done to federal budgets. If this recommendation is taken seriously, it is likely to mean less funding for other activities. Given political pressures to protect current budget allocations, how can we make this more than a platitude? Should we specify how this might be done, in the present budgeting context, or simply leave it as a generalized wish?"

"Recommendation 3, action step 3.1: HOW should the Federal government stimulate private investment in research on CAM modalities and approaches designed to improve self-care and wellness behaviors? An excellent idea, but too vague."

Under Research Training and Infra-structure, just before Recommendation #8, I noted that "NCCAM seems to be planning to discontinue funding of CAM research centers and to be returning to simple funding of individual research or education grants. This will have implications for how CAM researchers collaborate and interact, and for the range of CAM-related activities they can undertake. Does the WHC want to address this, or not? Most of #8 assumes that the Centers will continue."

"Is it also important to strengthen the ability to study CAM when used outside conventional medical clinical settings for research?"

** **"Does 9.1 recommend the right agencies?** In my earlier testimony I had recommended giving NIH and AHRQ joint responsibility for conducting and updating systematic reviews of peer-reviewed research literature on safety, efficacy, and costs of CAM practices and products. Washington insiders took me aside and suggested that the National Library of Medicine might be better positioned to do this and might be freer from political pressures to shape reviews. They suggested that AHQR has received such heavy criticism that it is very cautious about what it does. Is this good advice?"

Chapter Four: Education and Training of CAM and Conventional Practitioners I had more trouble with this chapter, because I thought some of the recommended action steps did not recognize the range of useful CAM training programs that now exist. Some work well as they are, and might be hampered by trying to force them into the "alternative medical school" model that works well for chiropractery and naturopathy. Specifically,

1.6: Should CAM training programs be made more uniform? What will be gained? What will be lost?

1.7: Are we trying to convert all CAM practice to a variation on the medical model? For what kinds of training programs are common backgrounds in science, physiology, etc., as understood in western medicine needed? Might such training be superfluous, or hamper the kind of training being given in some modalities?

1.8: A good suggestion. Why not try it first with Chiropractic colleges and Colleges of Naturopathy?

1.9: An interesting idea. Voluntary or mandatory? And what content?

Chapter Five: CAM Information Development and Dissemination: An important topic. Some of the content of this chapter repeats what is elsewhere. We should decide what belongs where....

The first recommendation is too vague, and action step 1.2 seems too global. How would we accomplish that goal?

Chapter Six: Access to and Delivery of CAM: This chapter struck me as being the most problematic chapter in the report. It advocates a particular solution to problems of access and delivery, rather than laying out the problems that are under discussion, the range of solutions that are in contention, currently, and suggesting advantages and disadvantages of the various ways in which these issues currently are addressed. It totally ignores policy positions such as that adopted by the State of Minnesota, or the kinds of issues being looked at in California. If the chapter followed an alternate strategic approach, which I would recommend, it could acknowledge the variety of legitimate concerns that need to be addressed, the implications various solutions will have for the future, and pose a series of questions that need to be addressed when deciding these issues. I think it is important for this to be done. If the chapter does not take this kind of "balanced approach" it will generate contention and distrust, and the Commission might get charged with attempting to railroad solutions that benefit one CAM interest group at the expense of others. Some groups within CAM will see the present chapter as offering a version of the "AMA strategy" that was used in the early 20th century, when many of the traditions now seeking a legitimate role in health care were forced to the sidelines through political means. I think it is important to avoid that kind of labeling of the Commission's work.

More specific comments on chapter six:
Recommendation #1 will take the Commission into a highly political and politicized arena. I think it is unrealistic to assume that all states will follow a uniform set of recommendations, or that those who do accept such recommendations will apply them uniformly.

Instead, why not emphasize that regulatory reform is needed, and perhaps discuss how different types of regulatory reform will affect present CAM practice and its relation to conventional medicine?

I have not read the Federation of State Medical Boards' model guidelines to regular "unconventional medical practice", but I wondered whether State Medical Boards' concerns provide an appropriate model for us... E.g., One of the unresolved struggles within CAM concerns the extent to which MDs will dominate decision-making and practice for CAM uses. Without further explanation, this proposal sounds like it might be "asking foxes to guard the henhouse". Perhaps that's unfair. If p 8 spelled out what their model guidelines look like, readers could judge for themselves. The first paragraph of p 9 might be all right.

Recommendation #2 and its action steps, if adopted, could set in motion a set of dynamics that would change the historic character of much of CAM. Thus this recommendation and the way it is discussed in this draft could set off a hue and cry within the CAM constituency that could dissipate support for the Commission and its work. The chapter and its recommendations, as currently drafted, runs the risk of generating hostile reactions that could dominate discussion of the entire report.

(I am not suggesting that the Commission needs to avoid all controversy. Rather, the FIRST White House Commission of CAM Policy needs to set a tone for future discussion of contentious issues.)

I think the subject matter of this chapter would be better addressed by spelling out the issues that need to be considered when adopting policy in this area: e.g., protection of the public, maintaining free competition in the provision of CAM services, protection and preservation of CAM styles and traditions of working, freedom to choose health workers in whom one has confidence, etc. (I haven't thought out these parameters very well, but they at least get one started.) Then one can discuss the different solutions that are being advocated, and their advantages and disadvantages for each of the concerns you have identified. One might propose careful observation of the experiments currently underway re: regulation in different states, and propose a series of questions to ask about their effects over time. The answers to these questions, then could guide policy groups in the future who try to address these issues....

Chapter Seven: Coverage and Reimbursement is a strong chapter, overall. I suggest that the Commission should decide whether it is advocating "cost-benefit" studies or "cost effectiveness" studies. These have rather different implications for what one analyzes and how one draws conclusions. (I suspect you want to recommend "cost-benefit" analysis, which normally utilizes a much less complex set of variables and shorter time spans.)

On p 5, lines 14-23 strike me as making a somewhat naïve argument, that might be dismissed by health policy experts. "interventions known to be safe and beneficial should be reviewed and given consideration for coverage under health benefit programs (whether conventional medicine or CAM). I agree with the principle, but this recommendation ignores how benefits payments actually work. If something is an accepted procedure for reimbursement, it gets reimbursed **regardless of what else also is being done.** Thus adding CAM procedures to the approved list does nothing to discourage continuation of other, more expensive and possibly less effective treatments. Every time you add something to the approved benefits list you increase the cost for care-- This means that in order for such a recommendation to be taken seriously, and implemented, we will need to suggest a way to do this that leads to use of the cheapest and most effective strategies for dealing with a health problem, rather than a proliferation of health care costs.

"Equitable and impartial consideration of safe, effective CAM interventions—Coverage policies and processes need to indicate how to do this without escalating total health care spending.

What do we mean by "medically necessary" on pp 17-18?

Under discussion of the Tax Code, what about suggesting "performance-based" tax credits for CAM and prevention programs that lower health risks, during the time period before lowered disease care costs will compensate for the additional costs incurred in using these strategies? (action step 2.6 also)

Recommendation #2 might need an additional clause, such as this: "and develop reimbursement strategies that will encourage use of those services that are most effective for the least cost"

Chapter Eight: CAM in Wellness and Health Promotion has some excellent proposals, but the "voice" of the chapter needs work in order for it read persuasively.

Recommendation #1 probably needs rewording. We seem to advocate use of CAM and then ask for research to see if it works.... The last paragraph on p 8 seems to hand over responsibility for CAM promotion to groups unlikely to make this a high priority (e.g. Institute of Medicine and Public Health Association).

Recommendation # 2 and action steps 2.1 and 2.2 strike me as excellent.

The sidebar for workplace health promotion is excellent

Recommendation #3, action step 3.2 needs rewording. And here might be a place to advocate performance-based tax incentives....

P 13 "Federal programs should serve as a model..." How? And how relate this to cost-benefit concerns? Recommendation 4, action step 4-1 strikes me as too vague. It lists several agencies that should incorporate safe and effective CAM practices into their services, but does not suggest what or how.

4.3 struck me as particularly promising.

I also really liked 4.5, but wanted a bit more specificity about how this might be done.

Chapter Nine: Coordinating Federal CAM Efforts has some intriguing suggestions.

I would recommend changing some of the language used to describe the Advisory Council: "would bring together the various stake holders in CAM to develop an agenda that reflects public opinion" This language can be read as meaning that people with vested interests and money in the CAM community will shape public opinion. Some word other than "stake holders" might serve better.

I think the recommendation sets too limited tasks for this office: The office should do more than "coordinate and facilitate the **integration** of safe and effective complementary and alternative health care practices **into the nation's health care system**". It should also help preserve the independence of alternative medicine, etc., etc.

This chapter will be appealing IF chapters four and six have more balanced discussion of the issues they address, and IF chapter seven can address inclusion of reimbursement in a context that does not threaten major escalation of health care costs. If those problems are not addressed, various public interests are likely to resist creating a federal agency that could play a role they would consider as detrimental to the public's interest, or that might become a vehicle for interest-group domination of decision making.

This chapter provides a potentially attractive solution to how to move forward. This should not be the final ending note, however. **There needs to be some kind of summary statement that provides a powerful emotional appeal for proceeding with the agenda laid out in this report.**

PALLADIAN PARTNERS, INC.

1010 Wayne Avenue
Suite 1200
Silver Spring, Maryland
20910
301-650-8660
301-650-8676 (Fax)

February 20, 2002

Max Heirich, Ph.D.
University of Michigan
Lansing, MI

Re: Consulting Agreement with Palladian Partners, Inc., under Prime Contract No. N02-C0-14214, White House Commission on Complementary and Alternative Medicine Support

Dear Dr. Heirich:

I am pleased that you will be working with Palladian Partners, Inc., as a consultant to provide science writing services to the White House Commission on Complementary and Alternative Medicine. I look forward to a mutually rewarding relationship. This letter sets forth our agreement regarding your provision of professional services to Palladian Partners, Inc. ("Palladian" or "the Company") in connection with our contract referenced above with the National Cancer Institute. Such services shall be furnished during the term of this agreement in accordance with assignments established by Cate Timmerman (Palladian Co-President), myself, or our designate. The agreement is valid from February 20 until March 7, 2002 and can be extended as needed by mutual written consent. The agreement is subject to the termination provisions specified elsewhere in this agreement.

Statement of Work

The White House Commission on Complementary and Alternative Medicine is charged with producing a report from the Commission by March 7, 2002. Your assistance is requested to assist in the content editing for the sections concerning access and delivery of CAM services and products, and the training and education of CAM and conventional practitioners. The product will be the revised 2 sections of the report as listed above.

Terms of Payment

For your services, Palladian agrees to pay you a flat fee of $2000. We estimate that the job will take 40 hours. This agreement authorizes a flat payment of $2000 to perform the services specified above in the Statement of Work. In addition, we will reimburse you for up to 5 days of meals and incidental expenses at $46 per day or a total of $230.

Payment for services will be made within 30 days of submission of a properly completed invoice and progress report, and providing that all work and deliverables described in the invoice have been satisfactorily performed and/or completed. Work/deliverables are deemed satisfactory when they have been accepted and approved by our Government client and by a Palladian corporate officer or her designate. Guidelines for the preparation of invoices and progress reports are specified elsewhere in this agreement.

Expenses

In addition to the fee for services, Palladian will reimburse the following expenses:

- M&IE of $46 per day for up to 5 days.

Invoices

Your invoice shall be prepared and submitted to Palladian within 30 days following the last day of work under this assignment. Your invoice shall provide the your name, the Palladian internal reference number 7410-08, the address to which payment should be sent, and your Social Security Number or Federal Business Tax ID Number. Invoices shall be accompanied by a brief, bulleted report that includes a description of tasks performed, problems encountered and suggestions for their resolution, and number of hours and other costs (as authorized under "Expenses") expended. Palladian values your expertise and welcomes your suggestions for the improvement of the process used to cover and report on the PRG, so please feel free to include such suggestions in your report.

Property Rights and Confidentiality Issues

All data, reports, proposals, and other information generated as a result of your services under this agreement will become the sole property of Palladian and shall not be disclosed by you (in original or copy form) during the term of this agreement or thereafter except to the extent specifically authorized by the Company. Data that is deemed public information under the terms of Palladian's prime contracts shall not be subject to the restrictions of this paragraph.

During the term of this agreement and thereafter, you shall not disclose to any party business, financial, or other information concerning the Company, including but not limited to information concerning its business and/or marketing methods and operations, its customers' information, information about its subcontractors or from its subcontractors, its financial condition, or its personnel excepting, however, such information as is generally available to the public, or authorized for dissemination by you as part of your responsibilities under this agreement.

This agreement may be terminated at the Company's sole option if, during its term you become unable to work for one or more periods in excess of ninety (90) days or in the event of your death. This agreement may also be terminated at any time without notice in the event of a breach of its terms. In addition, either party to this agreement may terminate it as of the end of any calendar month during the term hereof by giving the other party no less than thirty (30) days advance written notice.

This agreement does not preclude your providing services or representation to other clients as long as the services do not conflict with the specific services being provided to the National Institutes of Health under the terms of this agreement. Any questions concerning possible conflicts of interest should be brought to Palladian's attention and a mutually acceptable written clearance obtained prior to your representation of any potentially competitive or conflicting client.

As a consultant to Palladian, you are not authorized to represent the Company except in the performance of your duties as defined by Ms. Cate Timmerman or myself or our designate. In no event shall you execute any document on behalf of the Company, or represent or suggest to any third party that you are authorized to bind the Company to any agreement or commitment.

It is understood that as a consultant you are not considered an employee of the Company. Palladian assumes no liability for the withholding or payment of any statutory taxes based on your consulting fees. You agree to hold the Company harmless for any and all losses, claims, damages, expenses, or liabilities that may be threatened against or incurred by the company, or any of its officer, directors, or employees, as a result of the Company's failure to withhold or make such payments for any of your negligent acts, omissions, or errors which may occur while you are providing services to the Company under the terms of this agreement. Not later than January 31 of the year following each calendar year in which you served as a consultant to Palladian, Palladian will mail you a Form 1099 which will include all fees paid to you by Palladian.

Finally, you agree that your services hereunder shall be in accordance with all applicable Federal, State, and Local laws, including the Procurement Integrity Provisions of the Office of Federal Procurement Policy Act Amendments of 1988 (the "Act"). Under the Act, if you are involved in supporting the Company's participation in a government procurement, you are specifically prohibited from discussing the future employment of a procurement official, offering to give or giving anything of value to a procurement official (including meals or entertainment), or soliciting or obtaining any proprietary or source selection information from the government or third parties from the time of the initiation of the procurement. If you become involved in supporting the Company's participation in a government procurement, you will be required to certify in writing that you will comply with the provisions of the Act.

The parties agree that the terms and conditions of the agreement contained herein shall be subject to and interpreted under the laws of the State of Maryland.

If the foregoing terms meet with your approval, please indicate your acceptance by executing and returning the enclosed copy of this letter to the undersigned.

Sincerely,

By: _____

Marion Millhouse Barker Date
Co-President

By: _____

Max Heirich, Ph.D. Date

Kaczmarczyk, Joseph (NCCAM)

From: Groft, Stephen (NCCAM)
Sent: Wednesday, February 20, 2002 5:01 PM
To: Kaczmarczyk, Joseph (NCCAM)
Subject: FW: URGENT: Concerning: N02-CO-14214-- Request for change to Advanced Understandings

Importance: High

Max Heirich for WHCCAMP consul...

Joe, Can you print this out plus the attachment? I am having difficulty printing the documents.

Steve

-----Original Message-----
From: Irving, Robin (NCI)
Sent: Wednesday, February 20, 2002 4:39 PM
To: Groft, Stephen (NCCAM)
Cc: Irving, Robin (NCI)
Subject: FW: URGENT: Concerning: N02-CO-14214-- Request for change to Advanced Understandings
Importance: High

Steve,

Palladian is requesting to utilize a consultant under your task order.

Please provide your approval/disapproval with this request.

Thank you.

Robin

Robin M. Irving
Contracting Officer
National Cancer Institute
Temporary Address as of 1/18/02: EPN/Suite 313
Telephone: 301/435-3777
Facsimile: 301/480-0241
e-mail: ri23j@nih.gov

-----Original Message-----
From: Holly Dodge [mailto:hdodge@iml104.datareturn.com]
Sent: Wednesday, February 20, 2002 4:35 PM
To: Robin Irving (E-mail)
Cc: Groft, Stephen (NCCAM); Marion Millhouse Barker (E-mail); Jean Kazares (E-mail)
Subject: URGENT: Concerning: N02-CO-14214-- Request for change to Advanced Understandings

Robin,

Palladian supports the WHCCAMP under contract N02-CO-14214. We have been asked by Dr. Stephen Groft, the TOM, to provide a content expert in the areas of (1) access and delivery of CAM services and products, and (2) training and education of CAM and conventional practicianers who will provide content editing for two of the sections of the report. Dr. Groft has identified Dr. Max Heirich of the University of Michigan as the expert he would like to use for this task. We would like permission to pay Dr. Heirich a flat fee of $2000 for his expert content editing services as well as reimburse him for up to 5 days of M&IE expenses at $46 per day. It is estimated that the job will take approximately 40 hours.

The need for this approval is immediate. The last meeting of the Commission is starting tomorrow, February 21st. Dr. Heirich's services will be needed immediately following the meeting. He will remain in town for an additional week, resulting in the additional M&IE expenses. He will be staying at a private home.

The addition of this expense will not cause a cost over run.

Please call me if you have any questions. I am attaching a consulting agreement for your review.

Note: Dr. Groft is in the office today but will be at the meeting tomorrow and Friday. I will be in the office on Thursday but out on Friday. Marion Millhouse Barker will be in the office on Friday.

thank you.

Holly Dodge
Palladian Partners, Inc.
1010 Wayne Avenue, Suite 1200
Silver Spring, MD 20910
Phone: (301) 650-8660 ext. 111
Fax: (301) 650-8676

Joe Fierro
(212) 746-6700
Prompt 16310
212-746-1347

Michele ✓ (we are changing)
Joe Rutherford
IG called
202-619-2990.
Wanted copy of report I told him we could give him a copy ē 2/14
See me & we can discuss before calling back, Steve

• Supply and Demand
(1) Access to Medical Treatment Act

Interim Repair
(2) FSMB
(3) Minnesota

Value of CAM or nonregulated

(4) Washington
Model

Ocean

1-212-746-6700
Pioneer · 16310

• Barriers to Access to CAM
• Where CAM is + is not relevant
• Regulation / Non-Regulation
• What needs to be Studied
• Characteristics of the Health Care System
• Costs of Products
• Disparities in Health Care (HP 2010 Goals)
• Uninsured

Portability of Practitioner

Distributive Justice Clause — Other Parts of Health System
Limited Resources (2010)
Maximize
Lee Anne Callahan -
Freeze → chronic illness - lost of organ Efficiency
Can be reversed
Potential Economic For
Micro to Macro
$ B - 3 Systems Levels of (SF)
Pract. ↔ Hospital - System
Rev Act → Health Center
- Current is Emphasis on Practitioner
- Impact on Pra
- need Studies to Evaluate MN, WA laws
Range of Options

States are confronted ē an array of decision -

A. and B. Hall — at Rochester

Offer Assistance to States to Evaluate

FSMB — assist Tracking

Conference on

Now that we have given the license

Institutional

Accreditation standards

- Tightened or modified
- Intended help us

Hospitals ⇒ Cardiology — Carl Reb

Org might assist members in adopting

- Host of issues at hospital, Residents + Medicine

enter the

Credentialing/accreditation

Liability

Introduction of Robots

NCQA/JCAHO — Specific

Demonstrate Projects — Evaluate

- Continuous Quality Improvement (CQI)
- Surveyor Training Program

Community Health Centers

Demonstration

Integration — How Hospice does implemented these practices

(Dan Schumacher) Dec 2000

(How they integrate, Adjust therapy

① Practitioner
② Institutions Burgery CAM...
Hospital + Free Standing Clinic
③ Integrated System

Chaplains integrated
④ Delivery System Level — Buy System ④ ?
- Kind of model - Independence of thought - Desire Choice
* Integration - ↔ at Practitioner Level
* Parallel Model How Integration Occurs
* Collaboration (workable Model)
④ Workable model
- Health Service Research - What things will do

Socioeconomic Health/Economic Disparities
Navajo Nation are there CAM services that might be useful in CA Community Health Centers

(initials)

(Chang, Draft 4) January 9, 2002 (4:39pm)

Draft Discussion Document for December 6-7, 2001 Meeting
TOPIC: Access and Delivery of CAM
Facilitators: Joseph Fins, Linnea Larson
Staff Lead: Michele Chang

Introduction:

Access to health care has been described as a multi-dimensional concept that balances factors such as human resources, financing, transportation, freedom of choice, public education, quality, and allocation of technology (1). There are other factors that contribute to the quantity and quality of care received by a population, and determine the nature and extent of access to care in the United States; many of these apply particularly to the access and availability of complementary and alternative medicine (CAM) in the United States. Among those considered by the Commission are the growth and influence of: chronic illness and their impact on disability and death; the availability of information, especially through the Internet; disparities in income and its impact on health; consumer involvement in their personal health care and consumer interest in CAM. In fact, the rise in CAM use is most often characterized as a "consumer-based movement," reflecting broader concerns by the American public to re-examine and revitalize how health care currently is delivered and received.

Many of the reasons influencing consumers' decisions to try unconventional approaches are the same as those stimulating change in the current health care system. Foremost among these include pressures to reduce the costs of health care, which are expected to reach the $2.1 trillion mark by 2007. CAM, especially those approaches that attempt to induce self-healing, offers opportunities to reduce the escalating costs of health care. For example, mind-body therapies, such as meditation and biofeedback, that are used to control chronic pain and stress have been estimated to eliminate 37 percent of doctor visits, potentially saving the country some $54 billion a year (2, 3).

Many of the holistic philosophies and traditions emphasized in CAM approaches focus on a prevention (rather than treatment) orientation, which tends to promote self-healing and rely on more healthy lifestyle and self-care changes, beginning early in life. This has potentially significant implications for both preventing and addressing chronic conditions, which are now the leading cause of illness, disability, and death in the United States, affecting nearly half of the U.S. population and accounting for the majority of health care expenditures. (4) Many patients who seek out CAM for chronic conditions suffer from syndromes (back pain, fibromyalgia, arthritis) for which a specific underlying cause of disease is unknown or cannot be stopped. For many of these patients, conventional medical approaches may not work well. The IOM's 2001 report, *Crossing the Quality Chasm*, reported than more than 40 percent of those who suffer from chronic conditions have more than one such condition, suggesting that coordinated care, including the supportive mechanisms that often characterize CAM approaches, may be particularly effective. For example, relaxation therapies, acupuncture and herbal medicine, all of which share an emphasis on spiritual health and mind-body links, have demonstrated effectiveness with chronic disease patients. (3)

Another influence on the use of CAM and on the health care system is the accessibility of health information through the Internet and other communication technologies. While the impact and opportunity presented by the rapid evolution of health information technology is addressed elsewhere in this report, it is important to acknowledge its influence on consumer demand for CAM products and services. As of 1997, 35 percent of US households owned a computer, approximately 25 million Americans used the Internet weekly, and some websites provide information on more than three hundred different diseases. (5) A growing number of patients are equipping themselves with more, often quite detailed, information, not only about conventional treatments to their ailments, but about more unorthodox approaches as well. The ready availability of consumer information about such topics, whether accurate or not, and the ability to experience diverse cultures around the world have had a significant impact on the accelerated consumer movement toward CAM.

Patients are increasingly more interested in being active participants in their health care decisions. This participation includes evaluating information about treatment options, accessing products and practices that enable them to explore those options, and engaging in activities that may help them remain healthy through all stages of life. (6) Consumers' expectations are expanding the definition of health care from beyond treatment of illness to include prevention and wellness. A 1998 study indicated that those who use CAM do so because they find such approaches

to be congruent with their own values, beliefs and philosophical orientations toward health and life. (7) As consumers become more empowered users of health care, whether to address chronic health conditions, or in an effort to increase overall wellness, their expectations for high quality, affordable, effective and safe health care from a range of providers and competent practitioners, both CAM and allopathic, also will increase.

Another factor influencing changes in the current health care system is the growing disparity of health indicators among U.S. populations. Research has found that income disparity between the rich and poor is the most powerful predictor of a nation's health as measured by life expectancy. (8) CAM services that are most commonly used by the general public, such as chiropractic, acupuncture, and massage therapy, are delivered primarily through non-reimburseable mechanisms, paid for out-of-pocket by the majority of its users. However, among immigrant populations, another type of CAM exists, comprised primarily of culturally-based home remedies and provided by members of a community with little or no formal training in health care, whether conventional or CAM in orientation. Such care often is more readily available than conventional care in many immigrant communities, where patients may depend upon them first, especially for seemingly minor disorders or for chronic conditions for which there is little known treatment in conventional medicine. (9)

In 2000, the Kaiser Commission on Medicaid and the Uninsured (9) reported that the most common barrier to care cited by immigrants was cost, followed by language. A supplement to the 2001 Surgeon General's Report on Mental Illness (10) also underscored the barriers for adequate health services experienced by racial and ethnic minorities collectively. The report cited a constellation of barriers, many of which operate for all Americans: cost, fragmentation of services, and lack of availability of services. In the absence of affordable care, many immigrants, especially the uninsured, look to culturally-based home remedies to treat illness and disease.(9)

In the context of this more overall lack of access to care, adequate and appropriate access and delivery of CAM by qualified practitioners also possibly is most limited among those who can least afford to pay out-of-pocket. The cost of maintaining public health centers (county hospitals, public health centers), through which such care might be delivered to such populations, continues to increase. CAM proponents argue that many of the patients waiting hours for treatment are suffering from problems that might be appropriately treated by qualified CAM practitioners (acupuncture, homeopathy, bodywork). Many of the indigent and homeless that comprise the patient population at publicly run health centers, clinics and hospitals also present a diverse range of health challenges, including current or former alcohol and drug addiction problems. The use of appropriate CAM approaches by Federally funded programs has been shown to play a significant and cost-effective role in the recovery of these patients.

The consumer movement toward increased CAM use is only one of the forces through which health care is changing. Access to CAM will be subjected to the same demands placed on access to conventional health care: more efficient and effective use of available resources. To accomplish resource management goals will require, at least, identifying clearly intended outcomes for care, using evidenced-based best practices to achieve measurable goals, and improving overall systems of care delivery.

The Commission believes that CAM practitioners and the health care institutions delivering such care also should be properly regulated and accountable to the public. This chapter addresses the respective regulatory roles of Federal and State governments and those regulatory issues attendant to the delivery of CAM services and oversight of the broad spectrum of institutions through which CAM services are delivered; lays out the challenges in delivering CAM services; provides an overview of current CAM service delivery models within the range of health care systems from hospitals to individual private practice, and provides recommendations regarding each of these major issues.

Issue 1: The Effects of Regulation on Access

Ideally, health care access would define an ability to choose from a wide menu of conventional and CAM practices and products, with assurances that all practitioners are qualified and products are safe and efficacious. States regulate health care practitioners by helping to assure quality and accountability of professions and providing a process for professional conduct review and disciplinary action. However, there is much variability State-by-State in regulatory approaches to licensure and scope of practice of CAM practitioners. For example, chiropractors are licensed in all States, while acupuncturists, massage therapists, and naturopathic physicians are licensed in 40, 30,

and 11 States, respectively. These variations impact access to and delivery of CAM by limiting practitioners' ability to practice lawfully and obtain malpractice insurance.

Most practitioners, whether CAM or conventional, will practice where they have the legal authority to do so. For naturopaths and practitioners of oriental medicine, the most influential factor in distribution appears to be licensure; these clinicians are concentrated in Northeastern and Northwestern States, where the greatest professional opportunities exist. Similar observations have been made about specialty providers and nurse practitioners or physician assistants, whose number per capita in each State correlates with the professional prerogatives granted to them. (11) The variability of regulation between States for any given CAM practice, the role of regulatory bodies, and the ambivalence of CAM practitioners towards regulation all contribute to the lack of definition and clarity on this issue.

In general, States that have fewer CAM providers also appear to have the lowest numbers of physicians and physician assistants per capita, as well. A better understanding of CAM utilization in such areas is needed to determine what can be done to improve access to CAM within the proper context of other public health and medical needs. Additionally, more information is needed on what constitutes "appropriate access" to CAM to better facilitate the mobility of qualified CAM practitioners within the health care system, and in collaboration with current services.

Early studies of licensure sponsored by the U.S. Department of Labor focused on licensure's impact on workforce availability, and the cost and quality of services. (12) The principle findings challenged the conventional wisdom that occupational regulation results in higher service quality and benefits consumers beyond the increased cost that licensure causes. These reports recommended that regulation should evaluate carefully the need for new licensed occupations, assure the continuing competence of licensees and greater equity in the discipline of licensed practitioners, improve public representation on licensing boards, remove artificial barriers to interstate mobility, and remove the control of educational functions from boards.

In 1990, the Federal Trade Commission (FTC) reported that occupational licensing had the capacity to "protect the public's health and safety by increasing the quality of professionals' services through mandatory entry requirements, such as education." (13) The report also found that many occupational licensing restrictions often did not accomplish these goals, but rather had the effect of increasing prices and imposing costs on the consumers. Despite this, the FTC concluded that the "costs of licensing did not always exceed the benefits to consumers," and recommended that such cost-to-benefits ratios should figure into the consideration of any licensing proposal.

In view of these concerns about the adequacy of current regulatory systems, and in a effort to return the focus of such oversight to promote the public health, the Pew Charitable Trusts established the Pew Health Professions Commission in 1989. Recognizing that health care workforce reform would necessitate regulatory reform, the Pew Commission assembled the Taskforce on Health Care Workforce Regulation to identify and explore how regulation protects the public's health and to propose new approaches to health care workforce regulation to better serve the public's interest. (14)

In 1995, the Taskforce published 10 recommendations for regulatory reform and offered policy options under each recommendation as a way of stimulating debate and discussion by States. The 10 recommendations made by the Taskforce are as follows:

PEW Taskforce Commission Recommendations for Regulation of the Health Care Workforce

1. States should use standardized and understandable language for health professions regulation and its functions to clearly describe them for consumers, provider organizations, businesses, and the professions.
2. States should standardize entry-to-practice requirements and limit them to competence assessments for health professions to facilitate the physical and professional mobility of the health professions.
3. States should base practice acts on demonstrated initial and continuing competence. This process

must allow and expect different professions to share overlapping scopes of practice. States should explore pathways to allow all professionals to provide services to the full extent of their current knowledge, training, experience and skills.

4. States should redesign health professional boards and their functions to reflect the interdisciplinary and public accountability demands of the changing health care delivery system.

5. Boards should educate consumers to assist them in obtaining the information necessary to make decision about practitioners and to improve the boards's public accountability.

6. Boards should cooperate with other public and private organizations in collecting data on regulated health professions to support effective workforce planning.

7. States should require each board to develop, implement and evaluate continuing competency requirements to assure the continuing competence of regulated health care professionals.

8. States should maintain a fair, cost-effective and uniform disciplinary process to exclude incompetent practitioners to protect and promote the public's health.

9. States should develop evaluation tools that assess the objectives, successes and shortcomings of their regulatory systems and bodies to best protect and promote the public's health.

10. States should understand the links, overlaps and conflicts between their health care workforce regulatory systems and other systems which affect the education, regulation and practice of health care practitioners and work to develop partnerships to streamline regulatory structures and processes.

The recommendations made by the Pew Commission, which focused primarily on the conventional health care workforce, stimulated significant response from that community and subsequently fostered a high level of regulatory activity and policy discussions that were captured in a 1998 follow up report by the Pew Commission. (15) Many of these recommendations and subsequent discussions are equally appropriate to the regulation of CAM practitioners.

For example, the PEW Commission's recommendation that "standardized and understandable language for health professions regulation and its functions" be used by States to most clearly describe them for consumers, provider organizations, businesses, and the professions applies directly to regulatory schemas for CAM, for many of the same reasons. "Licensure" of a given CAM modality in some States may consist of strict educational and credentialing requirements; in others, the term may simply involve payment of a fee. Licensure may define specific scopes of practice, or may not.

The Commission reviewed and found the mechanisms used by most States to regulate health care practices as a reasonable format to apply to CAM, provided they are well and uniformly defined and applied by regulatory bodies. The primary mechanisms are discussed below.

Mandatory Licensure prohibits the practice of a profession without a license. The Commission views such a schema as creating a legal distinction that should also denote a higher degree of professional evolution of the modality or discipline, including consensus within the profession, itself, as to standards of education, training and practice, and the ability to self-regulate. To ensure that mandatory licensure emphasizes public protection rather than economic or market protection of licensees from untrained/unlicensed competitors, the Commission also suggests that this most rigorous of regulatory schemas be reserved for those disciplines that involve, not only the most complex and sophisticated body of knowledge and skills, but which, commensurately, may offer the greatest potential of risk to the client. Therefore, mandatory licensing may be most appropriately applied to naturopathic physicians, or chiropractors.

Title Licensure permits anyone to practice the art, but only those granted a license may use the designated title. Such licensure requires a certain demonstrable level of skill or training for those who would claim a particular occupational title. For example, any practitioner may incorporate massage into their approach, but only a credentialed massage therapist may use the title or describe his or her services as "massage therapy." The Commission recognizes the value of such a schema: While it may help consumers to distinguish between

practitioners who have specialized in a particular skill, and those who simply demonstrate a more generic knowledge or understanding; and it also allows a broader use of intrinsically supportive, arguably non-intrusive healing approaches by many practitioners and professionals. This is consistent with two of the Pew Commission recommendation, i.e., that "States... facilitate the physical and professional mobility of the health professions," and that "States ...base practice acts on demonstrated initial and continuing competence" to "allow and expect different professions to share overlapping scopes of practice" appropriate to their current knowledge, training, experience and skills.

A third mechanism used by States is *Registration*, which typically imposes lower educational and training requirements than licensure, and requires that a provider register his or her name, address and training with a designated State agency, which has the power to receive consumer complaints and revoke registration. While non-registered individuals are prohibited from practicing, usually few if any requirements relating to training, knowledge and skill are imposed. The Commission recognizes the importance of this schema, particularly for the great many CAM practitioners that offer intrinsically non-intrusive, supportive care, utilizing approaches that reflect much more individualistic and artful interpretation and may require less sophisticated and complex education and training. Therefore, a registration schema may be most appropriately applied to those CAM practitioners, such as aromatherapists, who present low potential risk to their clients, as reflected by the range of their training and of the art that they practice, as well.

Exemption is a special status granted by most States to religious healers, exempting them from medical licensing statutes provided they practice within the tenets of a recognized church (i.e., praying vs recommending medication). The Commission recognizes the unique and critical role that religious and cultural healers play in communities. While it is clear that a better understanding is needed of healing practices that are based primarily in cultural or religious beliefs, the Commission felt that such healers should continue to be provided a special exemption, but recommends that regulatory bodies carefully monitor and regulate practitioners who use such healing arts outside of its traditions, especially a defined community.

Several of the Pew Commission recommendations to reform healthcare workforce regulation speak directly to streamlining regulatory functions, and increasing accountability of regulatory systems and bodies to the public. This has particular relevance to CAM practitioners, viewed as "emerging professions" within the overall framework of modern healthcare in the United States.

Clearly, the power to protect citizens' health, safety, and welfare authorizes States to decide who may practice medicine, and to establish licensing boards that admit or exclude persons from practice. The U.S. Supreme Court has affirmed the constitutional right of State licensing boards to require a specific educational credential for health professionals. Therefore, occupational regulation is a "State's right." However, the Federal government also has contributed to the shape of health professional regulation through its reimbursement and other policies in Medicare and Medicaid; research on regulation's effects on health care cost, access and quality; practitioner data collection; education funding; and other initiatives. A simple example of the Federal regulatory effect is the mandate for States to license nursing home administrators, and to regulate nurse aides as a condition for Medicare and Medicaid reimbursement.

States, who have the authority to determine who will be granted a professional health care license and what will be the requirements for licensure, registration or exemption, often look to national professional groups to set standards of education and training as prerequisites to licensure, and to create accrediting bodies that can set standards and evaluative criteria for professional educational institutions. As outlined earlier, this regulatory process ostensibly creates a distinction between professional and non-professional occupations based on technical training and qualification.

The Federation of State Medical Boards of the United States, Inc., is a national organization comprised of the 69 medical boards of the United States, the District of Columbia, Puerto Rico, Guam and the U.S. Virgin Islands. The Federation primarily serves to establish and promulgate professional standards of quality, safety and integrity of health care through physician licensure and practice. Recognizing the growing interest of the public in CAM practices and products, as well as that of many licensed physicians, some of whom may be incorporating CAM

approaches and products into their practices, the Federation also has underway an initiative to develop model guidelines for State medical boards to use in regulating the use of "unconventional medical practices." These guidelines, currently under review, are expected to be released in 2002.

In keeping with its overall mandate, in its draft guidelines to States regarding CAM practices, the Federation recognizes and preserves a wide latitude in physicians' exercise of their professional judgment, not precluding the use of methods that are "reasonably likely to benefit patients without undue risk." The States are encouraged to establish and apply standards for effectiveness and safety equally to conventional and CAM practices and products. Therefore, licensed physicians should not be found guilty of "unprofessional conduct to practice medicine in an acceptable manner" solely on the basis of utilizing unconventional practices, but rather on a uniform set of professional guidelines that emphasize patient evaluation, adequate informed consent, thorough documentation, follow up, and appropriate consultation.

The discussion and debate stimulated by the Pew Health Commission's 1995 recommendations have also had an effect on States' considerations of CAM, especially as practiced by licensed physicians. Pre-empting even the FSMB guidelines, the Texas State Board of Medical Examiners published Standards for Physicians Practicing Integrative and Complementary Medicine in November 1998. These standards recognized "health care methods of diagnosis, treatment, or interventions that are not acknowledged to be conventional but that may be offered by some licensed physicians in addition to, or as an alternative to, conventional medicine, and that provide a reasonable potential for therapeutic gain in a patient's medical condition and that are not reasonably outweighed by the risk of such methods." The guidelines to determine violations focus on patient evaluation, adequate informed consent, thorough documentation, follow up, and appropriate consultation.

[ED NOTE: we will include here a table describing the oversight/regulatory bodies of licensed CAM practices, State-by-State]

Most licensed practitioners must follow a legal and ethical code to refer the patient to another licensed medical health care provider when the patient's clinical condition exceeds the practitioner's scope of competence or understanding. If the practitioner violates this duty to refer and the patient is injured, the patient may sue for malpractice. In addition, the practitioner who fails to refer when necessary may face professional discipline from the relevant regulatory board. The duty to refer helps to ensure that all practitioners, both allopathic and unconventional, remain within the scope of their competence. These are critical protections that are not provided to the public when CAM practitioners and professionals remain unregistered or unlicensed.

Ostensibly, the goal of regulating CAM practices is to establish standards that protect consumers from incompetent practitioners, however, current regulatory schemas have been used quite effectively by organized professional groups as entry barriers of other potential health care providers into the competitive market. The Commission believes that the highest priorities to consider are the quality of care, treatment and patient safety, and that a regulatory infrastructure for CAM practices and products is necessary to do so. **In fact, the Commission strongly believes that regulation of CAM practitioners is necessary, feasible and highly beneficial to the public's safety.** Any such regulatory scheme also must consider and promote efforts toward a more coordinated care approach that incorporates and appropriately integrates the best of conventional medicine and CAM approaches. To ensure that this goal remains primary, at least two regulatory issues must be addressed: Professional practice authority, and regulatory and oversight structures.

Before making recommendations on these primary issues, it is important to note several unique challenges that face regulation of CAM practitioners. First, dispute amongst CAM practitioners, themselves, continues as to how much training should be required for licensure in any given field; the extent to which such training should be required for licensure in any given field; and whether and how such education and training can incorporate intuitive and individualized expression of professional health care services. From the CAM provider's perspective, licensure presents a tension between the desire to increase standardization of CAM education, training, and practices across States and the desire to keep CAM practice flexible, non-standardized, and linked to subjective, interpersonal and intuitive aspects of care. While increased licensure of CAM may help facilitate research and ease referrals, enhance patient access and increase consumer protection, it also may decrease the inherent differentiation of CAM

(individualization of services, time spent per patient, range of patient options).

Secondly, the ambiguity and variance of what is considered "CAM" along a health professional continuum makes the useful assessment of CAM as value-added services difficult, at best. In September 2001, the University of California, San Francisco's Center for Health Professions published "Profiling the Professions: A Model for Evaluating Emerging Health Professions," (16) which discusses this evolutionary process. In addition to questions to help characterize the viability and growth trends of an emerging profession, the UCSF report outlined the need for a professional consensus description. Questions posed by the UCSF report included: How does the profession describe itself in terms of the types of care it provides, and the types of care beyond its professional scope? Are there differences of opinion within the profession about the range of care that is appropriate for the profession to provide? What interventions and modalities does the profession use? What is the diagnostic range and scope of pathology of the profession? Such descriptive statements are essential tools that enable both the public and other health professionals evaluate and understand, not only the practice itself, but how and whether the practice provides a value-added service.

Relatedly, a third concern is the overlap of approaches and technique between CAM modalities. For example, homeopathy and acupuncture are included in many States' definition of the practice scopes for naturopathy or chiropractic. Currently, even licensed CAM providers can be prosecuted for unlicensed medical practice if they are considered to have exceeded their scope of practice (e.g. massage therapists who offer emotional counseling and support, chiropractors who provide nutritional advice, nurses who offer therapeutic touch). The potential for criminal liability creates fear and uncertainty in CAM practice; it is often difficult to predict boundary violations. (Licensed professionals inherently overlap in their scope of practice even in conventional care). If "whole person" medicine is the goal, these boundaries become even more ill-defined.

To address many of these concerns, the Commission considers Federal support an important factor in fostering the emergence of CAM professions. For example, consideration should be made as to whether Federal support should be provided to CAM practitioners' efforts to establish a single, national, voluntary self-regulatory body, funded by registration fees, that will contribute to and uphold national standards for the practice of CAM; determine training and minimum levels of clinical competence for its specific modality; foster collaborative opportunities between its members and conventional practitioners; support, promote and publicize evidence for effectiveness, safety, and efficacy; serve as a national data bank for all practitioners under that profession and as the official liaison between its members and State regulators and professional oversight institutions; and provide an effective, accessible, supportive, and publically accountable mechanism (including disciplinary sanctions and publication of the findings of professional conduct committees) for addressing complaints about practitioners from members of the public. This body should work to advance public confidence in its practitioners, and demonstrate the readiness and ability of the profession to self-regulate. The establishment of a single lead organization should not preclude the continuation of healthy, progressive debate and exploration within the profession's members of divergent mechanisms and approaches, but should seek simply to organize its general philosophy around a consensus scope of practice, and provide accountability to the public.

Professional Practice Authority

The determination of just which CAM practitioners are permitted to provide what specific services remains among the most controversial and complex issues when considering regulation. Often characterized as "turf battles," the argument over scopes of practice is not unique to CAM. The Pew Health Commission's Taskforce on Workforce Regulation found that, despite the ostensible goal of regulation to protect consumer interests, regulatory changes to practice acts always occurred at the request of professions, and never were done at the request of public or consumer advocates. (15) The Taskforce found that every proposal by one party for changes to one practice act is viewed by another as expansions, encroachments, and infringements, regardless of the competence or qualification of the first party.

As discussed earlier in this chapter, contributing to this confusion is the use of terms to describe levels and functions of regulation, not only among States, but between professions. This lack of uniformity in language limits effective professional practice and mobility, creates barriers to high quality health care, and confuses regulators, legislators, professionals and the public.

The inconsistency of State regulatory schemas and the lack of uniformity in terms have direct impact on efforts toward collaborative care. For example, hospitals that attempt to make CAM treatments available to patients may face liability for negligent referrals within the institution to potentially unqualified practitioners. (17) At issue is the variability, inconsistency and reliability of the wide range of certifications and licenses available from CAM professional organizations, especially those which do not carry national consensus even among a given CAM modality. The liability, then, falls on the hospital or clinic, who must formulate and defend credentialing standards and procedures of each CAM practice for which it would like to refer. Similarly, managed care organizations face the same task of selecting which CAM practices and practitioners to include in their payment networks from among a diverse assortment of variously-certified providers. This task is compounded for those organizations that operate across State lines, and which must then contend with completely divergent occupational certification and licensure regimes State-to-State.

The Commission recognizes an urgent need to have clarity about the appropriate roles for CAM practitioners, professionals and clinicians at all levels of the health care system. The Commission believes that CAM practitioners need an appropriate level of legal authority granted by the State, both to protect and ensure the public's access to safe and effective practices. It seems clear that, given the diversity within the field, no single, overarching system of regulation, such as a national (Federal) licensing act, is appropriate to encompass all the different CAM practitioners, professionals, or address variations in State needs.

The Commission also recognizes that these different CAM practitioners and professionals may aspire to – and be qualified for – widely differing roles within the health care system, involving very different levels of intervention. For example, the scope of practice and education of a CAM professional such as an accredited naturopathic physician, may allow him to examine a patient, diagnose a health condition and treat the condition (all States include these functions under the definition of the "practice of medicine.") This type of scope of practice reflects a greater level of potential risks to and needs of patients, and therefore requires more regulatory oversight than CAM practitioners who use less comprehensive approaches. Regardless of the orientation of the practitioner, whether allopathic or CAM, those who practice comprehensive health care approaches must demonstrate evidence of effectiveness and safety, educational, ethical and practice standards, and other characteristics of a cohesive professional status, all of which facilitate accountability to the public. An increasing number of CAM professional organizations are moving toward such professional status, adopting national standards for examination, certification, and accreditation. Such credentials promote public confidence in the safety and efficacy of these endeavors, and make more State-to-State uniformity of regulation more feasible.

It remains the prerogative of States to determine the scope of practice authority for any health care provider, and the mechanism, i.e., registration, licensure, by which such authority is implemented. Concerns over excessive or intrusive Federal regulation into States' and private market affairs are most likely sufficient to effectively eliminate the possibility of "Federalized" health professions regulations. It will be more important for Federal agencies – through reimbursement and facility licensing, education funding and other efforts– to facilitate the development, dissemination, and evaluation of uniform (non-Federal) entry-to-practice standards, model scopes of practice, and innovations in education and workplace design.

The Commission fully acknowledges the different roles and authorities of both the Federal and State governments in regulating CAM practitioners. The intention of the recommendations made in this report is not to usurp these responsibilities but rather to provide guidance for actions to improve the public's access to qualified, safe and effective CAM practitioners. While the Commission was able to identify many of the major issues and challenges to increasing appropriate access to CAM, it was not possible to develop the myriad policy and operational guidelines needed to move from discussion to action. Such a process requires the involvement a broad cross-section of stakeholders. For this reason, the Commission considers a Federally appointed, national advisory policy board critical to the next phase of policy development on issues related to the access and delivery of CAM. The advisory policy board should be comprised of a broad representation of members from the health care arenas, including, but not limited to CAM practitioners and professionals, CAM educators, researchers and policy makers; members of the allopathic professions, including educators, researchers and policy makers; insurers, and others in the health care industry; State and Federal regulators of health care practitioners, and representatives from professional oversight institutions and organizations.

The Commission offers the following framework for understanding the evolution of CAM practitioners and professionals as a tool for States to use when considering regulation of CAM practitioners and professionals.

CAM Professionals Ready for Licensure: The most evolved category of professional status is comprised of providers with an established, well-articulated and cohesive healing philosophy, defined practice standards, accredited education, state licensing, documented safety and at least some research substantiation of effective outcomes. These professionals are most ready to collaborate with conventional health care providers, but may lack the legal authority from States to practice at all. Many of these professionals already collaborate informally with conventional health care providers, usually as part of a supportive or palliative care approach.

Emerging CAM Professions: This is the most dynamic category of professional evolution, where lay and inconsistently trained practitioners are working to establish standards. Many of these so-called "emerging professions" enjoy rich traditions of education, training and practice in other countries, but may still be working toward establishing professional cohesiveness on such standards in the United States. Many levels of qualified practitioners exist in this status, and may already be collaborating informally with conventional health care providers and more professionally-evolved CAM practitioners.

Static Practitioners: Self-proclaimed or minimally educated healers who practice without apparent standards or community oversight comprise the currently least dynamic category of professional evolution. These practitioners may use titles associated with more evolved CAM professions, but do not adhere to the educational, training or other practice standards established by those professions.

Conventionally- trained CAM Practitioners: These providers are most often comprised of conventionally-trained allopaths who utilize therapies and practices that are highly controversial or excluded from conventional standards of care. They usually do not identify with a specific CAM profession, but may ascribe to certain empirical philosophies that tend to characterize CAM, rather than allopathic approaches. Most often individual practitioners, they are unlikely to organize as a profession, and focus their efforts on the development of their particular and unique technology or approach.

Traditional healers: These practitioners do so within a community that provides centuries-old traditions and oversight, such as Native American healers, shamans, and curanderos. They do not identify with a specific CAM "profession," and often relate only to their cultural origins in any organizational sense, with little interest in recognition outside of their communities.

From the consumer's perspective, access to competent CAM practitioners must be improved, as well as their ability to choose from among many types of CAM practitioners, or from among coordinated care plans that integrate conventional and CAM care. The public has a reasonable expectation that the care they access is provided by a competent practitioner able to help them navigate through multiple choices and decisions about the care they can receive.

Regulation and Oversight

In addition to assuring the competence and qualifications of the CAM practitioner, the consumer expects that the facility through which care is delivered also is safe and accountable. Most health care facilities and organizations are regulated by private organizations through accreditation processes that substitute for licensure.

The largest such private organization is The Joint Commission on the Accreditation of Health Care Organization (JCAHO), which evaluates and accredits nearly 18,000 health care organizations and programs in the United States. An independent, not-for-profit organization, JCAHO uses professionally based standards against which compliance of health care organizations are measured.

JCAHO's evaluates and accredits a long list of organizations, including general, psychiatric, children's and rehabilitation hospitals; health care networks (including Health Maintenance Organizations (HMOs); Integrated Delivery Networks (IDNs), Preferred Provider Organizations (PPOs), and managed behavioral health care

organizations; home care organizations, including those that provide home health services, personal care and support services, home infusion and other pharmacy services; durable medical equipment services and hospice services; nursing homes and other long term care facilities, including subacute care programs, dementia programs and long term care pharmacies; assisted living facilities that provide or coordinate personal services, 24-hour supervision and assistance (scheduled and unscheduled), activities and health-related services; behavioral health care organizations, including those that provide mental health and addiction services, and services to persons with developmental disabilities of various ages, in various organized service settings; ambulatory care providers, including outpatient surgery facilities, rehabilitation centers, infusion centers, group practices and others; and clinical laboratories. CAM, which is delivered primarily through out-patient (private practitioners) facilities, and is not included on this list, and little or no standards exist to regulate them.

JCAHO and most other accreditation organizations that are used by regulatory bodies to ensure quality health care require that staff of such facilities be licensed, meet relevant training and experience standards, demonstrate current competence, and have acceptable health status. In addition, the Health Plan Employer Data and Information Set (HEDIS 2.0) reports on general consumer satisfaction with provider accessibility and interaction, turnover, and board certification status. In some cases, individual health plans may also require medical and other staff to provide information on disciplinary or other actions taken against them, and many plans include some degree of "economic credentialing" to assess practice patterns against the organization's philosophical principles or business plans. While many regulatory and quality control mechanisms that organizations such as JCAHO implement are sufficiently broad enough to incorporate CAM products and services, current language of such standards, and professional awareness and sensitivity to the issue is lacking.

For example, one JCAHO standard addresses "the relationship of the hospital and its staff members to other health care providers, educational institutions, and payers." More specific guidance on how a facility applies such a standard to incorporating qualified CAM practitioners into a treatment plan could greatly increase the collaboration among practitioners and enhance a patient's access to a wider menu of effective services that include CAM.

JCAHO is governed by a 28-member Board of Commissioners that includes nurses, physicians, consumers, medical directors, administrators, providers, employers, labor representatives, health plan leaders, quality experts, ethicists, health insurance administrators and educators. This composition is reflective of most accrediting bodies, and presently most do not include CAM practitioners or experts in these fields. The Commission strongly supports JCAHO and other lead organizations to include CAM practitioners or experts on their governing boards, but even more, such constituencies should be included on informal networks, technical advisory committees, and other discussion forums.

The Commission considers lead organizations such as JCAHO to be critical to the on-going process of public and professional education on access to CAM. In particular, the Commission recognizes JCAHO's potential to convene professional forums to help promote consensus around appropriate access and delivery of CAM in clinical settings; to educate providers, particularly the conventional medical community, about policy discussions and consensus reached on such issues; and to inform the public about standards regarding appropriate, safe and effective delivery of CAM, and what these standards mean to them.

Issue 2: Coordinated Delivery Systems

Increasingly, health providers are being challenged to develop practice protocols and other methodologies that coordinate care across the continuum. The foundation of such care is built best by first establishing a strong base of primary care. As defined by the Institute of Medicine in 1996, primary care involves the "provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing sustained partnership with patients, and practicing in the context of family and community" (18) All health care practitioners, including CAM providers, should adequately understand and appropriately value the role of primary care, which should remain the launching point for all care, regardless of the providers. A more comprehensive discussion of the role that CAM practitioners and professionals may play with regard to primary care is included in another chapter of this report.

Integrative, or collaborative health care should not be about promoting complementary therapies but about providing comprehensive, collaborative, personalized care by drawing on the resources, skills and perspectives of a wide variety of disciplines, specialties and therapies, including complementary and alternative therapies when clinically appropriate. In the same vein, defining integrative, or collaborative health care should not be either polarizing or divisive. By pairing a holistic philosophy (comprehensive, collaborative and personalized) with a systematic and well reasoned clinical strategy, integrative health care treats illness and promotes health in a manner that always keeps the patient and community at the center.

The emergence of CAM approaches as a consumer movement suggests a shift from the application of using only science and technology to overcome disease and dysfunction, to the acknowledgment of an integrated, self-healing life system with the role of internal self-regulation, personal attitudes and beliefs, and the healing nature of relationships as paramount. Consumers are doing their own research, and serving as individual research models, trying alternatives to conventional treatments, and pressing for more options. Nutrition, exercise and lifestyle changes that include increasingly more CAM products and practices play a significant role in preventing and treating disease, and improving quality of life. In most instances, health care providers can be used to guide consumers to safe and effective paths to recovery and health. In all cases, providers should be well-trained, highly qualified practitioners.

In response to growing patient (and health practitioner) dissatisfaction with the current system, innovative centers and practitioner groups are emerging at a growing rate. The trend toward patient-centered (rather than diagnosis-centered) and self-healing care is beginning to be reflected in employee assistance programs, hospice centers and community-based public health clinics and services.

CAM, like all health care services, is delivered through the public or private health care sectors. The public delivery system, in this context, includes Federal health systems (including those of the military and Veterans Administration), public hospital systems, community health centers, local public health clinics, home care, etc. Private sector systems include office-based practices of medical and health professionals, hospitals, multiple-facility health care systems, clinics, nursing homes, home health agencies, etc. These systems continuously evolve, especially in response to the mechanisms under which the systems are financed and other market pressures. For example, managed care has had a significant impact on systems of delivery, and managed care itself has changed in response to market pressures. CAM practitioners are most often found in private sector settings, and are usually in solo or small office-based practices. Increasingly, hospitals, managed care organizations, health insurers and large, self-insured corporations are developing models whereby CAM therapies are made available to members/subscribers/ employees. These models bring CAM to the practice of conventional medicine through referral, consultation, co-management, and adjunct (supportive) therapies. The spectrum of existing models, all relatively new, is broad and includes:

Solo practitioners deliver often multi-modal CAM services in an office-based practice or outpatient (ambulatory) setting. In some cases, several such CAM practitioners may share office space without working collaboratively on cases, although they may refer to one another as appropriate.
CAM clinics, usually a group CAM practitioners, work collaboratively to offer patients integrated services. Such clinics may include allopathic practitioners, either as part of the integrative services on-site, or as case consultants.

Vertically integrated services are usually CAM clinics, but may be solo practitioners, that are linked with primarily allopathic delivery systems, such as teaching hospitals or community health clinic networks. Such services operate independently of the allopathic system, but are considered adjunct.

Because most of CAM is delivered through the private practice arena, it is less readily available to the populations served by community health centers and others who cannot afford to pay out-of-pocket for services. CAM practitioners who participate in referral or practitioner networks usually do so at discounted rates, a system that works as a disincentive for most CAM practitioners. Currently, few incentives exist to encourage more CAM practitioners into either the public or managed care delivery systems. Until these issues are resolved, CAM services and products will remain largely inaccessible to the populations in most need.

As new delivery models for CAM develop, the need to assure accountability and quality will become even more critical. The Institute of Medicine's report, *Crossing the Quality Chasm*, identifies six aims for improvement, all of which apply equally to conventional and CAM care (4):

Safe: avoiding injuries to patients from the care that is intended to help them.

Effective: providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and overuse, respectively).

Patient-centered: providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.

Timely: reducing waits and sometimes harmful delays for both those who receive and those who give care.

Efficient: avoiding waste, including waste of equipment, supplies, ideas, and energy.

Equitable: providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socio-economic status.

A particularly salient example of both the need for collaborative care, and of how well CAM approaches can be incorporated into a care system can be found in end-of-life care. While the incorporation of CAM is applicable throughout the life-cycle, by the year 2020, 20% of the world's population will be older than 65 years. In this country, 8% of the population currently is older than 65 years and in 2020, it is estimated that 25% will be older than 65 years (roughly 65 million older adults). As the population ages, problems in end of life care have been increasingly well-documented, from under-treated pain to unwanted or futile therapies. Among the concerns for older adults is polypharmacy, the use of multiple medications. Older adults consume approximately 25% of prescription medication each year. In this country, it has been estimated that older adults take an average of 5 medications at any one time, often mixing them with over-the-counter medications and nutriceuticals. Given the significant increase in the number of adverse drug effects known to occur with the number of medications, this presents a particular public safety concern. The potential for CAM therapies to reduce the number of medications older adults take provides an important and cost-sensitive opportunity.

End-of-life care is not limited to the elderly. A report by the Association of American Medical Colleges defined end-of-life issues as those that the individual person faces when confronted with a condition in which dying is a distinct possibility. (19) In this context, no clear demarcation exists between active treatment of an illness and the end of life. Rather, end-of-life refers to the entire time, even during treatment of an illness, when dying becomes an important consideration. For the patient, personal spirituality and culture may significantly affect his beliefs, attitudes and behaviors toward end-of-life health care interventions.

Indeed, there is evidence to suggest that spirituality may be helpful to people as they cope with dying or with loss. For example, patients with advanced cancer who also found comfort from their religious and spiritual beliefs had diminished pain; women with breast cancer reported that their spiritual beliefs helped them cope with their illness and with facing the possibility of death. In a national survey by the American Pain Society, prayer was stated as the most common non-drug method for dealing with pain, followed by relaxation response, meditation, touch and massage. The work of Dr. Herbert Benson on the role of meditation, specifically the relaxation response, as an adjunct to treatment of patients with serious disease is well-known in the medical community. Despite clear evidence of the important role of spirituality in end-of-life care, and the availability of Clinical Pastoral Education (CPE)-trained chaplains and other spiritual care providers, current systems of care do not easily incorporate spirituality into the care of patients.

The 1999 report of the Association of American Medical Colleges (Report III of the Medical School Objectives Project) suggested strategies to improve medical student education on spirituality, cultural issues and end-of-life care. Demonstration projects that further explore the potential benefits and opportunities of collaborative care (that incorporates or coordinates conventional and CAM approaches) is both appropriate and of critical value.

ACCESS AND DELIVERY RECOMMENDATIONS

RECOMMENDATION 1.

The Commission recommends that access to qualified practitioners, affordable, safe and effective CAM services, and beneficial CAM products be better facilitated for all Americans.

RECOMMENDATION 2.

The Commission recommends that practitioners who provide CAM services and/or products be regulated by States using a more standardized and understandable framework that includes exemption categories, registration, and licensure, and that ensures accountability to the public.

Action Items:

1. The Secretary of DHHS should convene a national policy advisory committee to: a) address issues related to the licensing and certification of CAM practitioners; b) provide guidance to States as they develop regulatory and oversight standards applicable to CAM practitioners; and c) provide a forum for dialogue on other issues related to maximizing access to qualified practitioners, safe and effective CAM services, and beneficial CAM products.

2: DHHS and other appropriate Federal agencies should utilize health care workforce data and data from national surveys on CAM to identify current and future health care needs that qualified CAM practitioners may help to address.

3. The Federal Government should convene conferences on effective approaches to the integration of safe and beneficial CAM into allopathic settings, using successful models of integrated care, such as hospice settings, community health clinics, and the private and non-profit sector, and make this information available to practitioners and the public.

4. The Secretary of DHHS should produce a report on indigenous healing traditions in the United States that identifies common use and practices, and provides recommendations to improve collaboration between such practices and current health care systems in a manner that protects the cultural heritage of such traditions, appropriately educates health care practitioners, involves members from these traditions, and maximizes access to qualified practitioners, safe and beneficial services, and effective products.

5. The Federal Government, in collaboration with States, should assist CAM practitioners and organizations, especially those that are unlicensed, as they move towards developing consensus within their respective modalities and disciplines on: Definition / Description of the Profession/Practice; Safety and Efficacy; Regulation and Oversight; Education and Training; and the Viability of the Profession, for consideration by States and regulatory bodies in determining the appropriate regulatory status of these practitioners, including exemption, registration, or licensure.

6. The DHHS' advisory committee should work closely with State legislatures and regulatory boards to develop guidelines for the regulation and oversight of licensed and registered practitioners who utilize CAM services and products.

7. Nationally recognized accrediting bodies of health care organizations and facilities should consider increasing on-going access to CAM expertise to ensure that processes to develop accreditation standards reflect emergent developments in the health care field.

8. Nationally recognized accrediting bodies of health care organizations and facilities should consider re-evaluating current standards to explicitly apply to CAM, and to develop guidance documents to promote appropriate collaboration and foster understanding and awareness of CAM.

ACCESS AND DELIVERY REVISED AND NEW RECOMMENDATIONS

DECEMBER 21, 2001 (Revised)

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Action Items:

1. The Secretary of HHS (together with a designated Federal office for CAM) should convene a national policy advisory committee to: a) address issues related to the licensing and certification of CAM practitioners; b) provide guidance to States as they develop regulatory and oversight standards applicable to CAM practitioners; and c) provide a forum for dialogue on other issues related to maximizing access to qualified practitioners, safe and effective CAM services, and beneficial CAM products.

2: Utilize health care workforce data and data from national surveys on CAM to identify current and future health care needs that qualified CAM practitioners may help to address.

[A recommendation for demonstration projects to evaluate the usefulness, effectiveness and cost-benefits of collaborative care models at three delivery levels: office-based; free-standing CAM clinics, and vertically integrated services will be added to either the Research and/or the Coverage and Reimbursement chapters. However, it was also suggested that this particular "research-oriented" recommendation strengthens the Access section and should also be covered here as an additional action item. Regardless, the text in the Access chapter will be revised to discuss the need for such projects, including the importance of the results of such studies should inclusion in loan-forgiveness programs of CAM ever be considered or evaluated more formally.]

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6. The HHS' advisory committee (through the designated Federal office for CAM) should work closely with State legislatures and regulatory boards to develop guidelines for the regulation and oversight of licensed and registered practitioners who utilize CAM services and products.

7. State regulatory boards should develop processes to protect CAM and conventional practitioners who use CAM services or interventions in IRB-approved research should not be from being sanctioned solely for their use of such approaches.

8. Nationally recognized accrediting bodies of health care organizations and facilities should include appropriate CAM representation in accreditation processes.

9. Nationally recognized accrediting bodies of health care organizations and facilities should incorporate in their accreditation processes CAM services and products, and CAM practitioners.

[Recommendations on a Food Stamp benefit are being considered by Wellness and Access staff for proper disposition into the text.]

Draft Discussion Document for December 6-7, 2001 Meeting
TOPIC: Access and Delivery of CAM
Facilitators: Joseph Fins, Linnea Larson
Staff Lead: Michele Chang

Introduction:

Access to health care has been described as a multi-dimensional concept that balances factors such as human resources, financing, transportation, freedom of choice, public education, quality, and allocation of technology (1). There are other factors that contribute to the quantity and quality of care received by a population, and determine the nature and extent of access to care in the United States; many of these apply particularly to the access and availability of complementary and alternative medicine (CAM) in the United States. Among those considered by the Commission are the growth and influence of: chronic illness and their impact on disability and death; the availability of information, especially through the Internet; disparities in income and its impact on health; consumer involvement in their personal health care and consumer interest in CAM. In fact, the rise in CAM use is most often characterized as a "consumer-based movement," reflecting broader concerns by the American public to re-examine and revitalize how health care currently is delivered and received.

Many of the reasons influencing consumers' decisions to try unconventional approaches are the same as those stimulating change in the current health care system. Foremost among these include pressures to reduce the costs of health care, which are expected to reach the $2.1 trillion mark by 2007. CAM, especially those approaches that attempt to induce auto-regulation and self-healing, offers opportunities to reduce the escalating costs of health care. For example, mind-body therapies, such as meditation and biofeedback, that are used to control chronic pain and stress have been estimated to eliminate 37 percent of doctor visits, potentially saving the country some $54 billion a year (2, 3).

Many of the holistic philosophies and traditions often emphasized in CAM approaches focus on a prevention (rather than treatment) orientation, which tends to promote self-healing and rely on more healthy lifestyle and self-care changes, beginning early in life. This has potentially significant implications for both preventing and addressing chronic conditions, which are now the leading cause of illness, disability, and death in the United States, affecting nearly half of the U.S. population and accounting for the majority of health care expenditures. (4) Many patients who seek out CAM for chronic conditions suffer from syndromes (back pain, fibromyalgia, arthritis) for which a specific underlying cause of the disease is unknown or cannot be stopped. For many of these patients, conventional medical approaches may not work well. The IOM's 2001 report, *Crossing the Quality Chasm*, reported than more than 40 percent of those who suffer from chronic conditions have more than one such condition, suggesting that coordinated care including such supportive mechanisms that often characterize CAM approaches may be particularly effective. For example, relaxation therapies, acupuncture and herbal medicine, all of which share an emphasis on spiritual health and mind-body links, have demonstrated effectiveness with chronic disease patients. (3)

Another influence on the use of CAM and on the health care system is the accessibility of health information through the Internet and other communication technologies. While the impact and opportunity presented by the rapid evolution of health information technology is addressed elsewhere in this report, it is important to acknowledge its influence on consumer demand for CAM products and services. As of 1997, 35 percent of US households owned a computer, approximately 25 million Americans used the Internet weekly, and some websites provide information on more than three hundred different diseases. (5) A growing number of patients are equipping themselves with more, often quite detailed, information, not only about conventional treatments to their ailments, but about more unorthodox approaches as well. The ready availability of consumer information about such topics, whether accurate or not, and the ability to experience diverse cultures around the world have had a significant impact on the accelerated consumer movement toward CAM.

Patients are increasingly more interested in being active participants in their health care decisions. This participation includes evaluating information about treatment options, accessing products and practices that enable them to explore those options, and engaging in activities that may help them remain healthy through all stages of life. (6) Consumers' expectations are expanding the definition of health care from beyond treatment of illness to include prevention and wellness. A 1998 study indicated that those who use CAM do so because they find such approaches to be congruent with their own values, beliefs and philosophical orientations toward health and life. (7) As consumers become more empowered users of health care, whether to address chronic health conditions, or in an effort to increase overall wellness, their expectations for high quality, affordable, effective and safe health care from a range of providers and competent practitioners, both CAM and allopathic, also will increase.

Another factor influencing changes in the current health care system is the growing disparity of health indicators among U.S. populations. Research has found that income disparity between the rich and poor is the most powerful predictor of a nation's health as measured by life expectancy. (8) CAM services that are most commonly used by the general public, such as chiropractic, acupuncture, and massage therapy, are delivered primarily through non-reimburseable mechanisms, paid for out-of-pocket by the majority of its users. However, among immigrant populations, another type of CAM exists, comprised primarily of culturally-based home remedies and provided by members of a community with little or no formal training in health care, whether conventional or CAM in orientation. Such care often is more readily available than conventional care in many immigrant communities, where patients may depend upon them first, especially for seemingly minor disorders or for chronic conditions for which there is little known treatment in conventional medicine. (9)

In 2000, the Kaiser Commission on Medicaid and the Uninsured (9) reported that the most common barrier to care cited by immigrants was cost, followed by language. A supplement to the 2001 Surgeon General's Report on Mental Illness (10) also underscored the barriers for adequate health services experienced by racial and ethnic

minorities collectively. The report cited a constellation of barriers, many of which operate for all Americans: cost, fragmentation of services, and lack of availability of services. In the absence of affordable care, many immigrants, especially the uninsured, look to culturally-based home remedies to treat illness and disease.(9)

In the context of this more overall lack of access to care, adequate and appropriate access and delivery of CAM by qualified practitioners also possibly is most limited among those who can least afford to pay out-of-pocket. The cost of maintaining public health centers (county hospitals, public health centers), through which such care might be delivered to such populations, continues to increase. CAM proponents argue that many of the patients waiting hours for treatment are suffering from problems that might be appropriately treated by qualified CAM practitioners (acupuncture, homeopathy, bodywork). Many of the indigent and homeless that comprise the patient population at publicly run health centers, clinics and hospitals also present a diverse range of health challenges, including current or former alcohol and drug addiction problems. The use of appropriate CAM approaches by Federally funded programs has been shown to play a significant and cost-effective role in the recovery of these patients.

The consumer movement toward increased CAM use is only one of the forces through which health care is changing. Access to CAM will be subjected to the same demands placed on access to conventional health care: more efficient and effective use of available resources. To accomplish resource management goals will require, at least, identifying clearly intended outcomes for care, using evidenced-based best practices to achieve measurable goals, and improving overall systems of care delivery.

The Commission believes that CAM practitioners and the health care institutions delivering such care also should be properly regulated and accountable to the public. This chapter addresses the respective regulatory roles of Federal and State governments and those regulatory issues attendant to the delivery of CAM services and oversight of the broad spectrum of institutions through which CAM services are delivered; lays out the challenges in delivering CAM services; provides an overview of current CAM service delivery models within the range of health care systems from hospitals to individual private practice, and provides recommendations regarding each of these major issues.

Issue 1: The Effects of Regulation on Access

Ideally, health care access would define an ability to choose from both conventional and CAM practices and products, with assurances that all practitioners are qualified and products are safe and efficacious. States regulate health care practitioners by helping to assure quality and accountability of professions and providing a process for professional conduct review and disciplinary action. However, there is much variability State-by-State in regulatory approaches to licensure and scope of practice of CAM practitioners. For example, chiropractors are licensed in all States, while acupuncturists, massage therapists, and naturopathic physicians are licensed in 40, 30, and 11 States, respectively. These variations impact access to and delivery of CAM by limiting practitioners' ability to practice

lawfully and obtain malpractice insurance.

Most practitioners, whether CAM or conventional, will practice where they have the legal authority to do so. For naturopaths and practitioners of oriental medicine, the most influential factor in distribution appears to be licensure; these clinicians are concentrated in Northeastern and Northwestern States, where the greatest professional opportunities exist. Similar observations have been made about specialty providers and nurse practitioners or physician assistants, whose number per capita in each State correlates with the professional prerogatives granted to them. (11) The variability of regulation between States for any given CAM practice, the role of regulatory bodies, and the ambivalence of CAM practitioners towards regulation all contribute to the lack of definition and clarity on this issue.

In general, States that have fewer CAM providers also appear to have the lowest numbers of physicians and physician assistants per capita, as well. A better understanding of CAM utilization in such areas is needed to determine what can be done to improve access to CAM within the proper context of other public health and medical needs. Additionally, more information is needed on what constitutes "appropriate access" to CAM to better facilitate the mobility of qualified CAM practitioners within the health care system, and in collaboration with current services.

Early studies of licensure sponsored by the U.S. Department of Labor focused on licensure's impact on workforce availability, and the cost and quality of services. (12) The principle findings challenged the conventional wisdom that occupational regulation results in higher service quality and benefits consumers beyond the increased cost that licensure causes. These reports recommended that regulation should evaluate carefully the need for new licensed occupations, assure the continuing competence of licensees and greater equity in the discipline of licensed practitioners, improve public representation on licensing boards, remove artificial barriers to interstate mobility, and remove the control of educational functions from boards.

In 1990, the Federal Trade Commission (FTC) reported that occupational licensing had the capacity to "protect the public's health and safety by increasing the quality of professionals' services through mandatory entry requirements, such as education." (13) The report also found that many occupational licensing restrictions often did not accomplish these goals, but rather had the effect of increasing prices and imposing costs on the consumers. Despite this, the FTC concluded that the "costs of licensing did not always exceed the benefits to consumers," and recommended that such cost-to-benefits ratios should figure into the consideration of any licensing proposal.

In view of these concerns about the adequacy of current regulatory systems, and in a effort to return the focus of such oversight to promote the public health, the Pew Charitable Trusts established the Pew Health Professions Commission in 1989. Recognizing that health care workforce reform would necessitate regulatory reform, the Pew

Commission assembled the Taskforce on Health Care Workforce Regulation to identify and explore how regulation protects the public's health and to propose new approaches to health care workforce regulation to better serve the public's interest. (14)

In 1995, the Taskforce published 10 recommendations for regulatory reform and offered policy options for State considerations under each recommendation as a way of stimulating debate and discussion. The 10 recommendations made by the Taskforce are as follows:

PEW Taskforce Commission Recommendations for Regulation of the Health Care Workforce

1. States should use standardized and understandable language for health professions regulation and its functions to clearly describe them for consumers, provider organizations, businesses, and the professions.
2. States should standardize entry-to-practice requirements and limit them to competence assessments for health professions to facilitate the physical and professional mobility of the health professions.
3. States should base practice acts on demonstrated initial and continuing competence. This process must allow and expect different professions to share overlapping scopes of practice. States should explore pathways to allow all professionals to provide services to the full extent of their current knowledge, training, experience and skills.
4. States should redesign health professional boards and their functions to reflect the interdisciplinary and public accountability demands of the changing health care delivery system.
5. Boards should educate consumers to assist them in obtaining the information necessary to make decision about practitioners and to improve the boards's public accountability.
6. Boards should cooperate with other public and private organizations in collecting data on regulated health professions to support effective workforce planning.
7. States should require each board to develop, implement and evaluate continuing competency requirements to assure the continuing competence of regulated health care professionals.
8. States should maintain a fair, cost-effective and uniform disciplinary process to exclude incompetent practitioners to protect and promote the public's health.
9. States should develop evaluation tools that assess the objectives, successes and

shortcomings of their regulatory systems and bodies to best protect and promote the public's health.

10. States should understand the links, overlaps and conflicts between their health care workforce regulatory systems and other systems which affect the education, regulation and practice of health care practitioners and work to develop partnerships to streamline regulatory structures and processes.

The recommendations made by the Pew Commission, which focused primarily on the conventional health care workforce, stimulated significant response from that community and subsequently fostered a high level of regulatory activity and policy discussions that were captured in a 1998 follow up report by the Pew Commission. (15) Many of these recommendations and subsequent discussions are equally appropriate to the regulation of CAM practitioners.

The Mechanics of Regulation

The power to protect citizens' health, safety, and welfare authorizes States to decide who may practice medicine, and to establish licensing boards that admit or exclude persons from practice. The U.S. Supreme Court has affirmed the constitutional right of State licensing boards to require a specific educational credential for health professionals. Therefore, occupational regulation is a "State's right." However, the Federal government has contributed to the shape of health professional regulation through its reimbursement and other policies in Medicare and Medicaid; research on regulation's effects on health care cost, access and quality; practitioner data collection; education funding; and other initiatives. A simple example of the Federal regulatory effect is the mandate for States to license nursing home administrators, and to regulate nurse aides as a condition for Medicare and Medicaid reimbursement.

Concerns over excessive or intrusive Federal regulation into States' and private market affairs are most likely sufficient to effectively eliminate the possibility of "Federalized" health professions regulations. It will be more important for Federal agencies – through reimbursement and facility licensing, education funding and other efforts– to facilitate the development, dissemination, and evaluation of uniform (non-Federal) entry-to-practice standards, model scopes of practice, and innovations in education and workplace design.

The Commission fully acknowledges the different roles and authorities of both the Federal and State governments in regulating CAM practitioners. The intention of the recommendations provided is not to usurp these responsibilities but rather to provide guidance for actions to improve the public's access to qualified, safe and effective CAM practitioners. For this reason, the Commission has included a recommendation for the development of a Federally appointed, national advisory policy board that will support and coordinate efforts with a designated Federal office for CAM to develop policy guidelines on issues related to the access and delivery of CAM. The advisory policy

board should be comprised of a broad representation of members from the health care arenas, including, but not limited to CAM practitioners and professionals, CAM educators, researchers and policy makers; members of the allopathic professions, including educators, researchers and policy makers; insurers, and others in the health care industry; State and Federal regulators of health care practitioners, and representatives from professional oversight institutions and organizations.

States, who have the authority to determine who will be granted a professional health care license and what will be the requirements for licensure, often look to national professional groups to set standards of education and training as prerequisites to licensure, and to create accrediting bodies that can set standards and evaluative criteria for professional educational institutions. This process of licensure ostensibly creates a distinction between professional and non-professional occupations based on technical training and qualification.

The Federation of State Medical Boards of the United States, Inc., is a national organization comprised of the 69 medical boards of the United States, the District of Columbia, Puerto Rico, Guam and the U.S. Virgin Islands. The Federation primarily serves to establish and promulgate professional standards of quality, safety and integrity of health care through physician licensure and practice. Recognizing the growing interest of the public in CAM practices and products, as well as that of many licensed physicians, some of whom may be incorporating CAM approaches and products into their practices, the Federation also has underway an initiative to develop model guidelines for State medical boards to use in regulating the use of "unconventional medical practices." These guidelines, currently under review, are expected to be released in 2002.

In keeping with its overall mandate, in its draft guidelines to States regarding CAM practices, the Federation recognizes and preserves a wide latitude in physicians' exercise of their professional judgment, not precluding the use of methods that are "reasonably likely to benefit patients without undue risk." The States are encouraged to establish and apply standards for effectiveness and safety equally to conventional and CAM practices and products. Therefore, licensed physicians should not be found guilty of "unprofessional conduct to practice medicine in an acceptable manner" solely on the basis of utilizing unconventional practices, but rather on a uniform set of professional guidelines that emphasize patient evaluation, adequate informed consent, thorough documentation, follow up, and appropriate consultation.

The discussion and debate stimulated by the Pew Health Commission's 1995 recommendations have also had an effect on States' considerations of CAM, especially as practiced by licensed physicians. Pre-empting even the FSMB guidelines, the Texas State Board of Medical Examiners published Standards for Physicians Practicing Integrative and Complementary Medicine in November 1998. These standards recognized "health care methods of diagnosis, treatment, or interventions that are not acknowledged to be conventional but that may be offered by some licensed physicians in addition to, or as an alternative to, conventional medicine, and that provide a reasonable

potential for therapeutic gain in a patient's medical condition and that are not reasonably outweighed by the risk of such methods." The guidelines to determine violations focus on patient evaluation, adequate informed consent, thorough documentation, follow up, and appropriate consultation.

[ED NOTE: we will include here a table describing the oversight/regulatory bodies of licensed CAM practices, State-by-State]

Most licensed practitioners must follow a legal and ethical code to refer the patient to **another** licensed medical **health care provider** when the patient's clinical condition exceeds the practitioner's scope of competence **or understanding**. If the practitioner violates this duty to refer and the patient is injured, the patient may sue for malpractice. In addition, the practitioner who fails to refer when necessary may face professional discipline from the relevant regulatory board. The duty to refer helps to ensure that all practitioners, both allopathic and unconventional, remain within the scope of their competence. These are critical protections that are not provided to the public when CAM practitioners and professionals remain unregistered or unlicensed.

Most States use one or more of the following mechanisms to regulate health care practices:
[Editor's note: it was suggested that clarifying language or examples should be inserted under each description.]

Mandatory Licensure prohibits the practice of a profession without a license.

Title Licensure permits anyone to practice the profession, but only those granted a license may use the designated title.

Registration typically imposes lower educational and training requirements than licensure, and requires that a provider register his or her name, address and training with a designated State agency, which has the power to receive consumer complaints and revoke registration. (A variation of the registration regulatory model has been implemented by Minnesota, and allows CAM practitioners and professionals to practice without licensure, provided they meet a number of basic requirements.)

Exemption is a special status granted by most States to religious healers, exempting them from medical licensing statutes provided they practice within the tenets of a recognized church (i.e., praying vs recommending medication).

Ostensibly, the goal of regulating CAM practices is to establish standards that protect consumers from incompetent practitioners, however, current regulatory schemas have been used quite effectively by organized professional groups as entry barriers of other potential health care providers into the competitive market. The Commission believes that the highest priorities to consider are the quality of care, treatment and patient safety, and that a

regulatory infrastructure for CAM practices and products is necessary to do so. **In fact, the Commission strongly believes that regulation of CAM practitioners is necessary, feasible and highly beneficial to the public's safety.** Any such regulatory scheme also must consider and promote efforts toward a more coordinated care approach that incorporates and appropriately integrates the best of conventional medicine and CAM approaches. To ensure that this goal remains primary, at least two regulatory issues must be addressed: Professional practice authority, and regulatory and oversight structures.

Before making recommendations on these primary issues, it is important to note several unique challenges that face regulation of CAM practitioners. First, dispute amongst CAM practitioners, themselves, continues as to how much training should be required for licensure in any given field; the extent to which such training should be required for licensure in any given field; and whether and how such education and training can incorporate intuitive and individualized expression of professional health care services. From the CAM provider's perspective, licensure presents a tension between the desire to increase standardization of CAM education, training, and practices across States and the desire to keep CAM practice flexible, non-standardized, and linked to subjective, interpersonal and intuitive aspects of care. While increased licensure of CAM may help facilitate research and ease referrals, enhance patient access and increase consumer protection, it also may decrease the inherent differentiation of CAM (individualization of services, time spent per patient, range of patient options).

Secondly, the ambiguity and variance of what is considered "CAM" along a health professional continuum makes the useful assessment of CAM as value-added services difficult, at best. In September 2001, the University of California, San Francisco's Center for Health Professions published "Profiling the Professions: A Model for Evaluating Emerging Health Professions," (16) which discusses this evolutionary process. In addition to questions to help characterize the viability and growth trends of an emerging profession, the UCSF report outlined the need for a professional consensus description. Questions posed by the UCSF report included: How does the profession describe itself in terms of the types of care it provides, and the types of care beyond its professional scope? Are there differences of opinion within the profession about the range of care that is appropriate for the profession to provide? What interventions and modalities does the profession use? What is the diagnostic range and scope of pathology of the profession? Such descriptive statements are essential tools that enable both the public and other health professionals evaluate and understand, not only the practice itself, but how and whether the practice provides a value-added service.

Relatedly, a third concern is the overlap of approaches and technique between CAM modalities. For example, homeopathy and acupuncture are included in many States' definition of the practice scopes for naturopathy or chiropractic. Currently, even licensed CAM providers can be prosecuted for unlicensed medical practice if they are considered to have exceeded their scope of practice (e.g. massage therapists who offer emotional counseling and support, chiropractors who provide nutritional advice, nurses who offer therapeutic touch). The potential for

criminal liability creates fear and uncertainty in CAM practice; it is often difficult to predict boundary violations. (Licensed professionals inherently overlap in their scope of practice even in conventional care). If "whole person" medicine is the goal, these boundaries become even more ill-defined.

To address many of these concerns, the Commission has recommended that Federal support be provided to foster CAM practitioners' efforts to establish a single, national, voluntary self-regulatory body, funded by registration fees, that will contribute to and uphold national standards for the practice of CAM; determine training and minimum levels of clinical competence for its specific modality; foster collaborative opportunities between its members and conventional practitioners; support, promote and publicize evidence for effectiveness, safety, and efficacy; serve as a national data bank for all practitioners under that profession and as the official liaison between its members and State regulators and professional oversight institutions; and provide an effective, accessible, supportive, and publically accountable mechanism (including disciplinary sanctions and publication of the findings of professional conduct committees) for addressing complaints about practitioners from members of the public. This body should work to advance public confidence in its practitioners, and demonstrate the readiness and ability of the profession to self-regulate. The establishment of a single lead organization should not preclude the continuation of healthy, progressive debate and exploration within the profession's members of divergent mechanisms and approaches, but should seek simply to organize its general philosophy around a consensus scope of practice, and provide accountability to the public.

Professional Practice Authority

The determination of just which CAM practitioners are permitted to provide what specific services remains among the most controversial and complex issues when considering regulation. Often characterized as "turf battles," the argument over scopes of practice is not unique to CAM. The Pew Health Commission's Taskforce on Workforce Regulation found that, despite the ostensible goal of regulation to protect consumer interests, regulatory changes to practice acts always occurred at the request of professions, and never were done at the request of public or consumer advocates. (15) The Taskforce found that every proposal by one party for changes to one practice act is viewed by another as expansions, encroachments, and infringements, regardless of the competence or qualification of the first party.

Contributing to this confusion is the use of terms to describe levels and functions of regulation, not only among States, but between professions. This lack of uniformity in language limits effective professional practice and mobility, creates barriers to high quality health care, and confuses regulators, legislators, professionals and the public.

The inconsistency of State regulatory schemas and the lack of uniformity in terms have direct impact on efforts toward collaborative care. For example, hospitals that attempt to make CAM treatments available to patients may face liability for negligent referrals within the institution to potentially unqualified practitioners. (17) At issue is the

variability, inconsistency and reliability of the wide range of certifications and licenses available from CAM professional organizations, especially those which do not carry national consensus even among a given CAM modality. The liability, then, falls on the hospital or clinic, who must formulate and defend credentialing standards and procedures of each CAM practice for which it would like to refer. Similarly, managed care organizations face the same task of selecting which CAM practices and practitioners to include in their payment networks from among a diverse assortment of variously-certified providers. This task is compounded for those organizations that operate across State lines, and which must then contend with completely divergent occupational certification and licensure regimes State-to-State.

The Commission recognizes an urgent need to have clarity about the appropriate roles for CAM practitioners, professionals and clinicians at all levels of the health care system. The Commission believes that CAM practitioners need an appropriate level of legal authority granted by the State, both to protect and ensure the public's access to safe and effective practices. It seems clear that, given the diversity within the field, no single, overarching system of regulation, such as a national (Federal) licensing act, is appropriate to encompass all the different CAM practitioners, professionals, or address variations in State needs.

The Commission also recognizes that these different CAM practitioners and professionals may aspire to – and be qualified for – widely differing roles within the health care system, involving very different levels of intervention. For example, the scope of practice and education of a CAM professional such as an accredited naturopathic physician, may allow him to examine a patient, diagnose a health condition and treat the condition (all States include these functions under the definition of the "practice of medicine.") This type of scope of practice reflects a greater level of potential risks to and needs of patients, and therefore requires more regulatory oversight than CAM practitioners who use less comprehensive approaches. Regardless of the orientation of the practitioner, whether allopathic or CAM, those who practice comprehensive health care approaches must demonstrate evidence of effectiveness and safety, educational, ethical and practice standards, and other characteristics of a cohesive professional status, all of which facilitate accountability to the public. An increasing number of CAM professional organizations are moving toward such professional status, adopting national standards for examination, certification, and accreditation. Such credentials promote public confidence in the safety and efficacy of these endeavors, and make more State-to-State uniformity of regulation more feasible.

It remains the prerogative of States to determine the scope of practice authority for any health care provider, and the mechanism, i.e., registration, licensure, by which such authority is implemented. The Commission offers the following framework for understanding the evolution of CAM practitioners and professionals as a tool for States to use when considering regulation of CAM practitioners and professionals.

CAM Professionals Ready for Licensure: The most evolved category of professional status is comprised of providers

with an established, well-articulated and cohesive healing philosophy, defined practice standards, accredited education, state licensing, documented safety and at least some research substantiation of effective outcomes. These professionals are most ready to collaborate with conventional health care providers, but may lack the legal authority from States to practice at all. Many of these professionals already collaborate informally with conventional health care providers, usually as part of a supportive or palliative care approach.

Emerging CAM Professions: This is the most dynamic category of professional evolution, where lay and inconsistently trained practitioners are working to establish standards. Many of these so-called "emerging professions" enjoy rich traditions of education, training and practice in other countries, but may still be working toward establishing professional cohesiveness on such standards in the United States. Many levels of qualified practitioners exist in this status, and may already be collaborating informally with conventional health care providers and more professionally-evolved CAM practitioners.

Static Practitioners: Self-proclaimed or minimally educated healers who practice without apparent standards or community oversight comprise the currently least dynamic category of professional evolution. These practitioners may use titles associated with more evolved CAM professions, but do not adhere to the educational, training or other practice standards established by those professions.

Conventionally- trained CAM Practitioners: These providers are most often comprised of conventionally-trained allopaths who utilize therapies and practices that are highly controversial or excluded from conventional standards of care. They usually do not identify with a specific CAM profession, but may ascribe to certain empirical philosophies that tend to characterize CAM, rather than allopathic approaches. Most often individual practitioners, they are unlikely to organize as a profession, and focus their efforts on the development of their particular and unique technology or approach.

Traditional healers: These practitioners do so within a community that provides centuries-old traditions and oversight, such as Native American healers, shamans, and curanderos. They do not identify with a specific CAM "profession," and often relate only to their cultural origins in any organizational sense, with little interest in recognition outside of their communities.

From the consumer's perspective, access to competent CAM practitioners must be improved, as well as their ability to choose from among many types of CAM practitioners, or from among coordinated care plans that integrate conventional and CAM care. The public has a reasonable expectation that the care they access is provided by a competent practitioner able to help them navigate through multiple choices and decisions about the care they can receive.

Regulation and Oversight

In addition to assuring the competence and qualifications of the CAM practitioner, the consumer expects that the facility through which care is delivered also is safe and accountable. Most health care facilities and organizations are regulated by private organizations through accreditation processes that substitute for licensure.

The largest such private organization is The Joint Commission on the Accreditation of Health Care Organization (JCAHO), which evaluates and accredits nearly 18,000 health care organizations and programs in the United States. An independent, not_for_profit organization, JCAHO uses professionally based standards against which compliance of health care organizations are measured.

JCAHO's evaluates and accredits a long list of organizations, including general, psychiatric, children's and rehabilitation hospitals; health care networks (including Health Maintenance Organizations (HMOs); Integrated Delivery Networks (IDNs), Preferred Provider Organizations (PPOs), and managed behavioral health care organizations; home care organizations, including those that provide home health services, personal care and support services, home infusion and other pharmacy services; durable medical equipment services and hospice services; nursing homes and other long term care facilities, including subacute care programs, dementia programs and long term care pharmacies; assisted living facilities that provide or coordinate personal services, 24-hour supervision and assistance (scheduled and unscheduled), activities and health-related services; behavioral health care organizations, including those that provide mental health and addiction services, and services to persons with developmental disabilities of various ages, in various organized service settings; ambulatory care providers, including outpatient surgery facilities, rehabilitation centers, infusion centers, group practices and others; and clinical laboratories. CAM is delivered primarily through out-patient (private practitioners) facilities, and easily could be included on this list, yet little or no standards exist to regulate them. [ED NOTE: *Information from JCAHO is pending on this issue. No formal guidelines exists*]

JCAHO and most other accreditation organizations that are used by regulatory bodies to ensure quality health care require that staff of such facilities be licensed, meet relevant training and experience standards, demonstrate current competence, and have acceptable health status. In addition, the Health Plan Employer Data and Information Set (HEDIS 2.0) reports on general consumer satisfaction with provider accessibility and interaction, turnover, and board certification status. In some cases, individual health plans may also require medical and other staff to provide information on disciplinary or other actions taken against them, and many plans include some degree of "economic credentialing" to assess practice patterns against the organization's philosophical principles or business plans. None of these regulatory and quality control mechanisms currently are applied to CAM service delivery.

JCAHO is governed by a 28-member Board of Commissioners that includes nurses, physicians, consumers, medical

directors, administrators, providers, employers, labor representatives, health plan leaders, quality experts, ethicists, health insurance administrators and educators. This composition is reflective of most accrediting bodies, and presently most do not include CAM practitioners or experts in these fields.

[Add Joe Fin's example of how pain assessment was added to the accreditation model. Clarify that this action item does not refer to organizations that accredit CAM schools....also include AHA documentation on the increasing use of CAM in hospitals...)

Issue 2: Coordinated Delivery Systems

Increasingly, health providers are being challenged to develop practice protocols and other methodologies that coordinate care across the continuum. The foundation of such care is built best by first establishing a strong base of primary care. As defined by the Institute of Medicine in 1996, primary care involves the "provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing sustained partnership with patients, and practicing in the context of family and community" (18) All health care practitioners, including CAM providers, should adequately understand and appropriately value the role of primary care, which should remain the launching point for all care, regardless of the providers. A more comprehensive discussion of the role that CAM practitioners and professionals may play with regard to primary care is included in another chapter of this report.

Integrative, or collaborative health care should not be about promoting complementary therapies but about providing comprehensive, collaborative, personalized care by drawing on the resources, skills and perspectives of a wide variety of disciplines, specialties and therapies, including complementary and alternative therapies when clinically appropriate. In the same vein, defining integrative, or collaborative health care should not be either polarizing or divisive. By pairing a holistic philosophy (comprehensive, collaborative and personalized) with a systematic and well reasoned clinical strategy, integrative health care treats illness and promotes health in a manner that always keeps the patient and community at the center.

The emergence of CAM approaches as a consumer movement suggests a shift from the application of using only science and technology to overcome disease and dysfunction, to the acknowledgment of an integrated, self-healing life system with the role of internal self-regulation, personal attitudes and beliefs, and the healing nature of relationships as paramount. Consumers are doing their own research, and serving as individual research models, trying alternatives to conventional treatments, and pressing for more options. Nutrition, exercise and lifestyle changes that include increasingly more CAM products and practices play a significant role in preventing and treating disease, and improving quality of life. In most instances, health care providers can be used to guide consumers to safe and effective paths to recovery and health. In all cases, providers should be well-trained, highly qualified practitioners.

In response to growing patient (and health practitioner) dissatisfaction with the current system, innovative centers and practitioner groups are emerging at a growing rate. The trend toward patient-centered (rather than diagnosis-centered) and self-healing care is beginning to be reflected in employee assistance programs, hospice centers and community-based public health clinics and services.

CAM, like all health care services, is delivered through the public or private health care sectors. The public delivery system, in this context, includes Federal health systems (including those of the military and Veterans Administration), public hospital systems, community health centers, local public health clinics, home care, etc. Private sector systems include office-based practices of medical and health professionals, hospitals, multiple-facility health care systems, clinics, nursing homes, home health agencies, etc. These systems continuously evolve, especially in response to the mechanisms under which the systems are financed and other market pressures. For example, managed care has had a significant impact on systems of delivery, and managed care itself has changed in response to market pressures. CAM practitioners are most often found in private sector settings, and are usually in solo or small office-based practices. Increasingly, hospitals, managed care organizations, health insurers and large, self-insured corporations are developing models whereby CAM therapies are made available to members/subscribers/ employees. These models bring CAM to the practice of conventional medicine through referral, consultation, co-management, and adjunct (supportive) therapies. The spectrum of existing models, all relatively new, is broad and includes:

Solo practitioners deliver often multi-modal CAM services in an office-based practice or outpatient (ambulatory) setting. **In some cases, several such CAM practitioners may share office space without working collaboratively on cases, although they may refer to one another as appropriate.**

CAM clinics, usually a group CAM practitioners, work collaboratively to offer patients integrated services. Such clinics may include allopathic practitioners, either as part of the integrative services on-site, or as case consultants.

Vertically integrated services are usually CAM clinics, but may be solo practitioners, that are linked with primarily allopathic delivery systems, such as teaching hospitals or community health clinic networks. Such services operate independently of the allopathic system, but are considered adjunct.

Because most of CAM is delivered through the private practice arena, it is less readily available to the populations served by community health centers and others who cannot afford to pay out-of-pocket for services. CAM practitioners who participate in referral or practitioner networks usually do so at discounted rates, a system that works as a disincentive for most CAM practitioners. Currently, few incentives exist to encourage more CAM practitioners into either the public or managed care delivery systems. Until these issues are resolved, CAM services

and products will remain largely inaccessible to the populations in most need.

As new delivery models for CAM develop, the need to assure accountability and quality will become even more critical. The Institute of Medicine's report, *Crossing the Quality Chasm*, identifies six aims for improvement, all of which apply equally to conventional and CAM care (4):

Safe: avoiding injuries to patients from the care that is intended to help them.

Effective: providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and overuse, respectively).

Patient-centered: providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.

Timely: reducing waits and sometimes harmful delays for both those who receive and those who give care.

Efficient: avoiding waste, including waste of equipment, supplies, ideas, and energy.

Equitable: providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socio-economic status.

A particularly salient example of both the need for collaborative care, and of how well CAM approaches can be incorporated into a care system can be found in end-of-life care. While the incorporation of CAM is applicable throughout the life-cycle, by the year 2020, 20% of the world's population will be older than 65 years. In this country, 8% of the population currently is older than 65 years and in 2020, it is estimated that 25% will be older than 65 years (roughly 65 million older adults). As the population ages, problems in end of life care have been increasingly well-documented, from under-treated pain to unwanted or futile therapies. Among the concerns for older adults is polypharmacy, the use of multiple medications. Older adults consume approximately 25% of prescription medication each year. In this country, it has been estimated that older adults take an average of 5 medications at any one time, often mixing them with over-the-counter medications and nutriceuticals. Given the significant increase in the number of adverse drug effects known to occur with the number of medications, this presents a particular public safety concern. The potential for CAM therapies to reduce the number of medications older adults take provides an important and cost-sensitive opportunity.

End-of-life care is not limited to the elderly. A report by the Association of American Medical Colleges defined end-of-life issues as those that the individual person faces when confronted with a condition in which dying is a distinct possibility. (19) In this context, no clear demarcation exists between active treatment of an illness and the

end of life. Rather, end-of-life refers to the entire time, even during treatment of an illness, when dying becomes an important consideration. For the patient, personal spirituality and culture may significantly affect his beliefs, attitudes and behaviors toward end-of-life health care interventions.

Indeed, there is evidence to suggest that spirituality may be helpful to people as they cope with dying or with loss. For example, patients with advanced cancer who also found comfort from their religious and spiritual beliefs had diminished pain; women with breast cancer reported that their spiritual beliefs helped them cope with their illness and with facing the possibility of death. In a national survey by the American Pain Society, prayer was stated as the most common non-drug method for dealing with pain, followed by relaxation response, meditation, touch and massage. The work of Dr. Herbert Benson on the role of meditation, specifically the relaxation response, as an adjunct to treatment of patients with serious disease is well-known in the medical community. Despite clear evidence of the important role of spirituality in end-of-life care, and the availability of Clinical Pastoral Education (CPE)-trained chaplains and other spiritual care providers, current systems of care do not easily incorporate spirituality into the care of patients.

The 1999 report of the Association of American Medical Colleges (Report III of the Medical School Objectives Project) suggested strategies to improve medical student education on spirituality, cultural issues and end-of-life care. Demonstration projects that further explore the potential benefits and opportunities of collaborative care (that incorporates or coordinates conventional and CAM approaches) is both appropriate and of critical value.