Public Interest Colloquium

Medical Necessity: Current Concerns and Future Challenges

Held March 31–April 1, 2005
Washington, DC

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“...to serve as a public resource on selected healthcare legal issues”
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Preface and Acknowledgements

This report summarizes the discussion and findings of the American Health Lawyers Association’s (Health Lawyers) 2005 Public Interest Colloquium, Medical Necessity: Current Concerns and Future Challenges. The Colloquium was held March 31–April 1, 2005, in Washington, DC. As chair of Health Lawyers’ 2004–2005 Public Interest Committee, I am pleased to present this Colloquium Report to health policymakers, the healthcare industry, the media, our members, and the public as Health Lawyers’ nonpartisan contribution to the debate on this important policy issue. Health Lawyers’ Public Interest commitment arises from a phrase in the Association’s mission statement that pledges that the organization “. . . will serve as a public resource on selected healthcare legal issues.”

Focus and Objectives of the 2005 Colloquium

Although medical necessity has long been central to coverage and payment decisions made under public and private health insurance programs in the United States, the term remains an often invoked but nebulous concept. Government health programs, private health plans, legislators, and health policy analysts employ the term “medical necessity” in disparate ways. For patients and healthcare providers, who are directly affected by coverage and payment decisions based on “medical necessity,” the use and application of the term often seems inconsistent and unclear.

Conducted every two years, Health Lawyers’ Colloquiums provide a forum for an in-depth, nonpartisan examination of a complex health policy issue that has a clear legal nexus. The meetings feature discussion by a roundtable of experts who represent major interests that are involved with the Colloquium’s topic. The twelve-member panel for the 2005 Colloquium included representatives of key constituencies, including federal and state government, consumer advocates, employers, policy analysts and researchers, and participants representing physicians, nursing homes, insurers, and other healthcare and industry groups. (A list of the panelists appears on page iv.)

To ensure a collegial dialogue on health policy topics that often provoke intense partisan debate, Colloquiums are conducted before a small, invited audience of Health Lawyers leaders and representatives of several nonpartisan, policy-focused organizations. This report preserves confidentiality of the views expressed in the meeting by not attributing comments to specific participants.

Health Lawyers convened the 2005 Colloquium with the goal of facilitating a nonpartisan discussion of legal, regulatory, and administrative issues that would help advance the debate on medical necessity. The Colloquium had two objectives: (1) To identify key constituencies’ major concerns with respect to current public and private sector processes for making medical necessity determinations; and key constituencies’ major concerns with current public and private sector processes for adjudicating challenges to medical necessity determinations; and (2) To identify key characteristics of an ideal system for public and private rulemaking processes for medical necessity determinations; and key characteristics of an ideal system for adjudicating challenges to medical necessity determinations, with an emphasis on identifying better ways to interpret and apply the rules governing adjudications.

Health Lawyers believes the 2005 Colloquium met its objectives. This report summarizes the expert panel’s facilitated discussion of key constituencies’ concerns as well as their identification of various characteristics of an ideal system for making medical necessity determinations. The report includes nine proposed, incremental changes on which the panel achieved consensus (see “Identifying Points of Consensus and Disagreement” on pages 24-26. Further, the report presents the initial framework of a more comprehensive approach to medical necessity determinations, based on “informed patient choice,” that emerged from a special presentation and discussion led by noted Dartmouth epidemiologist and researcher John E. Wennberg, MD, MPH. (See, “Special Presentation and Discussion: Practice Variation and Medical Necessity” on pages 13-16). Health Lawyers looks forward to working with Dr. Wennberg in coming months to develop this innovative proposal in more detail.

Health Lawyers hopes that the report’s summary of the Colloquium discussion will be helpful to policymakers and other stakeholders as medical necessity is discussed in ongoing national efforts to address such issues as rising healthcare costs, the provision of healthcare benefits (including potential coverage of emerging and experimental treatments and technologies), and coverage of the uninsured. We believe that readers of the Colloquium report will gain an appreciation of the complex issues involved in application of the concept of medical necessity to healthcare
procedures and treatments. We are pleased to present this report on the 2005 Public Interest Colloquium as Health Lawyers’ nonpartisan effort to advance the debate on medical necessity.

**Acknowledgements**

This report on the 2005 Colloquium reflects the commitment, work, and support of a number of dedicated individuals.

First, Health Lawyers is deeply grateful to the many donors—individuals, law firms, healthcare organizations, and businesses—whose generous financial contributions helped make possible both the Colloquium and publication of this report. Their names are listed on the inside front and back covers of the report.

Second, Health Lawyers sincerely thanks the members of the Colloquium panel. Their willingness to take time from their busy schedules to participate in an intensive one-and-one-half-day discussion is deeply appreciated. Their knowledge, energy, and spirit of cooperation produced the thorough, nonpartisan examination of medical necessity issues that is summarized in this report.

Health Lawyers extends a special thank-you to Gerald R. Peters (Latham & Watkins LLP), for his skill in facilitating the Colloquium discussion. Jerry is a past member of the Public Interest Committee and a Health Lawyers Fellow, a designation established in 2004 to recognize life-long leaders of the Association.

To provide a common basis for the Colloquium discussion, Health Lawyers researched and wrote a background paper on medical necessity (see Appendix A) that panelists received in advance of the Colloquium event. We owe a huge debt of gratitude to the task force of experienced Health Lawyers members who developed the issue paper. These individuals are: David Abelman (Tufts Associated Health Plans, Inc.), Dennis M. Barry (Vinson & Elkins LLP), Timothy P. Blanchard (McDermott, Will & Emery), Donna Z. Eden (Law Offices of Donna Z. Eden), Harvey M. Tettlebaum (Husch & Eppenberger, LLC), Thomas E. Bartrum (Waller, Lansden, Dortch & Davis), Katherine Benesch (Duane Morris, LLP), James P. Kelly (Kelly Law Firm, PC), David E. Matyas (Epstein, Becker & Green PC), and Adele A. Waller (Barnes & Thornburg). Two Health Lawyers members offered their time on an ad hoc basis to ensure the quality and editorial excellence of the issue paper: Margaret M. (Peg) Manning worked closely with Tim Blanchard to draft and format several iterations of the issue paper for review by the task force. Joel M. Hamme (Powers, Pyles, Sutter & Verville PC), chair of Health Lawyers’ Practice Groups Committee, graciously volunteered to review the issue paper from the standpoint of organization of the information, readability, and clerical accuracy. A most sincere thank-you is extended to Peg and Joel for their important contributions.

Appreciation also goes to Health Lawyers’ Board of Directors and, in particular, the members of the 2004–2005 Public Interest Committee: Timothy P. Blanchard (McDermott, Will & Emery), Elise Dunitz Brennan (Doerner, Saunders, Daniel & Anderson LLP), Almeta E. Cooper (Ohio State Medical Association), Donna Z. Eden, (Law Offices of Donna Z. Eden), Philip L. Pomerance (Arnstein & Lehr), Richard L. Shackelford (King & Spalding), and Adele A. Waller (Barnes & Thornburg LLP). The Committee’s technical oversight of the Colloquium and Colloquium Report entailed months of discussion and planning to bring this important public interest initiative to completion.

Finally, Health Lawyers acknowledges and thanks our association staff, whose interdepartmental teamwork was essential to the success of the Colloquium and publication of this report. Special thanks are extended to Joseph A. Kuchler, Director of Public Interest and Public Affairs and project director of the Colloquium, for working closely with me in editing the final draft of the issue paper on medical necessity and for his exceptional skill in distilling the wide-ranging, one-and-one-half day Colloquium discussion into the summary and findings that are the focus of this report. Health Lawyers also sincerely appreciates the design and production support provided by Mary Boutsikaris, Art Director/Graphic Designer, and the numerous contributions of Ana Mayer, Public Interest Department Administrative Assistant, in planning the Colloquium event.

With sincere appreciation,

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Medical Necessity: Current Concerns and Future Challenges

March 31—April 1, 2005
Washington, DC

Colloquium Topic Selection Criteria

The topic selected for a Health Lawyers’ Colloquium must be one that:

- Is in the public interest or has a charitable component;
- Has a clear legal nexus;
- Is timely;
- Draws diverse constituency participation; and
- Is practical.

Colloquium Objectives

To provide a neutral forum that provides a frank exchange of views and analyses among various constituency groups with differing, and sometimes adverse, points of view. To explore the basis for these differences and identify ways and means of accommodating the differences in the course of pursuing their respective missions to serve the public interest.

To crystallize the intersection of policy, business, and regulatory issues in an effort to have a constructive impact on the substantive debate over these issues.

To create opportunities for representatives of different groups to identify shared goals and interests and to develop potential collaborative working relationships.

To publish a report based on the findings of the Colloquium. To disseminate the report to Health Lawyers members, participating constituency groups, policy and law makers, academicians, and others in order to educate key players in the debate and those who are charged with advising clients on these matters.

To provide an environment throughout the Colloquium that allows for the free exchange of views and articulation of tensions while preserving confidentiality and appropriate anonymity for Colloquium participants in the written report.
Question 1:  
What are the key concerns of the following stakeholders with respect to public and private policymaking/rulemaking processes for medical necessity determinations as they are conducted today:  
(a) Patients/consumers;  
(b) Physicians and other healthcare practitioners;  
(c) Institutional providers and healthcare systems;  
(d) Payors and Risk-Pool Stakeholders: Government Healthcare Programs, Private Health Plans, Employers, and Individuals

Question 2:  
What are the key characteristics of an ideal system for public and private policymaking/rulemaking processes for medical necessity determinations? Is there a better rulemaking model?

Question 3:  
What are stakeholders’ key concerns with the public and private adjudication processes for challenges to medical necessity determinations, with an emphasis on the interpretation and application of medical necessity rules?

Question 4:  
What are the key characteristics of an ideal system for the public and private processes of adjudicating challenges to medical necessity determinations, with an emphasis on identifying better ways to interpret and apply the rules governing adjudications?

Question 5:  
What points of consensus and points of disagreement emerged from the overall discussion at Health Lawyers’ 2005 Colloquium, Medical Necessity: Current Concerns and Future Challenges?
The 2005 Colloquium began with a warm welcome and introduction from the chair of Health Lawyers’ Public Interest Committee. The chair explained Health Lawyers’ non-partisan public interest role, remarked on the importance and timeliness of the Colloquium topic, and reviewed the time frames and ground rules for the discussion. She emphasized that Health Lawyers sought to establish an impartial atmosphere and maintain a non-partisan stance in all aspects of the 2005 Colloquium— the expert panel’s facilitated discussion, the published report that would summarize the Colloquium discussion and findings, and the issue paper on medical necessity. The principal concerns of stakeholders that emerged from the panel’s discussion are summarized below.

### Patients

The discussion of patients’ concerns generated one of the recurring themes of the colloquium discussion, that policies governing medical necessity, and the application of medical necessity in specific healthcare situations, need to be patient-centered. As a health industry representative expressed it, “At the end of the day, patients and families and significant others are looking for peace of mind—that ‘I did the best I knew how to do.’ But healthcare is so complex that people often don’t know if they’re doing the right or the best thing.” The panel agreed that consumers want access to clear coverage information that is backed by a simple, fair, prompt, and transparent system for coverage policies. Given the opportunity, most patients will want to discuss treatment options and participate in care decisions that have medical necessity implications. The healthcare system and policymaking processes currently are not structured to empower consumers in this fashion, however. Further, opportunities for individual consumers to influence the rulemaking process are limited. A number of national, state, and local organizations advocate on patients’ behalf, but, as a panelist from one such organization explained, “Many consumer groups do not have the financial resources that, perhaps, enable some provider groups to play an effective, ongoing role in the process of designing [medical necessity] rules.”

“At the end of the day, patients and families and significant others are looking for peace of mind—that ‘I did the best I knew how to do.’ But healthcare is so complex that people often don’t know if they’re doing the right or the best thing.”

—A health industry representative

### Physicians

The discussion of patients’ concerns flowed logically into the important role physicians should play in helping patients make treatment decisions that have medical necessity implications or in appealing claims that have been
Physicians are motivated by their training, professional code of ethics, and licensure requirements to make medical decisions that are patient-centered. A physician panelist noted that in their daily encounters with patients, physicians are motivated not so much by the familiar dictum, “first, do no harm,” as by their desire to “do the right thing for every patient every time.” A policy analyst expressed physicians’ frustration with “medical necessity” as a perceived loss of control over medical decisions. “I think physicians feel that they used to own medical necessity, but they’ve lost that ownership. They owned the control of the term and how it was applied, because it was applied by physicians with relatively little oversight by plans,” the panelist asserted.

Physicians and other healthcare professionals also are frustrated by the financial losses that result from claims that are denied on the basis of medical necessity. They have invested substantial time and money in education and training and have a reasonable expectation of being paid for services rendered. Vague or non-existent medical necessity standards, inadequate guidance, and, ultimately, adverse medical necessity interpretations interfere with patient-physician relationships and threaten a physician’s ability to practice in a manner that the physicians and other practitioners find professionally rewarding and financially satisfactory.

Physicians worry that, in some instances, adverse claims processing determinations and retrospective audit findings may expose them to unwarranted but potentially devastating allegations of false claims and fraud.

Physicians generally view the process of appealing medical necessity decisions as repetitive, complex, and frustrating.

Institutional Providers and Health Systems

Nonprofit and for-profit institutional providers are committed to serving their communities and operating in a manner that generates operating margins or profits that allow them to carry out their mission. With respect to medical necessity determinations, these providers feel vulnerable to accusations of fraud and abuse violations with respect to their maintenance of utilization review processes and medical staff discipline. As one participant explained, “Increasingly they feel called on to be the policemen on medical necessity, and that’s a new role that puts additional pressure on their credentialing processes and their medical staff discipline and so forth. It’s a role providers may not be suited for, but they fill it, often without having input into the rule-making that they need [to oversee compliance-related activities].”

In the past, hospitals were exposed to relatively minor regulatory sanctions regarding their maintenance of utilization review processes and medical staff discipline. In recent
years, however, hospitals have been investigated and penalized with both civil and criminal sanctions for allegedly failing to conduct these activities or otherwise take appropriate action to prevent the provision of, and billing for, services that are not reasonable and necessary.

Payors and Risk-Pool Stakeholders: Government Healthcare Programs, Private Health Plans, Employers, and Individuals

Government healthcare programs, health insurers, managed care organizations, and other payors and risk-pool stakeholders have a fiduciary responsibility to administer their programs and plans in a manner consistent with the law, governing plan documents, the rights of the insured, and the interests of policy holders. Their interests with respect to medical necessity include:

- Assuring access to beneficiaries and enrollees at reasonable rates;
- Balancing fiscal responsibility with fair payment for services;
- Monitoring utilization to achieve appropriate access to and provision of healthcare services;
- Establishing procedures to address high cost treatments whose benefits are unclear, including emerging technologies, sexual-dysfunction and other “lifestyle” drugs, and complementary and alternative medicine (CAM). (For a discussion of CAM and medical necessity, see Appendix B.)
- Maintaining a cost-effective appeals process that is not so porous that medically unnecessary services are approved.
- Minimizing fraud and abuse activities and “gaming” of the system; and
- Maintaining the public health (considered primarily a government function).

Employers are concerned both with holding down healthcare costs and acting as advocates for their workers with respect to coverage and medical necessity. They desire more information on how medical necessity decisions are made and current information on the medical effectiveness of various treatments and procedures.

Individuals (that is, the public) want to know that government programs and private health plan contracts are being administered according to rules that are “fair” and rational, that health benefits to which they are entitled (by law or by contract) will be there when they need them, and, generally, that “things are being done properly.” Individuals have dual identities with respect to medical necessity, however. Any citizen is both a potential patient and a payor, either as a taxpayer or through his or her own out-of-pocket payments for healthcare. As payors, they are concerned about unnecessary surgeries and other examples of overutilization. When care for themselves or their loved ones is involved, however, they have an understandable tendency to regard suggested treatments or procedures as appropriate.

During the discussion, a private plan representative cautioned against assuming that the tension between providers and health plans regarding utilization “means that somehow people are accusing each other of nefarious activity. That is not the case.” Rather, the concept of medical necessity has developed over the course of time as an “inevitable result” of a system where, on the one hand, consumers' faith in their physicians “results in overcare” while, on the other hand, payors seek a mechanism to control overutilization in an economic sector that does not respond to normal market forces. A physician representative agreed that, “We should be careful not to conclude that we can draw a line down the middle of the street and medically necessary care is on one side and medically unnecessary care is on the other.”

—A physician representative
can draw a line down the middle of the street and medically necessary care is on one side and medically unnecessary care is on the other.”

A federal agency panelist stressed that the government’s interest is to promote high quality care, that is, care that is safe, effective, efficient, timely, and patient-centered. Achieving that involves educating both providers and patients on the latest findings with respect to quality of care.

A policy researcher raised the issue of using cost effectiveness in determinations of medical necessity. Another panelist noted that a number of state Medicaid programs’ include cost effectiveness in their definitions of medical necessity, but Medicare is precluded from considering the cost/benefit tradeoffs of new treatments. “So, for government programs,” the panelist said, “it is interesting that for the aged [under Medicare], we can’t talk about costs, but we can for the poor [under Medicaid].” A physician representative maintained that cost does enter into Medicare decision making through local decisions by carriers and fiscal intermediaries that approve the most cost effective course of treatment when two or more treatments are judged equal from a quality perspective. A government representative stressed the need for flexibility. For Medicaid, which provides care at the local level, “Cost is a relative concept, it reflects a local population’s desires and what they’re willing and not willing to pay for. Cost is always on the table because taxpayers are concerned about it. What we really need to be focused on is effectiveness and that is where the whole debate about quality comes into play and where we need to empower our local physicians, and especially independent practice physicians, with the information they need for better decision making.”

A policy analyst observed that Medicare generally is viewed as more accountable to the public than private sector firms. Private firms will play a major role in the implementation of the new Medicare Part D prescription drug benefit, however, and the question arises, “since Medicare will be paying for services provided under Part D, should these private drug plans be required to have [for medical necessity determinations] the types of open process and transparency that we emphasize so much in the national fee-for-service program.”
The agenda next moved to a dialogue on the principal characteristics of an ideal public and private policymaking/rulemaking system for medical necessity determinations. “This topic,” the facilitator stated, “is the heart of the Colloquium discussion. What improvements can we suggest to policymakers; how can we make a better system?” He opened with the question, “Can there be a unified solution, or is the nature of public versus private so different that you can’t implement a unified approach?” That question dominated the rest of the first morning of the Colloquium, with the panel discussing the strengths and weaknesses of a national versus local approach within the context of the patient-centered philosophy that everyone earlier agreed must be the cornerstone of an ideal policymaking/rulemaking system for medical necessity determinations.

Topics that arose within the discussion included:

- Engaging key constituencies in the development of a unified public/private system;
- National rulemaking versus local standards, including the need for flexibility at the local level in implementing national standards or guidelines and the most appropriate way to involve consumers and the private healthcare sector in the development of medical necessity guidelines and their own care decisions;
- The role of science in medical necessity determinations;
- Cost effectiveness as a consideration in medical necessity determinations; and
- The question of whether the rulemaking system governing medical necessity determinations is “broken” and, if so, how it should be fixed.

Engaging Key Constituencies in Developing a Unified Public/Private System

In response to the facilitator’s opening question about whether the ideal system would be a unified public/private approach, one panelist cited hospice care as an example of “a system in which the values and motivations of the patient, the payors, the professionals that deliver the service, everybody seems to be in line. The rules are written to support the patient, the client, within the context of the family.”

A researcher employed by a private firm called for “more input by all the stakeholders in an upfront process of determining [medical necessity].” Organizations representing the constituencies would act as proxies for their individual members, “but you would have millions of people involved—something we don’t have now.”

Employers, the speaker noted, are an example of organizations that are starting to recognize the role of medical necessity and are acting as proxies for their workers. “There will never be enough employee input into this issue. So employers become proxies who act on behalf of the workers that they insure.” Another panelist later suggested using polls and focus groups to solicit consumers’ views.

“There will never be enough employee input into this issue. So employers become proxies who act on behalf of the workers that they insure.”

—A health policy researcher

A panelist from a consumer group underscored the importance of patient input but noted that it often is difficult to get individual consumers to participate in the regulatory process.

“The challenge for state and local governments,” another panelist stated, “is to create an infrastructure that accommodates the uniqueness of local situations and empowers local physicians and patients to make some decisions on their own.” A Health Lawyers participant asked “Do those local market variations relate to medical necessity or do they fall under questions of benefit design, benefit categories, and exclusion types of issues?” The panelist replied, “It’s all interconnected.”

A researcher who has focused on treatment patterns suggested that medical necessity criteria potentially
could be linked to requirements for quality improvement and a requirement that patient preference be the driving force in situations where there is a choice of treatments with trade-offs. “This might be a way, then, of evolving a system that could actually understand what medical necessity is over time,” the speaker asserted. He gave the example of early stage breast cancer where the options for treatment are mastectomy, lumpectomy, or radiation. He noted that physician preferences are different for each of these options. The issue gets even more complex for other diseases like prostate cancer where there are different treatment choices but we do not yet know the long term outcomes, the panelist explained.

The researcher further explained that the ideal approach he envisioned would be an interconnected model built upon communication between physicians and patients about the latest research on a patient’s treatment options and the patient's involvement in the treatment decision based on discussion with his or her physician. The panelist commented, “The unified rule I would like to see would be very hard to implement, but under it patients would be offered full information on treatment choices [that fall within a health plan’s coverage standards], and when they don’t know what they want, they would receive the least expensive one. But patients should not be offered treatments for which there is basically no evidence that it works, although I would make the exception for PSA [prostate screening] and other things that get introduced into the marketplace.” Decisions would not be dictated by numerical analysis, however. The speaker explained, “Rather, the process of shared decision making and informed patient choice, as I like to call it, has to be built into the system of care as part of our way of assuring that medical necessity is based on the patient’s point of view.”

### National Rulemaking Vs. Local Standards

The facilitator next polled the panel on the question, “Should there be a national process, a rule-making process that is a standard for both payors and the private sector? Or should there be separate processes?” Opinion was divided on the question. Most of the panelists recognized that national rulemaking would provide consistency and would carry the weight of regulatory authority, but several speakers expressed concerns that national standards would not provide the flexibility needed by payors at the local level or by physicians and patients in making treatment decisions. Highlights of the discussion are presented below.

A consumer representative called for medical necessity guidelines rather than rules. “With an inflexible national rule you immediately create constituencies on opposing sides. You lose consumers because they feel that there is no individual flexibility. You lose the physician community, you lose the local policymakers such as Medicaid officials. The [more inflexible] the rule, the more you close the minds of the various stakeholders from whom you want buy-in.”

“The challenge for state and local governments is to create an infrastructure that accommodates the uniqueness of local situations and empowers local physicians and patients to make some decisions on their own.”

—A government official
“With an inflexible national rule you immediately create constituencies on opposing sides. You lose consumers because they feel that there is no individual flexibility. You lose the physician community, you lose the local policymakers such as Medicaid officials. The [more inflexible] the rule, the more you close the minds of the various stakeholders from whom you want buy-in.”

—A consumer representative

A physician panelist pointed out that Quality Improvement Organizations have developed local guidelines that are used to screen cases for physician review. “Whether the review is for quality [of care] or for utilization, that is, medical necessity, those cases are screened and sent out to physicians for peer review. There is a system used for medical necessity that works, and it is local,” the speaker stated.

A payor representative expressed skepticism about national guidelines and emphasized the value of consumer choice. “I’m not a hundred percent convinced. I believe that guidelines become rules and standards of care in the courts, so I’m not sure what a debate on guidelines versus rules achieves. Another issue is that different rules, different processes, different guidelines come with different costs. On the private side, at least, I believe there is value to providing alternatives to consumers so they can decide to pay more or pay less and they get different packages of care as a result. I think that’s a good thing.” The speaker acknowledged the value of consistent guidelines or standards for government health plans, however. “You may want one set of rules [for government plans] so there’s consistency across the country, so that all taxpayers are treated alike,” the speaker concluded.

A consumer representative expressed support for national rules that prohibit payment for services that have been shown not to be medically necessary, “but I would caution that national rules should not inhibit innovation and development of new treatments.”

A government agency representative endorsed the idea of national rulemaking: “I believe there needs to be some sort of national policy setting process and that there should be evidence of effectiveness, that the benefits outweigh the harms for [the treatments and procedures] that we deem medically necessary. I don’t believe that at the local level people have the resources to determining that across the board.” The speaker stressed the need for communication to physicians and patients, “so that if we develop national recommendations for various therapies, that information actually gets used.”

A researcher and consultant asserted that a “centralized and mandatory” system is needed to address the “patchwork” of policies that are in place. “Because it isn’t mandatory, we end up with all these variations. From a consumer’s point of view, it is outrageous that you could be a member of United Healthcare and they’ve decided that something’s effective or medically necessary for you and somebody in the Aetna plan doesn’t get that treatment—and yet, the evidence [on effectiveness] may be the same.” At the same time, the speaker concluded, “I’ve seen [national] bodies come and go that attempted to gather evidence and be the authoritative source and then get defunded or disappear for one reason or another. So I think it’s very difficult to develop centralized, consistent policies in this country.”
The academician who earlier suggested an integrated model based on empowering physicians and patients (by providing current research information about the patient’s treatment options) suggested that government seek to influence medical practice through economic incentives to ensure that physicians who wish to follow “best medicine” guidelines “actually get paid to do that. Right now, it’s not that way at all.” The speaker continued, “I’m not talking just about rewarding physicians who provide [known] effective treatments like diabetic eye screening and so forth, I’m talking about [rewarding] physicians who conscientiously bring the patient into the equation for decision making . . . . And finally, I believe the real explanation of variations in per capita costs across Medicare has nothing to do with evidence-based medicine at all; it’s related to how frequently doctors see patients with chronic illness and that has to do with how many doctors work in a given market. So you see the complexity of trying to iron out variation. Information is one small piece of it, an absolutely essential piece of it, but there’s a lot more work to be done at the problem assistance level and the capacity of the system. So we shouldn’t assume that we can solve all these problems with one single strategy.”

**The Role of Science in Medical Necessity Determinations**

Several panelists emphasized that ensuring that all guidelines or standards are grounded in sound medical science would be an essential element of an ideal system for making medical necessity determinations. A healthcare provider representative expressed the challenge as “How do we create a new medical necessity system that’s based on science and where new information is widely disseminated, so people will say, ‘Yes, that makes a lot of sense and I feel good about [a given medical decision]’?” The panel expressed strong support for ensuring that medical necessity guidelines are based on sound science but acknowledged that this will need to be achieved over time as research on medical effectiveness grows and dissemination of the latest findings to the medical community and payors is streamlined and accelerated.

An academician stated, “I have less faith that [centralized] rules and guidelines will accomplish the ultimate objective, which is to ensure that medical necessity is determined on a scientific basis and that the care that you get is scientifically based. . . . I believe the [national] role should be the gathering of evidence, facilitating research, and disseminating the fruits of research and consensus. But we’re a pluralistic society and we have a lot of views and a lot of people who have different views, and I think a centralized guideline and rulemaking process is doomed to failure. I’m convinced that Medicare would be out of business if we had started with national coverage decisions in 1967, rather than the decentralized, pluralistic way in which the program has proceeded.”

**Cost Effectiveness as a Consideration in Medical Necessity Determinations**

The panel acknowledged that the question of what role, if any, cost effectiveness should play in medical necessity determinations has important policy implications. A researcher/business consultant broached the topic during the opening discussion on key constituencies’ interests and concerns. The panelist noted that

> “How do we create a new medical necessity system that’s based on science and where new information is widely disseminated, so people will say, ‘Yes, that makes a lot of sense and I feel good about [a given medical decision]’?”

—A health industry representative
Characteristics of an Ideal Policymaking/Rulemaking System for Medical Necessity Determinations

a number of state Medicaid programs include cost effectiveness in their definitions of medical necessity, but that Medicare is precluded from considering the cost/benefit tradeoffs of new treatments.

The topic of cost effectiveness was not directly addressed in the discussion of an ideal system for rulemaking, but several panelists interjected noteworthy comments. In calling on the Medicare program to issue “a better definition of the criteria for decision making on coverage rules,” a consumer representative stated, “One of the reasons this debate about cost effectiveness is such a problem is that Medicare has never been willing to address the issue. It’s very controversial, of course, but in the absence of rules that identify the factors that go into coverage determinations, [the cost effectiveness element can’t be determined].”

In response to the facilitator’s question, “How can we make sure that the right thing is done for every patient? Is there an economic factor to that?,” a physician representative replied, “There’s an economic factor only in this sense: if there are two equal treatments, certainly the least expensive should be chosen.” The speaker also noted that economic considerations contributed to some Medicaid programs’ initial decisions not to pay for heart transplants, “but I think gradually, that’s been overcome and, at least in our state, they have realized that [heart transplants] are an appropriate, reasonably safe, and worthwhile procedure.”

Is the Rulemaking System Broken and, If So, How Can It Be Fixed?

The facilitator next asked the panel, “How broken is the current rulemaking system? I’ve heard suggestions about establishing medical necessity guidelines, or perhaps national rules, but not a lot of, ‘It’s broken, and here’s what we need to do to fix things.’” The facilitator clarified that for purposes of the Colloquium discussion the term “rulemaking” would be used as shorthand for policymaking or the general standards and criteria that govern medical necessity determinations, in contrast to the application of medical necessity to individual healthcare cases.

A physician representative suggested there really is no coherent national system for determining medical necessity and hence nothing to focus on as ‘broken.’ He suggested that the panel look upon the discussion as “an opportunity to build something.” That “something” is to empower physicians by “concentrating on the physician-patient relationship as being the key, individual people as being the key—and build from that.” A key regulatory change, the speaker suggested, would be “to improve the reimbursement of primary care physicians and primary care services so that it’s not lost money for physicians to take enough time to [explain treatment options and potential consequences].”

A panelist who is both a researcher and a physician commented that “rulemaking processes for medical necessity as they’ve evolved are largely irrelevant to current problems in the U.S. healthcare systems.” The remedies suggested by the previous speaker “in reality do not relate to medical necessity rulemaking, they have to do with the whole process with which healthcare is delivered.” The panelist argued for a solution under which “necessity has to be defined in terms of patient preferences [within a health plan’s covered services], not committees who decide what they need.”

The facilitator then asked the panel, “So, it appears that the answer to stakeholders’ concerns is bigger than just the rulemaking process. Is that correct?” A panelist who represents institutional healthcare providers replied, “Yes, an image that comes to mind is that baseball umpires are on the field, debating about whether the strike zone should be moved a little bit—and actually the whole stadium is on fire. So, if you’re asking, can the rulemaking process be used to transform the system, starting with using scientific evidence to develop standards for medical necessity, yes, that’s a fundamental question. And can it start with rulemaking? I think it can. But that’s the strike zone, and while it’s worth talking about, I believe there are bigger issues here.”

A payor representative expressed the opinion that there is “tremendous physician dissatisfaction” in healthcare generally and, to the extent that medical necessity rules contribute to that, then “it would be a positive thing if we could develop processes that engage physicians and empower them,
“I would like to ensure that health plans that have posted [medical necessity] information on their Web sites inform the public, so consumers could review that information and better understand the rules.”

—A health policy researcher

and you would still protect the risk pool on the payor side.”

A researcher said the “brokenness” of the current medical necessity process is “one of the most relevant issues [in the Colloquium discussion].” She called for educating the public on “how the process works, how coverage and medical necessity decisions are made at the broader level and at the individual level.” The speaker noted that information about medical necessity criteria is posted on many health plans’ Web sites and is accessible to the public by clicking on the “provider” section of the site. “I would like to ensure that health plans that have posted [medical necessity] information on their Web sites inform the public, so consumers could review that information and better understand the rules,” the speaker concluded.

An academician stated that process is important, “but has limitations.” Today there is far more openness about medical necessity decisions, but that has not brought greater satisfaction with the medical necessity process. This speaker suggested that “the problem lies with the criteria for making [medical necessity] decisions and there’s not yet any consensus on the factors that need to be taken into account in making those decisions.” Prompted for specific changes, the speaker noted that reducing the time required for decisions is important, including addressing concerns about the amount of evidence needed to make a decision. The major concern is “what are the criteria, and that’s where we need a real debate with all the stakeholders.”

A Health Lawyers participant suggested that given the trend in benefits toward high-deductible plans, and the availability of individually funded health savings accounts (HSAs), consumers would “begin voting with their feet and start making decisions on what they need.” Focusing on the rulemaking process might be “putting the cart before the horse—what’s really needed is to provide information to patients so that [through discussion with their physician], they can start making decisions on what they need, including what’s economically feasible for themselves, since they’re starting to pay from their own pocketbooks.”

A researcher noted that the role of high deductible plans and HSAs would depend on “what is the target of ‘medical necessity’ at a given moment.” Immunizations, for example, are routinely viewed as medically necessary. With respect to treatments for chronic conditions, however, “anybody’s health savings account will be wiped out in the first few months of treatment, and they’ll be susceptible to whatever forces determine the distribution of healthcare resources to the patient cohort to which [the individual] belongs.” The speaker saw a potential role for HSAs in cases of “preference-sensitive” care decisions where patients have treatment options. “In those cases, applying a high deductible conceivably might sharpen the preference argument.”

The same panelist noted that the discussion often seemed to equate benefit design with medical necessity decisions. He stressed that “You need to be precise in discussions of medical necessity in terms of the different categories of services. For example, if the subject is an effective care measure—such as administering a beta blocker after a heart attack—for which there is evidence that it works and there are no trade-offs, then the medical necessity decision should be rule-driven to ensure that anyone who needs [a beta blocker] receives one. On the other hand, patients
who are facing elective surgery face a very different set of issues [with respect to medical necessity].”

Picking up on the previous speaker’s comment about not confusing benefit design with medical necessity determinations, a payor representative provided this clarification, “A system for determining medical necessity should not be equated with mandated coverage. A health plan still should have the option of stating what they will cover and what they won’t, and consumers should have the option of what they want to buy. So just because [a procedure or treatment] meets medical necessity criteria doesn’t mean that for any given plan, it will be something that is offered for coverage.”

A government agency representative suggested that an important element of an ideal system would be a sun-setting provision under which procedures that were deemed, or not deemed, medically necessary would be periodically reviewed and updated. “Evidence certainly changes over time; new technologies come along. So what’s medically necessary today may not be medically necessary five years from now or vice versa. Accordingly, there should be a mechanism of periodically reviewing procedures and treatments in terms of medical necessity.”

“A system for determining medical necessity should not be equated with mandated coverage. A health plan still should have the option of stating what they will cover and what they won’t, and consumers should have the option of what they want to buy.”

—A payor representative
Special Presentation and Discussion: Practice Variation and Medical Necessity

**Speaker:**

John E. Wennberg, MD, MPH
Director, Center for the Evaluative Clinical Sciences
Peggy Y. Thomson Professor for the Evaluative Clinical Sciences
Dartmouth Medical School
Hanover, NH

After lunch the facilitator introduced John E. Wennberg, MD, MPH, physician and an epidemiologist, for a special presentation and discussion with the panel on his research on unwarranted variations in medical treatment—and the potential for applying certain findings from that research to the development of a broad policy approach to addressing medical necessity. The panel discussed both Dr. Wennberg’s findings and an innovative proposal he subsequently offered that would link his research to the Colloquium panel’s evident interest in policy changes that would forge a partnership between patients and physicians in making treatment decisions with implications for medical necessity determinations.

This article summarizes Dr. Wennberg’s luncheon presentation as well as the panel’s discussion of his innovative proposal. That discussion mostly occurred during the session that immediately followed his presentation. (See, “Stakeholders’ Concerns with the Medical Necessity Claims Adjudication Process—and Suggested Solutions,” on pages 17-20.) Recognizing that time did not permit a full discussion of Dr. Wennberg’s concept, a Health Lawyers leader suggested at the end of the Colloquium that the Public Interest Committee work with him to further develop the proposal in the months ahead and to share that work with the Colloquium panel. Dr. Wennberg graciously agreed.

**Dr. Wennberg’s Presentation**

Dr. Wennberg and his colleagues at the Center for the Evaluative Clinical Sciences have developed the Dartmouth Atlas Project (“Atlas”), an ongoing study of the patterns of practice for beneficiaries enrolled in traditional fee-for-service Medicare. The Atlas is the culmination of fifteen years of research on the variations in medical treatment provided among 306 “hospital referral regions,” which are aggregates of smaller hospital service areas (see Exhibit 1).

Dr. Wennberg explained that researchers at Dartmouth have defined three major categories of medical services as a useful way of viewing unwarranted variations in treatment. Variations are judged “unwarranted” if they cannot be explained on the basis of illness, patient preference, or evidence-based medicine. The three categories can be distinguished on the basis of the relative importance of four factors in clinical decision making: medical evidence, clinical theory, patient preferences, and the local supply of healthcare resources. The categories of unwarranted variations in medical treatment are effective care, preference-sensitive care, and supply-sensitive care.1 Dr. Wennberg explained each category as follows:

**Effective Care**

This category refers to services whose use is supported by well-articulated medical theories and by strong evidence of efficacy in the form of randomized clinical trials or well-conducted cohort studies. There are no trade-offs for effective care—the benefits far exceed the risk. “These are the kinds of things that you could write rules about,” Dr. Wennberg explained. “If everybody has X they should get Y. If they have a heart attack, they should get a beta blocker. Or, if they’re in a certain age group, they should get an immunization.”

**Preference-Sensitive Care**

This category refers to services in which the medical decision involves a choice between at least two treatments with differing risks and benefits. Sometimes, the options are supported by strong evidence of efficacy. Examples include, Dr. Wennberg explained, whether to perform a lumpectomy or a mastectomy for breast cancer patients, or, in the case of certain non-cancerous prostate conditions, whether to carry out procedures where the trade-offs may be incontinence or loss of sexual function. Sometimes, the treatment decision must be made in the face of considerable scientific uncertainty about the outcomes of care—for example, the choice of surgery or conservative management for low-back pain.
Supply-Sensitive Care

This category refers to services that increase in frequency when the number of providers increases, but are not associated with any improvement in healthcare outcomes. A prime example in this category, Dr. Wennberg explained, is the number and frequency of office visits a physician may schedule for patients with chronic conditions such as congestive heart failure.

Dr. Wennberg suggested that the solution to unwarranted variations differs for each category of service and that the debate on medical necessity should be framed in terms of the systematic underuse of effective care, misuse of discretionary surgery, and overuse of supply-sensitive care.

Underuse of effective care needs to be resolved by assuring that all those in need of such services receive them. When there is strong evidence of the best practice, this practice should be the benchmark for medical necessity determinations.

For preference-sensitive care, where treatment options involve significant trade-offs that should be based on the patient’s own values, the determination of what is medically necessary for a particular patient should be based on the patient’s decision after an informed patient choice process. “To the extent that informed choice could become part of the medical tort system, it could accelerate the transformation of everyday practice in preference-sensitive care to the patient’s advantage,” Dr. Wennberg said. Preference-sensitive cases account for approximately 30 percent of Medicare expenditures.

The process of informed patient choice in a given care setting should be well defined, transparent, and subject to review. Patient decision aids must meet external standards to ensure that they (1) are evidence-based, (2) are up-to-date, (3) promote values clarification, and (4) provide information on all relevant treatment options including explicit identification of...
areas of significant scientific uncertainty and controversy. The quality of the informed patient choice should be evaluated and reported, using appropriate patient decision quality measures.

The informed patient choice process would be certified or accredited to ensure that the process adequately incorporates the patient’s values and provides information on all relevant treatment options, including explicit identification of significant scientific uncertainty and controversy. A health plan can define which treatment options will be covered and can establish differential co-payments for more expensive treatment options, and this information is material in the informed patient choice process.

Under informed patient choice, Dr. Wennberg stated, the role of the physician is to provide accurate information describing the “dilemma of choice” the patient faces and to encourage the patient to participate actively in the choice. This differs from the traditional standard of informed consent under which the physician makes the decision and obtains the patient’s consent. The key to building a more rational decision process, Dr. Wennberg explained, is the systematic use of patient decision aids. These are methodologies in which evidence-based scenarios are used to describe treatment options to the patient, who reflects on them and chooses one that comports with his or her value system.

Dr. Wennberg’s research has found that once patients are involved in the decision process, they often select a more conservative treatment than the option proposed by the physician. After completing the informed patient decision process, if the patient is still uncertain about which alternative to select, then the least expensive and least invasive alternative would be prescribed, he suggested.

The third category of care, supply-sensitive care, accounts for at least 50 percent of medical spending and is primarily provided to people with chronic illnesses. The level of spending on these conditions reflects the frequency of physician visits, hospitalizations, stays in intensive care units, referrals to specialists, and the use of imaging and other diagnostic tests. Dr. Wennberg’s research has found remarkable variations in the frequency of the use of these services among regions. He stated that medical evidence does not play a significant role in governing the frequency of use of supply-sensitive services; rather, variations exist due to the general assumption that more healthcare is better—that available resources should be fully utilized in managing chronic illness.

Research by Dr. Elliott Fisher and other Dartmouth scientists has found that more care is not necessarily better care. Populations of chronically ill patients who are treated more aggressively do not live longer or have improved quality of life. Thus, healthcare organizations with lower treatment intensity are more efficient. Dr. Wennberg’s proposed solution to variations in supply-sensitive care includes making available to employers and insurance companies information on the relative efficiency of specific healthcare organizations and physicians in managing chronic illness. Access to that information may stimulate payors to seek efficient hospitals and physicians for their provider networks. Thus, medically necessary care for the supply-sensitive category is care that corresponds to the benchmarks established by efficient healthcare organizations such as the Mayo Clinic or Intermountain Health Care, Dr. Wennberg explained.

Discussion with the Colloquium Panel

Building on the notion that patients and providers need more information both to understand medical necessity criteria and to make informed decisions when two or more courses of treatment are available, Dr. Wennberg later suggested a novel approach based on the findings in his presentation and the panel’s clear interest in changes that would establish a partnership between patients and physicians in making treatment decisions. He said, “I want to propose a new Medicare coverage rule, and this is for preference-sensitive conditions, that runs as follows. Generally, there would be no payment for discretionary surgery [or other discretionary treatments] unless the patient has selected that procedure through an informed decision process, a certified, informed patient decision process. . . . [The outcome then would be] that medical
necessity could be defined in terms of the informed patient’s decision, which is a very different concept than the idea that there is a set of things for which you put in the benefit package, because that will only work for treatments in the effective care [category]. Once there are trade-offs [as is the case with the preference-sensitive set of procedures], we have to address the decision process about what patients want.”

The panel explored Dr. Wennberg’s suggested model with considerable interest and raised a number of important considerations, including:

■ A physician representative endorsed the model if the “certified informed patient decision process” were changed to an informed patient decision process that was attested to by an “independent witness” such as a friend or family member.

■ A representative of employers suggested that the proposal include reimbursement for providers. “If we move to a system of informed choice and want to encourage providers and physicians to participate, we need to compensate them for that.”

■ In response to a question about how experimental treatments would be handled, Dr. Wennberg advocated the use of decision aids and informed decision making by patients about participating in clinical trials or off-label drug-based treatments. He explained, “We keep coming back to the question about experimental treatments. [In New England,] we’ve had some very interesting experiences with our decision aids in enrolling patients into clinical trials, particularly our large multicare clinical trial on back surgery, versus conservative medical management. The strategy has been to use a ‘decision aid,’ which lays out what’s known and not known about the problem and then asks the patient whether they would like to be enrolled in the clinical trial. If they say no, they are followed up as an observational study. If they say yes, they’re randomized in the classic way, and that’s really important in teasing out the external and internal validity problems, particularly in cases where patient preference is involved.”

Several panelists expressed caution about the impact of the suggested model on healthcare costs. A policy analyst asked how Dr. Wennberg’s model would constrain overutilization. He responded by emphasizing that the informed patient choice model is constrained by careful appeal to medical evidence; patients are not offered treatments that are inappropriate. He also suggested that copayments could be raised if experience demonstrated that selection of a more expensive treatment was causing expenditures to escalate. He noted that costs wouldn’t necessarily skyrocket, however, because experience shows “that once you get the patients involved in the decision process, their preferences very often are for more conservative treatment.”

A different policy analyst suggested that a tiering structure, similar that used in many formularies for drug coverage, might be employed to introduce cost consciousness into the decision making process. The tiers could be developed based on how clear the medical evidence is on the efficacy of a particular health service. This speaker raised an important concern about costs, however. “While I think it’s absolutely necessary that we have more informed public in terms of what their options are . . . I don’t see the purchasers of healthcare ever adopting a policy in which they can’t have a tool to negotiate cost.” A payor representative also noted that medical necessity criteria still would be needed to determine payments. Another panelist stated that employers would not embrace the model “unless they were convinced of its cost effectiveness.”

Stakeholders’ Concerns with the Medical Necessity Claims Adjudication Process—and Suggested Solutions

Following Dr. Wennberg’s presentation, the facilitator directed the panel’s attention to the Colloquium’s third major topic, identification of stakeholders’ concerns with the current process for adjudicating claims that are denied on the basis of medical necessity. That would be followed, the facilitator said, by a fourth topic, identification of the characteristics of an ideal medical necessity adjudication process. In actuality, the panel’s energetic discussion frequently moved from the identification of a concern to a suggested solution for that perceived problem. The afternoon session concluded with the facilitator inviting the panel to offer comments that brought together the interrelated elements of the discussion, or, as the facilitator explained, “to take the rulemaking process, the adjudication process, and benefits design, and, to the extent those are all inextricably tied together, suggest solutions that would make application of the medical necessity concept work better.”

Adjudication is broadly viewed as encompassing the administrative procedures that are used to process healthcare claims under a covered benefit.1 The facilitator began by asking the panel to develop its own working definition for purposes of the Colloquium discussion. An academician suggested that adjudication refers to “a decision, but also connotes the notion of applying an existing law, policy, or guidance document to a set of facts and making a decision that has a legal impact.” A physician participant suggested that the focus is on “claims that were denied based on medical necessity or appropriateness criteria. We are not talking about denials for cosmetic or other categorical exclusions. Denials for ‘investigational’ treatments should be part of the discussion,” he stressed. The panel also agreed that adjudication, for purposes of their discussion, would encompass claims decisions from the point of the initial determination, whether or not that decision led to an appeal. Relevant court decisions also would be taken into account.

One panelist suggested that perhaps a working definition of “medical necessity” was needed in order to discuss adjudications. The facilitator explained that, given the Colloquium’s focus on potential solutions, Health Lawyers decided to consider “medical necessity” as it is applied in practice and not to hamper discussion by a lengthy, and perhaps fruitless, effort to reach consensus on a definition of the term. To facilitate the discussion of adjudication, however, the facilitator asked the panel to quickly identify common characteristics of medical necessity as it is implemented by government and private health plans.2 The panel identified the following common characteristics of payors’ application of medical necessity policies to healthcare claims. The panel did not deem this a “definition” of the term, however:

- A medically necessary intervention is one that is safe and effective (that is, one that, based on the best available evidence, is deemed to produce more benefit than harm); and
- When two or more interventions are judged equally safe and effective, the medically necessary intervention would be the most cost-effective option.

Having clarifying terminology for the discussion, the panel identified a number of stakeholder concerns and suggested solutions with respect to the adjudication process governing medical necessity determinations.

A Call for Greater Clarity

The panel identified a lack of clarity as the principal concern of consumers, physicians, and institutional healthcare providers with both the adjudication process and the broader issue of medical necessity rulemaking. These stakeholders seek a simple, fair, prompt, and transparent system for healthcare coverage policies, medical necessity determinations, and adjudication of claims. Instead, they encounter a system that is characterized by extremely complex rules, perceived unfairness, delays in the resolution of disputed claims, and a lack of transparency at most levels.

Greater clarity is needed from start to finish, the panel agreed. A Health Lawyers participant observed that the system for medical necessity determinations and adjudications contains implicit as well as explicit rules. One help-
Stakeholders’ Concerns with the Medical Necessity Claims Adjudication Process—and Suggested Solutions

“Customer service is a disgrace. Patients, providers, institutional system—they all get the run-around. Customer service in healthcare is truly awful.”

—A policy analyst

A ful outcome to the Colloquium, this participant suggested, would be to “help identify where the implicit rules are lurking in the system.” An employers’ representative noted the absence of transparency in the system and a widespread perception that decisions are made unilaterally, through a “top-down” approach. Health plans’ customer service departments also contribute to the lack of clarity, a policy analyst suggested. “Customer service is a disgrace. Patients, providers, institutional system—they all get the run-around. Customer service in healthcare is truly awful,” this speaker forcefully stated.

A comment from a business consultant shifted the discussion away from the identification of concerns to a search for solutions that would provide greater clarity to patients, providers, and others. “More information is needed—it’s fine to say the system should be transparent and fair, but who will have responsibility for getting that information to patients?” this panelist asked.

Picking up on an idea mentioned during the morning session, the panel explored how greater clarity could be achieved through information sharing and discussion between physicians and patients on various treatment choices, including whether a given course of treatment might, or might not, be deemed medically necessary by the patient’s health plan.

Significant points raised during the discussion are summarized below.

A consumer representative commented, “One of the big problems for patients is just getting evidence to do an appeal. When a particular service is denied and appealed, it’s often very difficult for the patient to get access to evidence that would show their own medical necessity. This has a lot to do with physician willingness to cooperate and spend their time pulling together a record to support the claim. A solution might be to compensate physicians for the time they spend assisting beneficiaries with appeals,” the speaker suggested. An academician recommended “expansion of the ombudsman concept or the grievance appeals concept to [assign someone] formal responsibility for helping individual benefici-
“to make an informed choice.” Instead, “It’s just ‘sign these forms,’” the speaker said, and they find out the consequences later.

A Health Lawyers participant explained that healthcare providers give Medicare patients an “ABN” or “advance beneficiary notice” that gives beneficiaries or their families advance notification that the provider does not believe a treatment will be covered by Medicare, thus shifting financial liability to the beneficiary if the claim for the service is denied and allowing the provider to bill the patient or his or her family for the treatment. It can damage the doctor/patient relationship, the Health Lawyers speaker said, “when patients get a shocking surprise because they didn’t pay attention to the one additional form they were asked to sign.”

A panelist who is a physician asserted the need for “a witnessed conversation” when patients are asked to make treatment choices and sign medical forms. “I believe that one principle this [Colloquium panel] should endorse is to encourage patients to have a family member or friend participate in discussions about treatment or coverage, so that it’s a witnessed conversation.”

Shifting the focus to the resolution of disputes, a payor representative suggested adoption of independent medical review (IMR), as an alternative to judicial review. “It is essential that the ultimate decision-maker be neutral, objective, and have some scientific basis for their decision. The courts are absolutely the wrong places to decide whether something is medically necessary or not. You don’t want PR [public relations] issues to get involved,” the speaker asserted. A policy analyst echoed the payor call for nationwide use of IMRs, which currently are required in forty-three states. This speaker also suggested a need for multiple organizations to be provided in resolution of claims disputes “to provide checks and balances.” Medicare’s use of a single organization, the Center for Health Care and Dispute Resolution, to resolve disputes on managed care claims, “is not a good idea,” the speaker asserted.

Public/ Private Sector Roles

A consumer representative noted that the discussion swung from comments about public health plans to matters relating to private plans and asked, “What should be required of each sector?” With that cue, the facilitator focused on public and private sector roles in providing clarity on medical necessity determinations and adjudications. He asked each panelist to respond to the question, “Should the federal government use law and regulation to impose requirements on private plans?”

The panel was divided in its views on this topic. Several speakers endorsed a strong federal role with respect to both government and private health plans. For example, a consumer representative commented, “I think it’s fair to have a federally mandated procedure [covering government and private plans] to assist beneficiaries. It could be part of the definition of insurance.” However, a payor representative asserted that federal regulations governing adjudications “already exist in excruciating detail . . . . You’re talking about rules regarding how much time it can take to resolve a dispute. You’re talking about who can be involved in the decision making process. You’re talking about information that has to be provided back and forth with the member and how it’s provided and when it has to be provided. There’s really not much more that can be done on the adjudication process from a federal mandate standpoint.”

An academician took the middle ground on the question. “In a
In a previous job I reviewed the different processes for the adjudication of patient claims, including those denied on the basis of medical necessity, and I was astounded at the variety of different processes that exist at the federal and state levels—how balkanized they are.”

—An academician

previous job I reviewed the different processes for the adjudication of patient claims, including those denied on the basis of medical necessity, and I was astounded at the variety of different processes that exist at the federal and state levels—how balkanized they are.” The speaker asserted that “uniformity would be helpful, but I don’t know if we need a federal statute.” Perhaps a combination of state regulation and standards developed by a group such as the National Association of Insurance Commissioners could improve the flow of information to stakeholders, the panelist concluded.

 Seeking an Integrated Solution

The facilitator shifted the focus to a broader consideration of the colloquium topic and led a discussion that sought to weave the major themes of the colloquium dialogue into a potential integrated solution. Earlier discussions, he stated, showed that concerns with medical necessity arise from interrelated causes, “Our problems with medical necessity go back to things like design of the healthcare benefits package and even to the overall financial crisis in healthcare. In this segment, let’s talk in a more comprehensive way about potential solutions,” the facilitator said.

A consumer representative cited trigger point injections for pain as one example of “a disconnect between the design of Medicare rules and the way they’re applied.” The general explanation of a local coverage determination states that Medicare will cover no more than three injections, yet, several pages later, the document lists exceptions in which more than three injections will be covered. Local Medicare contractors, the speaker stated, “just flat deny anything beyond three injections. And beneficiaries have no idea that they were completely qualified to receive additional injections, because the second page (which has all the exceptions) is not known to them. I believe this is a tremendous problem, particularly when you combine a medical necessity situation in which the presumption is against coverage with the reality that many Medicare beneficiaries—aged, infirm, and noncombative—are not likely to appeal. In that type of system, unfair denials will occur,” the speaker concluded. Asked to suggest a solution, the panelist emphasized that medical necessity rules “shouldn’t be written in the negative, and perhaps it’s not a good idea to have so many highly-specific coverage rules.” A physician representative explained that Medicare and Medicaid coverage rules are developed by fiscal intermediaries in each state, based on input from a panel of physicians that meets semiannually. The initial denial in the previous speaker’s example likely was computer-generated, this panelist continued. “What you described results from a computer program that rejects claims for more than three shots. If that’s appealed, then they go down the list of exceptions.”

1 For example, a glossary on one insurer’s Web site defines adjudication as “The administrative procedure used to process a claim for service according to the covered benefit.” See http://www.cigna.com/health/consumer/medical/glossary.html#A. Last accessed 05/04/2005.

2 Note — The panel discussed the definition of medical necessity in greater detail during the Colloquium’s closing session on Day Two. (See pages 21–23.)
Examining the Term “Medical Necessity”

The Colloquium reconvened on the morning of April 1, 2005, for a closing, half-day session that began with a facilitated examination of the term “medical necessity.” The facilitator then directed discussion to the principal objective of the Colloquium, the identification of points of consensus and points of disagreement that emerged from the one-and-one-half day dialogue.

In the course of the Colloquium discussion and in conversations with Health Lawyers leaders during refreshment breaks, several panelists suggested that it would be helpful to devote a portion of the closing session to an examination of the term “medical necessity,” including the question of whether that term is so widely misunderstood or misinterpreted that it should be discarded and replaced with a more suitable phrase. Earlier, the facilitator explained that Health Lawyers decided to focus the Colloquium on solutions to perceived problems in the application of “medical necessity” rather than seek consensus from the panel on a common definition. Recognizing the panel’s interest in this topic, the facilitator led the panel in a brief examination of “medical necessity.”

As background for the discussion, the facilitator noted that it was clear from earlier discussions and from the Health Lawyers issue paper that “medical necessity” is problematic because in practice it seems to mean so many different things to different people. To a large extent how stakeholders view the term and, indeed, the application of the concept of medical necessity, “differs by where one sits in the healthcare system,” the facilitator observed. The discussion on “medical necessity” focused on two questions:

1. Should “medical necessity” be discarded and replaced with a more acceptable term?
2. Who makes the medical necessity determination?

Related questions that arose during the discussion included:

What standards should be applied in determining medical necessity?
What evidence should be considered? Who has the burden of proof? To what degree, and how, should providers or patients participate in developing general criteria that govern medical necessity determinations?

Medical Necessity: Is There a Better Term?

The panelists agreed that the terms “medical necessity” and “reasonable and necessary” do not convey the underlying concept very well and have contributed to confusion regarding coverage policy. An analyst who advises business clients suggested that “medical necessity” has accumulated so much “baggage” and “emotion” over time that it would be best to eliminate the term altogether. Arkansas’ Blue Cross/Blue Shield plan discarded “medical necessity” and replaced it with “clinical coverage criteria,” she explained. Embedded in that term, the analyst suggested, are considerations such as “effectiveness” and “appropriateness.” For some state plans or private plan, the term also might include a criterion of “least costly alternative.” An employers’ representative suggested that “efficient” was an important criterion, particularly for supply-sensitive care such as office visits, hospitalizations, ICU stays, and diagnostic tests. All of those are “appropriate” services, he stated, but they might not be “efficient” in terms of costs or consumption of resources.

A healthcare executive observed that whether the preferred term is “medical necessity” or “clinical coverage criteria,” many chronic conditions do not lend themselves to protocols or standardization. The treatment of Alzheimer’s Disease, Parkinson’s Disease, chronic depression, and congestive heart failure, he explained, requires an element of medical judgment that differs from case to case. Chronic conditions merit special consideration as the concept of “medical necessity” evolves,” he noted.

A physician representative drew a distinction between “medical necessity” as seen from a physician’s perspective, where the emphasis is on what a physician views as the best treatment for his or her patient in a given situation, and “medical necessity” as seen from a payor’s perspective, where the emphasis is on coverage and payment for a service. The speaker defended use of the term “medical necessity” when one is talking about a physician’s judgment of “what is necessary for this individual patient—today.” The facilitator suggested a middle ground. Payor organizations, he noted, provided
Examining the Term “Medical Necessity”

clinical guidelines to physicians, “but it’s in those margins that you described where many of the issues come up, where the patient might require something a little bit different than someone else,” he explained. A panelist from a government agency cautioned against making the easy assumption “that ‘medical necessity’ is a black and white kind of consideration. We’re really talking about various shades of gray.” Although the facilitator and a number of the panelists used the term “clinical coverage criteria” throughout the discussion in lieu of “medical necessity,” that substitution was not put to a vote and did not emerge as a formal recommendation of the Colloquium.

Who Makes the Medical Necessity Determination?
The discussion next addressed the question of stakeholders’ roles in the process of determining medical necessity. An analyst portrayed the determination process as “a power issue.” Physician will argue that “medical necessity” is the decision they make about the best care for an individual patient. Payors and employers, on the other hand, counter, “We’re paying for it. The decision should be ours.” Differing perceptions of “medical necessity” are one cause of the conflict, the analyst suggested, and a clarification of terminology may help resolve the question of roles. “Coverage decisions generally are about categories of services, not about physician visits or whether hospitalizations should be covered. I believe that a medical necessity decision, on the other hand, is the individual decision that a doctor makes about a patient with a specific condition.”

—A health policy analyst

covered. I believe that a medical necessity decision, on the other hand, is the individual decision that a doctor makes about a patient with a specific condition,” the speaker stated.

A researcher addressed the question from a broad perspective, discussing roles in the context of his earlier comments about variations in healthcare treatments across the country. Perhaps the grand challenge in addressing medical necessity, he suggested, is, “How do you take the traditional viewpoint that medical necessity is determined at the level of the individual doctor and his patient — including the question of whether to hospitalize, or how frequently he’s going to see somebody for follow-up visits—and convert that into a perspective that says, ‘What we’re really interested in doing is looking at the combination of the hospital and its doctors in treating a cohort of patients that are similar,’ and addressing these big differences [in treatment patterns]. Until we can figure out how to center medical necessity around treatment variations in the population base, I don’t think we’re going to get anywhere” in terms of an ultimate solution. The facilitator agreed and commented, “Until our knowledge is able to evolve along those lines, we’re still going to be wrestling over clinical coverage criteria and its application.” A physician representative acknowledged that while a treating physician should make the initial determination of what types of care are medically necessary for individual patients, the payment decision will be made by the health insurance company. That decision should be made by a review of the facts of the case by a peer physician, however, not simply by applying computer-based screening criteria, the speaker asserted. A payor representative explained that the approach described by the physician representative is, in reality, the process that insurers follow. Panelists recognized, however, that payors cannot enumerate all the clinical criteria that would be applicable to the full
range of services because it is not currently possible to stay abreast of developing science and professional opinion.

A researcher observed that the current claims processing system does not affect the variations in medical practice that were noted earlier. He said, “What is needed in the future is not a focus on the individual physician’s decision to hospitalize or to use an ICU, but rather [a focus on] the aggregate impact [on utilization] of physicians who are practicing in a given institution.” At the population level, the nation faces a utilization problem of “central tendencies” rather than an “outlier” problem with certain providers who overutilize services or provide unnecessary care. Current approaches to claims processing and medical review tend to take an outlier approach, however, focusing on claims that appear to be outside a norm or target range. Discussion suggested that this approach is unlikely to yield significant changes in utilization of services at the population level.

The panel generally endorsed the notion that advances in the development of evidence-based medicine would help eliminate disagreements regarding the appropriateness of particular interventions for a wider range of conditions. The panel recognized, however, that the majority of healthcare conditions are not yet backed by clear evidence-based findings and that further advances in this area will require the investment of both time and resources in appropriate research to develop coverage determinations that are consistently based on current scientific findings.

The facilitator concluded the discussion by asking whether more acceptable medical necessity policies might be developed if patients — or treating physicians and healthcare professionals acting on behalf of patients — played a more active role in the rulemaking process. “Is there any problem with the level of participation by providers, patients, the public, in making clinical coverage criteria decisions at program or plan levels?” the facilitator asked.

The panelists generally did not view the degree of participation by patients in the policy making process as a significant concern. A physician representative suggested the need was not for greater participation, but for individuals, particularly employees, to receive more information from health plans on their policies governing medical necessity determinations.

A healthcare executive had the final comment, suggesting that chronic care is a challenging “new frontier” for the development of clinical coverage criteria and medical necessity determinations. “If we like the complexity of the [Colloquium] discussion with respect to acute care, we’re going to love this discussion in ten years around long-term care plans,” he suggested. The growing popularity of long-term care insurance already is generating variations in coverage criteria for chronic care, the panelist stated.

“If we like the complexity of the [Colloquium] discussion with respect to acute care, we’re going to love this discussion in ten years around long-term care plans.”

—A healthcare executive
After one-and-one-half days of energetic but collegial dialogue, the Colloquium reached its denouement, the identification of points of consensus and points of disagreement that emerged from the overall discussion. The facilitator distributed a Health Lawyers-developed list of incremental solutions that emerged from the previous day’s discussion and reviewed each as a potential point of consensus. He asked panelists to clarify various incremental solutions and called on the group to discard suggestions that they believed were included in other incremental solutions or for which there was little or no support. The facilitator solicited discussion on the remaining incremental solutions and called for a vote on each item. Nine points of consensus and one point of disagreement emerged. Relevant points from this discussion, and the disposition of each item, are summarized below.

Points of Consensus

1. Establish formal mechanisms for education and decision making.

Discussion: The panel concluded that all stakeholders would benefit from education and that establishment of a formal structure or mechanism would ensure success. Patients need a better understanding of the healthcare system and healthcare policies, including healthcare financing and policies that underlie medical necessity determinations. Those who establish policies, including regulators and public and private payors, need information about the potential impact of their policies on other stakeholders. As a government panelist expressed it, “They can’t operate in a vacuum.” There was general support for a more formalized structure for setting medical necessity policies than currently exists, although a payor representative stated that this already exists. The panel recognized that financing was needed to ensure successful educational activities but did not reach a conclusion on that aspect of the topic.

Disposition: Unanimously adopted, although one panelist limited his approval to the education portion, stating he did not perceive a need for formal mechanisms for decision making on medical necessity.

2. Establish a clearinghouse—at the national, regional or local levels—to provide patients and providers/researchers with the latest scientific evidence on the effectiveness of various treatments and procedures.

Discussion: This point of consensus arose from the panel’s continued emphasis that (1) medical necessity determinations must be grounded in sound science to the extent possible, and (2) current information on the medical effectiveness of various procedures and treatments must be made readily available to healthcare providers, patients, and others. A healthcare executive sounded this theme during the Colloquium’s opening session, stating, “We don’t have a national body that screens [medical effectiveness] findings and feeds that ‘best-science’ type of information to the consumers and the provider community. That’s a huge hole and needs to be addressed on a nation-wide basis.”

Disposition: Unanimously adopted. The panel stressed that the use of “national” did not imply that the clearinghouse should be federally mandated or administered.

“Emphasizing the need to support truly efficient and effective management of chronic illness is one of the most important contributions [this Colloquium] could make.”

—An academician
3. Refine healthcare financing to more strongly encourage best practices in the management of chronic illness.

Discussion: The panel devoted considerable time to developing this proposal, the significance of which one participant assessed in these words: “Emphasizing the need to support truly efficient and effective management of chronic illness is one of the most important contributions [this Colloquium] could make.”

The proposed point of consensus originally addressed only physicians and called for providing financial incentives both for educating patients and for assisting with appeals.” The panel decided to address the “education” and “appeals” portions separately. During the panel’s later discussion of financial incentives for appeals, that recommendation emerged as a point of disagreement (see next section).

In addressing the education portion, the panel agreed that efforts to encourage patient education should focus on all healthcare professionals, including nurse practitioners and physician assistants, as well as physicians. The panel acknowledged that physicians are expected to educate patients on treatment options, but fulfillment of this expectation was viewed as “spotty,” in part because of financial considerations and because physicians increasingly are asked to limit the time they spend with patients. “The more patients you see, the more money you make” is how one panelist characterized today’s healthcare environment. Other participants pointed out that although billing codes exist for patient counseling, claims submitted under those codes often are denied. In the area of chronic care, a healthcare executive explained, claims submitted by physicians for daily or weekly office visits to explain care options and monitor a patient’s condition often are denied.

The discussion moved away from the idea of financial incentives as an add-on to current payments to a call by the panel for development of incentives as part of a broader refinement of healthcare financing that government and private plans should consider in the course of developing a holistic, best-practices approach to chronic care management.

Disposition: Unanimously adopted, with one abstention.

4. Require automatic sun-setting (expiration) and mandated re-review for clinical coverage policies under Medicare, and for private plans that do not already follow this procedure.

Discussion: A short discussion refined the proposal to recognize that most private plans periodically review their clinical coverage policies and update or sunset those that have been superseded by recent findings on medical effectiveness.

Disposition: Unanimously adopted.

5. Improve online accessibility to public plans’ and private plans’ clinical coverage policies.

Disposition: Unanimously adopted with no discussion.

6. Expand and improve Independent Medical Review, currently in place in forty-three states, to all states.

Disposition: Unanimously adopted after a short discussion.

7. Improve notice and communication concerning the details and availability of clinical trials.

Discussion: A healthcare executive explained that this proposal was designed to address two issues that were discussed earlier. “One is disclosure about clinical trials, and the second has to do with how long it takes new knowledge from clinical trials to get to practice.” An academician recommended, and the panel agreed, that a goal of reducing the lag in translating findings on investigational treatments into mainstream practice was beyond the scope of the Colloquium discussion.

Disposition: Unanimously adopted.

8. Expand the ombudsman concept.

Discussion: An analyst/consultant endorsed adoption and expansion of the ombudsman concept, employed in many other countries, “to assist patients with the resolution of patient concerns about their healthcare and payment for their healthcare.” Several panelists pointed out
that independent patient advocates, or employees with hospitals or private health plans, currently serve that function for many organizations in the United States. An academician cautioned that the ombudsman concept is fraught with political and semantic difficulties, including whether the function should be independently funded, the scope of an ombudsman’s duties and authority, and so forth. This speaker endorsed “exploration and expansion” of the core concept, however, as a “recognition that there does exist a kernel of an ombudsman/patient advocate function that is designed to assist people [at a basic level] in resolving disputes or concerns about their healthcare, whether those concerns are with a healthcare institution or a health plan.”

Disposition: Adopted unanimously. In a separate vote, the panel split on whether ombudsman programs should be funded independently or funded by the sponsoring organization.

9. Enforce current requirements that health plans and employers provide simple, clear information about the appeals process at the time a service is denied.

Discussion: The panel initially viewed this proposal as unneeded because it is related to the first point of consensus, which calls for establishing formal mechanisms for education and decision making. The panel concluded, however, that it was important to cast a spotlight on denials and the need for a health plan to provide a clear, simple explanation, at the time a service is denied, of the process through which an enrollee could appeal the plan’s decision.

Disposition: Unanimously adopted with one abstention.

Point of Disagreement

Financial reimbursement should be developed and implemented for treating physicians and other treating practitioners who assist beneficiaries in developing the medical aspects of appeals.

Discussion: The panelists expressed mixed views on a proposal to reimburse physicians and other practitioners for helping health plan enrollees assemble documents to support medical aspects of patients’ appeals of claims that are denied on the basis of medical necessity. A payor representative cautioned that implementation of the proposal “might turn doctors into contingency fee lawyers, and I’m not sure you want to do that.” Finding the financial resources to fund reimbursement for appeals assistance is another important consideration, this speaker added. A consumer representative rejected the “contingency fee” concern, noting that appeals assistance from caregivers would occur after, not before, a healthcare service was provided. As consumer advocates assist patients in filing appeals, this speaker explained, they often need information from the treating physician after the service has been rendered. “Currently, there’s no reimbursement for that, and that’s a big problem because many physicians are not willing to donate time writing letters [to assist in an appeal],” this panelist stated. A policy analyst supported the proposal and suggested that it be tested as a demonstration project.

Disposition: Based on the panel’s split decision—four voting Yes and five voting No, with two abstentions—the facilitator declared that this proposal was a point of disagreement.

At the conclusion of the panel’s identification of points of consensus and disagreement, Health Lawyers’ Public Interest Committee chair returned to the podium, thanked the participants for their stimulating discussion of medical necessity, and adjourned the 2005 Public Interest Colloquium.
AMERICAN HEALTH LAWYERS ASSOCIATION
2005 Colloquium
Medical Necessity: Current Concerns and Future Challenges

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IMPORTANCE OF THE TOPIC

Although medical necessity has long been central to coverage and payment decisions made under public and private health insurance programs in the United States, the term remains an often invoked but nebulous concept. Government health programs, private health plans, legislators, and health policy analysts employ the term “medical necessity” in disparate ways. For patients and healthcare providers, who are directly affected by coverage and payment decisions based on “medical necessity,” the use and application of the term often seems inconsistent and unclear.

Important questions remain largely unanswered, such as whether, or when, evolving medical devices, drugs, and technologies should be covered; the appropriate frequency of physician visits, diagnostic tests, and treatments for particular conditions; or whether a new but expensive service will be allowed when an established but less efficient service remains available. These issues are of great importance not only to patients, who may, or may not, receive the treatment they seek, but also to healthcare providers, whose professional judgment may be called into question and who may, or may not, receive payment for services furnished to patients.

In addition to issues of access and financial viability, adverse medical necessity determinations may have serious civil and criminal consequences for those accused of providing medically unnecessary care. Fraud and false claims cases, program integrity reviews, professional responsibility investigations, and malpractice cases frequently involve medical necessity issues. Finally, these decisions have the potential for substantial collateral consequences in connection with physician-patient relationships and public perceptions regarding the integrity of the healthcare delivery and payment systems in the United States.

As a nonpartisan contribution to the debate on medical necessity, the American Health Lawyers Association (AHLA) will conduct its 2005 Public Interest Colloquium, Medical Necessity: Current Concerns and Future Challenges, on March 31–April 1, 2005, in Washington, DC. The Colloquium will explore legal issues in the debate through a facilitated discussion among a broad-based panel of persons with different perspectives, experiences, and areas of specialization on the topic of medical necessity. This issue paper presents information on the history and application of the concept of medical necessity and the scope and objectives of the Colloquium discussion. The paper is being provided to the panelists before the Colloquium for their review and reflection — and as a thought-starter for the Colloquium discussion.

SCOPE OF THE DISCUSSION

Medical necessity is where the rubber meets the road in healthcare. A health plan’s scope of coverage is usually set forth in general terms in statute and regulations (for government programs) or in the insurance contract (for private plans). Most coverage schemes begin by specifying broad categories of covered and excluded (or noncovered) services. For example, physician visits may be covered, but podiatrist or optometrist visits may be excluded. A private health plan or government program may classify such services as “noncovered” or “excluded” even though many providers or patients may regard those services as “necessary.” Questions regarding the appropriateness of a plan or program’s benefit categories ultimately are questions of the allocation of society’s resources among its members and, as such, lie beyond the scope of this Colloquium. Once the broad policy decisions regarding benefit categories have been made and a plan put into operation, however, legal issues arise with respect to the meaning of the standard of medical necessity, as well as the processes for appeals regarding them. These are questions that the experts convened for the Colloquium are well-qualified to address.

The concept of medical necessity
is employed in some form by every health plan, including private health insurance, employer-based health insurance, government-sponsored health insurance, and means-tested government health programs. When delineating the scope of benefits — and ultimately the financial exposure of the plan — however, each plan has its own interpretation of, and procedures for determining, medical necessity. Some patients and providers argue that both government health programs and private health plans do an uneven job in providing guidance on the meaning of this fundamental coverage term.

Yet inappropriate medical necessity determinations3 — decisions regarding which health services or supplies are covered by a private health plan or government program — have the potential for devastating effects upon the health and well-being of individual patients. Such determinations also can undermine physician-patient relationships, erode public confidence in our healthcare systems, jeopardize the reputation and fiscal viability of individual providers, and weaken the financial status of plans.4 Reasonable minds can differ; medical progress occurs rapidly and plans may struggle to keep up; absent other controlling factors, patients and providers generally may tend to overutilize medical services; payors are widely believed to restrict services to the point of underutilization for profit maximization. Who has the final say about what is medically necessary?

Despite the gravity of the implications of these determinations, the processes for applying the concept of medical necessity in practice also vary from plan to plan, and the way in which they are made is often open to challenge as arbitrary and capricious; for example, some payors allow these determinations to be made based upon the judgment of individual physician consultants, plan medical directors, or nurse reviewers, without reference to published criteria or specific documentation requirements. Other payors provide more specific direction. Even in those instances where state governments have intervened to require certain decision outcomes or specify use of particular processes, the literature indicates that the decision-making process remains uneven and outcomes vary without explanation from state to state.

The Colloquium panel will not be asked to weigh in regarding the appropriateness of any particular medical necessity policy or interpretation, but will be well positioned to comment regarding procedural aspects of the medical necessity determinations process and to propose potential improvements.

As our nation considers fundamental reforms in an effort to address what is widely perceived as a health care “crisis,” this Colloquium will seek to promote a better understanding of conceptual structures used in medical necessity determinations that affect everyone, directly or indirectly, and to consider the strengths and weaknesses of the processes currently employed to make those determinations.

**OBJECTIVES OF THE 2005 COLLOQUIUM**

The 2005 Colloquium has two objectives:

1. To identify key constituencies’ major concerns with respect to current public and private sector processes for making medical necessity determinations; and key constituencies’ major concerns with current public and private sector processes for adjudicating challenges to medical necessity determinations; and

2. To identify key characteristics of an ideal system for public and private rulemaking processes for medical necessity determinations; and key characteristics of an ideal system for adjudicating challenges to medical necessity determinations, with an emphasis on identifying better ways to interpret and apply the rules governing adjudications.

AHILA sincerely hopes that these two “deliverables” from the 2005 Colloquium will be helpful to policymakers and other stakeholders as medical necessity is discussed in national efforts to address such issues as rising healthcare costs, the provision of healthcare benefits (including potential coverage of emerging and experimental treatments and technologies), and coverage of the uninsured.

Topics addressed in this discussion paper include:

- A short history of the context in which the current healthcare cost and access crisis developed;
- The role of medical necessity in the healthcare reform debate;
Appendix A
Issue Paper to Establish a Common Basis for the Colloquium Discussion

- Identification of stakeholders in the medical necessity debate and their key concerns and interests;
- A preliminary list of issues for consideration by the Colloquium panel, focusing on potential bases for improving the systems for making medical necessity determinations; and
- A set of five core questions developed by AHLA to guide the Colloquium discussion.

HEALTHCARE IN CRISIS: RISING COSTS AND REDUCED ACCESS TO CARE

Access to affordable and adequate healthcare for residents of the United States has been an issue of concern at least since the end of World War II. The perceived relative importance of the issue has varied over time, often in response to changes in the rates of healthcare cost inflation and the impact of measures taken to address that trend. A dramatic rise in healthcare spending preceded the managed care revolution that occurred in the early 1990s, for example.

As Americans born during the post-war “baby boom” approach retirement age, the issue has taken on particular critical importance for the largest government program, Medicare, which faces not only the rising per capita costs experienced by all health plans, but also substantial growth in the number of newly-eligible beneficiaries. Costs for private and employment-related health insurance rates are again soaring; the government programs designed to provide care for the aged, disabled, and impoverished are struggling under rising per capita costs and dramatically increasing eligible populations; and the number of persons without any form of health insurance is rising to levels unprecedented since health insurance became common after World War II.

Several statistics from the Center for Medicare and Medicaid Services’ (CMS) most recently issued report on national healthcare expenditures highlight the dimension of the problem of providing healthcare to all Americans:

- It is estimated that $1.6 trillion was spent on healthcare in the United States in 2002.
- Healthcare spending constituted approximately 15 percent of the gross domestic product in 2002.
- Healthcare spending is projected to rise to $3.1 trillion, or 17.7 percent of the gross domestic product, by 2012.
- Per capita healthcare expenditures between 1970 and 2002 — adjusted for inflation — increased more than 400 percent (from $1,300 to $5,540), and are expected to double again within six years.
- Government sources provided less than 25 percent of healthcare spending in 1960; in 2000, they provided more than 43 percent.

Skyrocketing healthcare costs always generate debate over reforming the nation’s healthcare “system.” A variety of factors typically are cited as the culprit: rising high prices in the “market basket” of healthcare goods and services; alleged overutilization by physicians and hospitals; alleged price-gouging by private health insurers; our aging population; the exponential growth of high-cost medical technology; the costs of medical malpractice insurance; and the costs of “defensive” medicine.

Not surprisingly, the reality is far more complex. For example, estimates of the impact of new medical technology on healthcare costs have ranged from 19 percent to 50 percent of the increases, both from the added costs of using the technology in appropriate cases and alleged overutilization. At the same time, it is undisputed that such technology can generate significant positive effects on the economy, including — but not limited to — healthcare cost-savings over the long-term.

Similarly, although the “graying of America” increases aggregate national healthcare costs to the extent that per capita expenses for seniors are higher, the absolute increase in healthcare costs that can be attributed to age is very small. At the same time, the fact that people are living longer and will increase the demand for healthcare also must be taken into consideration. America’s aging population adds to government
healthcare costs (primarily those of the Medicare program) perhaps not so much in per capita costs as in the sheer number of seniors who are covered by the program, a number that will grow exponentially as more and more “baby-boomers” become eligible for Medicare.

STRUCTURAL FACTORS: A DISJOINTED HEALTHCARE COVERAGE AND PAYMENT SYSTEM

Some analysts believe that the healthcare “crisis” in the United States is the result of structural flaws in our approach to healthcare because, unlike other major industrial nations, the United States has never established a universal healthcare system that guarantees coverage to all its citizens. Rather, Americans receive healthcare through a patchwork of private and government programs and mandated “uncompensated” care, developed over the past 75 years, that is resistant to meaningful reform largely due to its complexity. Further, our public-private patchwork does not guarantee coverage to all citizens. The number of uninsured persons in the U.S. rose to 45 million in 2003 and now stands at 15.6 percent of the population, according to latest annual data reported by the U.S. Census Bureau.8

The healthcare “marketplace” is unique in that it is dominated by government third-party payor programs, with private payers following the government’s lead in many areas. The result is a marketplace that is certainly not competitive in the classic economic sense.

Milestones in the development of the U.S. healthcare system are summarized below.

EARLY HEALTHCARE “SAFETY NETS”

At the beginning of the Twentieth Century, medical care was available to Americans who could afford to pay for it themselves, and to others who had access mainly through private charitable programs. Governmental efforts to establish health insurance programs date at least to President Theodore Roosevelt, who called for health insurance legislation to be implemented by individual states for the working classes. In 1935, President Franklin Roosevelt signed the Social Security Act, which encompassed old-age insurance, unemployment compensation, and maternal and child health programs. Health insurance was deemed too controversial to be included in the landmark legislation, however. In 1946, President Harry Truman signed into law the Hill-Burton program that provided federal assistance for hospital construction in exchange for hospital pledges to serve the poor. President Truman also proposed enactment of national health insurance, a concept that has been the center of controversy for nearly 60 years.

EMPLOYMENT-BASED INSURANCE

During World War II, national wage and price controls were imposed but did not extend to employee health benefits. Employers—faced with a labor shortage but having little flexibility in the wages they could offer—had a strong incentive to recruit and retain employees through the mechanism of job-based health insurance. Indemnity plans, the usual insurance model, were supported by workers because they were allowed to choose their own physicians and by the medical community because physicians were reimbursed on a fee-for-service basis for most services they provided. Today, more than half the people in the United States are covered by some form of employer-based health insurance, although that proportion has been steadily declining as costs increase and some employers, especially small businesses, have been priced out of the market.9

MEDICARE

The Medicare program of health insurance for the elderly was enacted in 1965 as Title XVIII of the Social Security Act. Medicare extended healthcare coverage to almost all Americans aged 65 or older (i.e., those receiving Social Security or railroad retirement benefits), and was expanded in 1972 to provide the same health coverage to the disabled.10 The program now covers approximately 40 million people, or roughly 14 percent of the U.S. population.11 Medicare’s principal components are Part A, “hospital insurance,” Part B, “supplemental medical insurance,” and Part C, Medicare + Choice (managed care), each of which has its own rules and
processes.\textsuperscript{12} (Part D, the Medicare Prescription Drug Benefit, was enacted in 2003 and is scheduled to become fully operational in 2006.)

Concerns over rising Medicare expenditures surfaced during the 1970s and continue to this day. Over the years, rising Medicare cost projections have prompted a variety of responses from lawmakers. In most cases, however, legislative changes were directed toward slowing the rate of increase in payments to providers rather than reducing benefits or increasing cost sharing by enrollees. Medicare’s prospective payment system for hospitals, the resource-based relative value scale approach to physician payments, resource utilization group-based payments for skilled nursing facilities, and prospective payment systems for home health services, rehabilitation services and outpatient services — all were designed to rein in the rate of increase in Medicare expenditures. Part D, the new prescription drug benefit, has raised concerns even before it is fully implemented. In a teleconference on February 8, 2005, Centers for Medicare & Medicaid Services Administrator Mark B. McClellan projected that the new drug benefit will cost the federal government about $720 billion over the ten-year period that begins with full implementation in 2006.\textsuperscript{13}

**MEDICAID**

Title XIX of the Social Security Act, also enacted in 1965, established Medicaid, a joint federal/state entitlement program that provides medical assistance for certain individuals and families with low incomes and resources — primarily low-income children, the institutionalized elderly and the disabled. Within broad national guidelines established by federal statutes, regulations, and policies, each state establishes its own eligibility standards; determines the type, amount, duration, and scope of services to be furnished; sets the rate of payment for those services; and administers its own program. Medicaid policies for eligibility, services, and payment are complex and vary considerably among states. The Medicaid program provided services to approximately 46 million people in 2001.

The Balanced Budget Act of 1997 established the State Children’s Health Insurance Program (“SCHIP”). This program allows states to offer health insurance for children up to age 19 who are not already insured. SCHIP is a state-administered program, with each state setting its own guidelines regarding eligibility and services. Some states provide SCHIP as an expansion of the Medicaid program, while others have created a separate program. In 2001, SCHIP served approximately 4 million children.

**ERISA**

The Employee Retirement Income Security Act of 1974, 29 U.S.C. §§ 1001 et seq. (“ERISA”), was intended to replace the patchwork of state regulation of pensions and health and welfare benefits offered by employers with a uniform set of federal regulations and standards. To achieve this goal, ERISA includes provisions that preempt state law. ERISA’s preemption provisions have been extensively interpreted in the courts and are important in the context of health insurance because preemption has been raised by private health plans, payors, insurers, and others, with some success, as a shield against novel theories of expanded liability in disputes related to the quality and medical necessity of care delivered to enrollees.

**MANAGED CARE**

The Congressional Budget Office has defined “managed care” as care that “involves a variety of interventions in healthcare delivery and financing intended to eliminate unnecessary and inappropriate care and to reduce cost. These interventions include reviewing and intervening in decisions about health services to be provided, either prospectively or retrospectively; limiting or influencing patients’ choice of providers; and negotiating different payment terms or levels with providers.”\textsuperscript{14} The managed care revolution began with the Health Maintenance Organization Act of 1973,\textsuperscript{15} which provided for the development and operation of health maintenance organizations (“HMOs”) primarily in an effort to ensure appropriate coordination and quality of care. HMOs soon became widely perceived as a vehicle to contain rising health-care costs, however.

The concept of “managed care”
quickly came to include within its umbrella not only HMOs but also preferred provider organizations (“PPOs”), “point-of-service” plans (“POSs”), and other entities involved in the coordination and delivery of healthcare. Although indemnity plans accounted for 96 percent of all job-based health plan enrollment in 1977 and 71 percent of the market in 1988, by 1998 indemnity plans held only 14 percent of the market, with HMOs at 27 percent, POS plans at 24 percent, and PPO plans at 35 percent.16

THE ROLE OF MEDICAL NECESSITY IN THE HEALTHCARE REFORM DEBATE

Certain broad economic and social policy questions that are raised by the current healthcare crisis and ensuing healthcare reform debate (What form should a national health insurance program take? What proportion of society’s resources should be devoted to fund it?) are beyond the scope of this Colloquium. The concept of medical necessity arises in broad health policy considerations, however, and is central to any proposed resolution of the tension between the costs of and demand for medical services. The proper interpretation of the concept of medically necessity — whether found in a private health plan contract or in federal or state law or regulation — is key to the functioning of any health insurance system. Its proper interpretation and application, and — more important — the processes by which these are determined, are well-suited to examination by the 2005 Colloquium.

To a certain extent, lawmakers and private sector entities have structured government programs and private health plans with an assumption that what is medically necessary is susceptible to scientific analysis and determination, and have assigned that determination to the treating physicians. Although valuable research now is occurring in the area of “evidence-based medicine,” medical necessity determinations are not yet made solely on the basis of scientific evidence and a physician’s judgment. The rapid pace of advances in medical technology, the inexorable rise in healthcare costs, and the development of an aggressive medical malpractice bar17 have created a legal and political landscape in which the motives of providers are routinely called into question and in which the use of scientific analysis has migrated from peer-reviewed journals to “battles of experts” in the courtroom testimony.

Today, a composite understanding of medically necessity indisputably is being applied by public and private programs. It is in part medical science and in part a political or societal decision regarding the allocation of scarce resources, that is, what “necessary” services are “reasonable” for taxpayers or members of an insurance risk pool to shoulder? As one researcher has reported, medical necessity continues as a concept to be “rarely defined, largely unexamined, generally misunderstood and idiosyncratically applied in medical and insurance practice. . . . Does anyone really know what medical necessity means?”18

To set the scene for further consideration of these issues, this paper next discusses stakeholders in the healthcare system and their interests; reviews existing and proposed interpretations of the medical necessity concept by a number of plans and programs as examples; and then focuses on the processes for making medical necessity determinations. Given the difficulty of prospectively specifying what services are, in fact, medically necessary, an analysis of the processes — both with respect to rulemaking and claims adjudication — clearly is warranted.

STAKEHOLDERS AND THEIR INTERESTS

As with most complex questions of public policy, a discussion of medical necessity issues requires the identification of stakeholders and understanding of their concerns with the current application of “medical necessity.”19

PATIENTS

Patients, including Medicare beneficiaries, Medicaid recipients, other government healthcare program patients, private indemnity plan enrollees, and managed care organization participants, have a reasonable interest in receiving timely and appropriate healthcare for their medical conditions. Patients generally desire whatever health services they believe will benefit them and base their
demands for healthcare on information from numerous sources, ranging from the advice of their treating physicians and other healthcare professionals to television advertising.

Patients also have an interest in access to clear information concerning what their policies or programs cover, both to allow reasonable decision-making on their part and to foster confidence in the healthcare delivery system.

Many patients understand that there must be limits on the items and services for which a healthcare financing mechanism, whether public or private, can pay. In order to make rational decisions regarding the healthcare recommendations of their physicians, patients need current, accurate information regarding the medical necessity policies and interpretations that apply to their personal circumstances. In some situations, patients may disagree with those interpretations, and will choose to pay for certain items or services out of their own pockets. Accordingly, patients have an interest in a simple, fair, prompt, and transparent system for identifying and, if necessary, challenging coverage policies and decisions.

Unintelligible coverage policies and opaque claims processing procedures have significantly frustrated and burdened patients for many years. Although the past decade has witnessed some improvement in these areas, practical opportunities for patients to secure changes in coverage policies or to appeal adverse determinations in time to make a difference in the care provided under their private or government health plan remain limited.

Most patients are not medically trained and also do not have access to the depth of information that is available to their providers on the costs and benefits of different treatments and services. In a rational economic system, patients thus are unlikely candidates for decision-making authority with respect to medical necessity. Moreover, the fact that the patient is ill or injured could be expected to influence his or her decisions toward overutilization, in the hope that something will be found to remedy an illness or successfully treat an injury.

Finally, the fact that a third party—employer, insurer or government program—is responsible for payment for medical services rendered to the patient poses the classic “moral hazard” problem of insurance economics: the failure of the market system to produce efficient results due to an unintended consequence of the insurance contract. Here, the risk is that one party (the patient) to a contract will change his or her behavior to the detriment of the other party (here, the employer and/or the insurer or program) after the contract has been entered, and seek more medical care than he or she would if he or she were being held personally financially liable for its cost.

**PHYSICIANS AND OTHER HEALTHCARE PRACTITIONERS**

All physicians assume a professional obligation to care for their patients as part of their training, professional code of ethics, and their licensure obligations. This obligation includes putting the interests of the patient first and striving to “do no harm.” Physicians and other providers and practitioners who furnish services to Medicare and Medicaid patients assume an explicit statutory obligation to prescribe or provide diagnostic and therapeutic services for the treatment of their patients consistent with their professional judgment and accepted standards of medical practice.

The trust that a patient places in the physician forms an integral part of the therapeutic process. Physicians and many other healthcare professionals have invested substantial time and money in education and training. Most are motivated both by the desire to do their best by their patients and by expectations of incomes proportionate to this investment. Vague or non-existent medical necessity standards, inadequate guidance, and, ultimately, adverse medical necessity interpretations interfere with patient-physician relationships and threaten a physician’s ability to practice in a manner that the physician finds professionally rewarding and financially satisfactory.

In the absence of meaningful standards and useful guidance from a payor, a physician is often presented with a choice among the following unacceptable actions: assume
the risk of non-payment if a payor deems the service not to be covered;²⁴ furnish a service only if the patient provides a commitment to pay if the service is not covered;²⁵ misrepresent the patient’s condition to the insurer in order to secure approval; or decide not to furnish or recommend a service.

Adverse claims processing determinations and retrospective audit findings pose a significant risk to many physicians’ livelihoods. In some cases, they expose physicians to unwarranted but potentially devastating allegations of false claims and fraud. Such allegations can trigger investigations by medical boards and adverse peer review actions by hospital medical staffs, medical groups, and managed care organizations.

The American Medical Association (AMA) has addressed the paramount importance of the physician’s obligation to the patient and the need to be vigilant against lay interference: “[P]hysicians should not be subjected to lay interference in professional medical matters and their primary responsibility should be to the patients they serve.”²⁶ Further, with respect to managed care contracts, the AMA warns physicians: “Before entering into contracts with third parties, physicians should attempt to . . . determine the possible impact on professionalism, independent clinical judgment, or patient care. Even if a shared goal can be identified, motivations or means to achieve a common goal may present an untenable conflict of interest. If negotiations to address these concerns fail, physicians should reject the contract.”²⁷ The AMA also cautions: “Physicians are [generally] free to enter into a wide range of arrangements. However, physicians should not sign contracts containing provisions that tend to undermine their ethical obligation to advocate for patient welfare.”²⁸

The treating physician once held the high ground as a respected professional authority, bound by medical ethics to do his or her best for the patient. After health insurance became widely available, physicians also presented the “moral hazard” problem for insurers. So long as a physician was not at risk for collecting from the patient for services rendered, a physician might be influenced to prescribe more treatment rather than less in efforts to attain a good result or appear to be trying “everything possible” to satisfy the patient or his family. The trend toward physician ownership of profitable diagnostic and therapeutic enterprises produced another potential incentive to order or furnish more services.

INSTITUTIONAL PROVIDERS AND HEALTH SYSTEMS

Both for-profit and nonprofit institutional providers have an interest in serving their communities and operating in a manner that produces the profits or operating margins that permit them to continue carrying out their mission. While these organizations are not licensed to practice medicine and do not exercise professional medical judgment regarding patient treatment, they nevertheless have an obligation to carefully credential physicians practicing within the organization and to limit clinical privileges to services that the physician is competent to provide.²⁹ In the past, hospitals were exposed to relatively minor regulatory sanctions regarding their maintenance of utilization review processes and medical staff discipline. More recently, however, hospitals have been investigated and penalized with both civil and criminal sanctions for allegedly failing to conduct these activities or otherwise take appropriate action to prevent the provision of, and billing for, services that are not reasonable and necessary.³⁰

While it might appear to be relatively simple for a hospital to monitor the services ordered and provided by its medical staff, the task is complicated by the manner in which the medical staff is organized, the due process rights and peer review rules that govern hospital-medical staff relationships, medical staff politics, and the implications of medical staff discipline for malpractice insurance.³¹ Notwithstanding the fact that hospitals and other institutional providers exercise limited control over treatment and ordering decisions of physicians, these facilities incur significant financial exposure for denied claims and unreimbursed expenses if services are determined to be medically unnecessary.³² Even if a hospital’s medical staff peer review process identifies that inappropriate services may have been furnished and disciplinary action has been taken
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against a member of the medical staff, it is possible — based on applicable state peer review rules — that only very limited information may be conveyed to the hospital’s compliance staff with regard to such reviews. The hospital must also be careful in handling peer review information to avoid inadvertently compromising applicable legal privileges and immunities that may be important in the defense of potential allegations of malpractice, battery (i.e., lack of informed consent), or consumer fraud.33

With the enactment in 1983 of the Medicare inpatient prospective payment system, hospitals received a strong incentive to exercise more control over the practices of physicians on their medical staffs in order to encourage the provision of services in a cost-efficient manner. Over time, hospitals have exerted control through a “carrot and stick” approach, or the use of incentives and disincentives. Initially, hospitals employed the “stick” through “economic credentialing,” or using medical staff processes to remove or limit privileges of physicians who were judged to be practicing inefficiently.34 Strong resistance by medical staffs resulted in limited implementation of economic credentialing. Some hospitals then tried a “carrot” approach to the perceived problem of inefficient physician practice patterns, implementing “gain-sharing” programs through which physicians share in cost savings that result from improved practice patterns. Gainsharing raises serious issues under the civil monetary penalty statute that bars hospitals from offering payments to physicians “to reduce or limit services” ordered for government patients35 as interpreted by the Office of the Inspector General.36

GOVERNMENT HEALTHCARE PROGRAMS, HEALTH INSURERS, AND OTHER PAYORS

Government healthcare programs, health insurers, managed care organizations, and other payors have a fiduciary responsibility to administer their programs and plans in a manner consistent with the law, governing plan documents, the rights of the insured, and the interests of policy holders. Operating fairly but also in a fiscally responsible manner is a tough task. The Centers for Medicare and Medicaid Services and other payors, public and private, regularly wrestle with medical necessity issues in an effort to balance their competing fiduciary obligations.

The legal concept of medical necessity is essentially an insurance coverage limitation provision that arises from legislation or contract. Definitions and limitations on insurance coverage are an essential element of an insurance contract or program budget because they define the risk assumed by the third-party payor. The incentive of health insurance plans or government agencies to minimize expense and, in the case of private insurance companies, to maximize profits cannot effectively be removed from the system. It should, however, be recognized and appropriately addressed in developing processes for medical necessity determinations that will protect patients and providers while limiting risks for payors.

Many would argue that the “managed care” revolution succeeded in controlling costs.37 Between 1960 and 1990, the share of gross domestic product absorbed by health expenditures grew by an average of 45 percent per decade. From 1990 to 2000, however, health expenditures as a share of gross domestic product grew just 11 percent, with virtually no growth between 1992 and 1998, when managed care was at its prime.38 The stability of health expenditures was reflected in health insurance premiums during the 1990s. Employer health premium increases topped out at 18 percent in 1989 and then steadily fell to less than 1 percent in 1996 before rising to 5.3 percent by 1999.39 By the late 1990s, the pendulum of public opinion began swinging against managed care. Consumers and providers responded to perceived widespread abuses in managed care. Of primary concern were physician incentive structures that supposedly rewarded underutilization by creating an environment in which furnishing less care ensured better economic returns for providers. Various critics alleged that under managed care patients could not choose their doctors; that physicians lost independence in practice modes and medical decision-making; that physician compensation was falling; and that the appeal of the medical profession as a career path was diminishing. Innovation
was reportedly stifled and financial “bean counters” reportedly were denying medically necessary care solely to enhance the insurers’ bottom lines.

Once again, the reality is far more complicated than popular perceptions. Empirical studies do not support the conclusion that the utilization controls of managed care necessarily or generally lead to lower quality of care.40 In fact, managed care processes — such as the use of evidence-based guidelines, care management programs, patient and physician reminders, and the inclusion of coverage for preventive care — can ensure that patients receive services when they otherwise might not. In the mid-1990s, managed care plans denied only 2 percent to 6 percent of all claims for physician-recommended care, and those statistics include not only denials for lack of medical necessity, but also denials on other grounds, such as duplicate submissions, excluded benefits, and unenrolled patients. Plans reportedly denied less than one-half of 1 percent of all claims on medical necessity grounds, and about two-thirds of initial denials ultimately were approved.41

Despite the positive data, the public perception of abuse and resentment against perceived restrictions grew, and legislatures and the market responded. States mandated that certain benefits be covered by insurers and that the insurers open up their provider networks. Some states enacted legislation to require that members be given an opportunity for independent, or external, review of medical necessity denials. Some states legislatively defined the meaning of medical necessity, and Congress proposed to do the same through the “Patient Bill of Rights.”

In terms of a market response, the popularity of HMOs was declining by the early 2000s in favor of the less restrictive PPO managed care model. While the PPO model still emphasizes medical necessity as a prerequisite to coverage, pre-authorization is generally not as intense, members are not required to receive all care through gate-keeper referrals, and members can receive care outside of the carrier’s network, albeit at somewhat reduced levels of benefits. Between 1996 and 2001, enrollment in HMOs fell from 31 percent to 23 percent of covered workers, while PPO enrollment grew from 28 percent to 48 percent.42 Not surprisingly, as managed care loosened restrictions on enrollees and providers, costs again rose.43

**RISK-POOL STAKEHOLDERS: EMPLOYERS, TAXPAYERS, AND CONSUMERS**

Those who pay for healthcare, whether through premiums, cost-sharing, or taxes, have an interest in receiving value for their expenditures, in receiving fair treatment, and in avoiding “free riders.” Here is where the “reasonableness” prong of the medical necessity criterion can produce heated discussions in the halls of government, boardrooms, and kitchens across America. Some of the debated areas regarding reasonableness include futile end-of-life services; psychiatric, behavioral, and substance abuse services; treatments for obesity and infertility; and so-called “lifestyle” drugs such as contraceptives and Viagra. The “necessary” prong has also been debated in these same settings with equal vigor. The fact that a promising but costly new medical technology appears to hold the last remaining hope for a family member may influence relatives to cite preliminary research findings to argue that it is necessary for their loved one’s treatment, despite the high cost of the new technology. Questions also abound regarding whether “alternative” healthcare approaches (that is, anything other than traditional allopathic, osteopathic, or chiropractic medicine) should be accepted and included within coverage.

**GOVERNMENT**

State and federal governments have an interest in maintaining the public health and assuring reasonable access to healthcare for all members of society at affordable rates. Governments also must balance budgets and seek to minimize fraud, abuse, and waste in the healthcare system. Without sound and well-understood medical necessity policies, and procedures to allow challenges by affected parties, appropriate and beneficial services may be forgone, less effective care may be rendered, and health conditions in the community may go untreated. Diminished quality of life, unnecessary public health risks, and higher costs may
result from delays in treatment. At the same time, government entities, large and small, must operate within available funding and face tough policy choices.

In addition, law enforcement agencies are charged with investigating and prosecuting those who violate our laws and regulations and those who commit fraud against our citizens and corporations. Unlike “traditional” fraud—such as billing for services that were not provided, services that were entirely worthless, services furnished by unauthorized persons, or defective goods—allegations of healthcare fraud or false claims based on lack of medical necessity (or lack of documentation of medical necessity) are much more difficult to identify and prove. The task of prosecuting these offenses would be easier if the governing policies were clearer and better publicized.

**THE PUBLIC**

All members of the public are either patients or potential patients. Understandably, they tend to be somewhat inconsistent in their views regarding the issue of medical necessity. As one observer noted in 1985, “while [Americans] nod knowingly at published accounts of unnecessary surgery — surely we all ‘know’ that doctors are ripping us off — they react with horror when government-sponsored, utilization-review decisions ‘throw old people out of the hospital.’”

Society has a strong interest in maintaining the public health, supporting a fair and efficient system, protecting financial integrity of government programs, avoiding fraud and abuse, and promoting respect for the law and the government. “Program integrity” ought to mean more than only saving money. It should entail a commitment to properly administer all aspects of a plan. Citizens want to know that government programs and private health plan contracts are being administered according to rules that are fair and rational, that health benefits to which they are entitled (by law or by contract) will be there when they need them, and that things are being done properly. While there have been numerous examples in the news about government and corporate corruption that results in hardship for regular citizens, healthcare is simply too important for our well-being to permit such a lack of confidence to persist.

**MEDICAL NECESSITY: THE QUEST FOR DEFINITIONS AND STANDARDS**

**THE PROBLEM**

As a result of our fragmented coverage and payment system, no single health plan serves a majority of our citizens. In calendar year 2000, private insurance plans and government programs each accounted for about one-third of total national healthcare expenditures, according to CMS estimates published in 2002. Private insurance paid 34 percent of the total; CMS programs paid 33 percent; other public programs paid 12 percent; other private programs paid 6 percent; and out-of-pocket spending accounted for 15 percent. There is also considerable variation in benefits and coverage. Private plans differ in benefits and coverage rules from employer to employer and group to group. Even the programs administered by CMS differ substantially, as Medicare is an insurance program that collects premiums but is administered somewhat differently by contractors in different geographical areas, while Medicaid and SCHIP are means-tested public assistance programs that are administered differently by each state.

Because the Medicare program affects the largest contingent of Americans, that program’s application of medical necessity might suggest a model for all plans. In reality, however, Medicare’s interpretation of what is “medically necessary” often is delegated to various regional fiscal intermediaries and carriers, quality reviewers, and other government contractors. The result is that a Medicare beneficiary residing on one side of a street could receive a medical necessity determination quite different from his or her neighbor across the street, if that street is the dividing line between contractor jurisdictions. The Medicaid and SCHIP programs, by design, present similar issues. Because each state is afforded broad discretion in developing its own Medicaid plan, a person in one state might well be unable to obtain Medicaid payment for a service that a similarly-situated person in a neighboring state readily obtains.
EXISTING “STANDARDS”

To provide a context in which to consider issues related to medical necessity, this paper next presents examples of existing and proposed medical necessity definitions and standards from selected government programs and private plans.

**Medicare**

The Medicare statute provides coverage for a long list of specific categories of items and services (for example, inpatient and outpatient hospital services, home health, durable medical equipment, and laboratory tests) and identifies certain items and services that are always excluded from coverage. Within the covered categories, the Medicare program limits program coverage to items and services that are “reasonable and necessary for the diagnosis or treatment of illness or injury.” Recognizing that medical standards of care at the time that Medicare was enacted were effectively local, Congress specifically authorized local variations in services and payment rates, following the practice in private insurance indemnity plan schemes in many respects. Congress authorized matching payments to the states to furnish medical assistance to individuals without sufficient resources “to meet the costs of necessary medical services,” but only “as far as practicable.” States must establish “reasonable standards . . . for determining eligibility for and the extent of medical assistance under the plan which . . . are consistent with the objectives of” the Medicaid statute. The United States Supreme Court has interpreted this language to confer broad discretion on states and concluded that states are not required to fund unnecessary medical services. At the same time, the Court noted that “serious statutory questions might be presented if a state Medicaid plan excluded necessary medical treatment from its coverage.”

Federal regulations confirm that states may limit services “based on such criteria as medical necessity or on utilization control procedures.” Services provided in state Medicaid plans “must be sufficient in amount, duration, and scope to reasonably achieve [their] purpose” and States may not arbitrarily deny or reduce the amount, duration, or scope of required services because of the diagnosis, type of illness, or condition.

In applying these standards, federal courts have generally held that a Medicaid plan that does not cover medically necessary services is not reasonable and is inconsistent with the objectives of the Medicaid statute. The federal Courts of Appeals differ regarding the amount of discretion that states have in defining medical necessity, however. The First Circuit has held that states are not automatically required to provide every service that an individual physician may prescribe, but may have input into deciding whether a service is, in fact, medically necessary at a “macro” policymaking level. Other federal circuits give the states less latitude. Because states are not required to provide medically unnecessary services, their best opportunity to limit coverage is in defining medical necessity. State definitions of medical necessity that are reasoned and supported by medical evidence are more likely to be upheld, demonstrating that in the realm of medical necessity, the process of decision-making may be as important as the substance of the decision itself.

An example of recent state legislation addressing scope of coverage in an effort to reduce Medicaid program spending is found in Tennessee, where the legislature
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in 2004 revised its definition of medical necessity for use in TennCare, the state’s Medicaid program.67 Under the new law, to be considered “medically necessary,” each item or service must:

■ “be required in order to diagnose or treat an enrollee’s medical condition;”

■ “be safe and effective” — that is, “the reasonably anticipated medical benefits of the item or service must outweigh the reasonably anticipated medical risks based on the enrollee’s condition and scientifically supported evidence;”

■ “be the least costly alternative course of diagnosis or treatment that is adequate for the medical condition of the enrollee;” (including “where appropriate, no treatment at all”); and

■ have “adequate . . . empirically-based objective clinical scientific evidence of its safety and effectiveness for the particular use in question.”68

This appears to be most stringent statutory definition of medical necessity currently in use by a Medicaid program.

State Legislatures

State legislatures can and do impose upon private health insurance plans minimum standards governing what items and services must be included in plans offered in the state. In addition, other governmental entities, especially at the state level, skew the marketplace by mandating coverage of certain procedures by private health plans and indemnity insurance companies. Thus, what is medically necessary is often affected by particular legislative mandates.

Seventeen states have enacted legislation that addresses medical necessity within the context of private health plan contracts.69 Massachusetts defines medical necessity simply as “healthcare services that are consistent with generally accepted principles of professional medical practice.”70 By contrast, Hawaii’s statutory definition approximates those found in modern industry practices. It provides that, to be considered medically necessary under a plan contract, an item or service must be:

■ “for the purpose of treating a medical condition.”

■ “the most appropriate delivery of level of service, considering potential benefits and harms to the patient.”

■ “cost-effective for the medical condition being treated compared to alternative health interventions, including no intervention. . . . cost-effective shall not mean lowest price.”

■ “known to be effective in improving health outcomes; provided that (A) Effectiveness is determined first by scientific evidence; (B) If no scientific evidence exists, then by professional standards of care; and (C) If no professional standards of care exist or if they exist but are outdated or contradictory, then by expert opinion.”71

The wisdom of mandating benefits through legislation has been debated, with insurers preferring to structure their products and pricing as they see fit, and certain patients and providers demanding coverage for therapies of interest. For example, by 1995, in response to intense political pressure, persistent lobbying, and aggressive litigation, the legislatures of seven states had enacted statutory mandates requiring health insurers to cover autologous bone marrow transplantation (ABMT) for breast cancer.72 ABMT is a cancer treatment in which bone marrow or stem cells are removed from the patient and then reinfused after the patient has undergone high dose chemotherapy.73 ABMT, a very expensive therapy that costs over $80,000 per transplant, was considered by health plans to be of unproven effectiveness74 and to cause significant side effects, including death in up to 7 percent of cases.75 As a result of statutory mandates and decisions such as Fox v. Health Net, Inc.,76 more than 41,000 patients underwent ABMT during the 1990s, notwithstanding a growing body of evidence that the treatment was not effective.77 In April 2000, the New England Journal of Medicine reported the results of a large randomized controlled trial, concluding that ABMT had “proved to be ineffective and should be abandoned.”78 The therapy was ultimately abandoned as a treatment for breast cancer,79 but only after billions of dollars and immeasurable human costs were incurred in connection with tens of thousands of women who received ABMT in lieu of
available treatment alternatives. The financial cost, of course, was ultimately borne by the members of the insurance risk pool and their employers through increased premiums.

Private Health Plan Contracts

The Federal Employees Health Benefits Plan (FEHBP) provides coverage to federal employees through contracts with more than 100 private plans. FEHBP reportedly determines medical necessity by considering whether items and services are:

- Appropriate to prevent, diagnose, or treat your condition, illness, or injury;
- Consistent with standards of good medical practice in the United States;
- Not primarily for the personal comfort or convenience of the patient, the family, or the provider;
- Not part of or associated with scholastic education or vocational training of the patient; and
- In the case of inpatient care, cannot be provided safely on an outpatient basis.

American Medical Association

In response to efforts to incorporate cost-effectiveness criteria into definitions of “medical necessity,” including efforts to define medical necessity in terms of “lowest cost criteria” as the shortest, least expensive, or least intense in terms of level of treatment, care, or service provided, the American Medical Association (AMA) in 1998 adopted the following patient-and-physician oriented definition of medical necessity:

healthcare services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is: (a) in accordance with generally accepted standards of medical practice; (b) clinically appropriate in terms of type, frequency, extent, site, and duration; and (c) not primarily . . . for the convenience of the patient, treating physician, or other healthcare provider.

Patient Advocates

An example of standards for medical necessity developed from patients’ perspective is one presented by the National Health Law Program. NHLP published its recommended definition of medical necessity for use in Medicaid managed care contracts that were implemented in a number of states in the 1990s:

The managed care plan must provide all medically necessary care, including services, equipment, and pharmaceutical supplies. Medically necessary care is the care which, in the opinion of the treating physician, is reasonably needed:

- to prevent the onset or worsening of an illness, condition, or disability;
- to establish a diagnosis;
- to provide palliative, curative or restorative treatment for physical and/or mental health conditions; and/or
- to assist the individual to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the individual and those functional capacities that are appropriate for individuals of the same age.

Each service must be performed in accordance with national standards of medical practice generally accepted at the time the services are rendered. Each service must be sufficient in amount, duration, and scope to reasonably achieve its purpose; and the amount, duration and scope may not arbitrarily be denied or reduced solely because of the diagnosis, type of illness or condition.

Advocates for beneficiary groups with special needs, such as the disabled and patients with multiple chronic conditions, have also proposed formulations of medical necessity that take into account those beneficiaries unique conditions.

Government Regulators

In addition to their broad authority to establish prospectively coverage categories and guidelines through statutes and regulations, the legislative and administrative branches of government have played an important but sometimes unrecognized role in the interpretation and enforcement of “medical necessity.”
For more than a decade, government agencies have focused substantial attention and resources on the investigation and prosecution of fraud and abuse in healthcare programs. Although the original focus of these initiatives was on incontrovertible cases of fraud, usually involving billing for services not furnished, in recent years prosecutors and “whistleblowers” have begun to bring cases premised upon the provision of allegedly unnecessary services or the maintenance of insufficient documentation.

Unfortunately, this enforcement shift into an area of far greater ambiguity — medical necessity — has not been accompanied by the articulation of clearer standards or lesser penalties. Instead, providers and practitioners are confronted by threats of enormous penalties under the federal False Claims Act in cases that can encompass genuine differences of opinion. Pre-litigation settlements are the rule, given the unacceptable level of exposure in such cases. As a result, the physicians and insurance administrators that usually decide such issues play no role in these cases.

Other examples of instances in which government regulators play an indirect role in determining medical necessity include:

- In 2000, the state of Texas and Aetna U.S. Healthcare executed an Assurance of Compliance to resolve allegations by the state against Aetna U.S. Healthcare regarding violations of the Texas Deceptive Trade Practices-Consumer Protection Act. The settlement agreement defined “medically necessary care” as “healthcare services and supplies that under the applicable standard of care are appropriate: (a) to improve or preserve health, life, or function; or (b) to slow the deterioration of health, life, or function; or (c) for the early screening, prevention, evaluation, diagnosis or treatment of a disease, condition, illness, or injury.” Included in the settlement is this definition of the cost effectiveness of services and supplies: “[A] treatment is cost effective if it is the least expensive medically necessary treatment selected from two or more treatments that are equally effective.”

- In 2000, the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) included in the OIG Compliance Program for Individual and Small Group Physician Practices a list of four important “risk factors” that were to be considered by physician practices in designing compliance programs. Two of the four risk factors make reference to “reasonable and necessary” services. One states: “[A] physician practice should be aware that Medicare will only pay for services that meet the Medicare definition of reasonable and necessary.” Physicians are admonished to “only bill those services that meet the Medicare standard of being reasonable and necessary for the diagnosis and treatment of a patient.” The only provision ever approaching a definition or standard in the compliance guidance document, however, is this: “Billing for services, supplies and equipment that are not reasonable and necessary involves seeking reimbursement for a service that is not warranted by a patient’s documented medical condition. See 42 U.S.C. 1395i(a)(1).”

Experience to date suggests that consensus on a definition of medical necessity is unlikely to be attained. Although private plans and government programs must begin with general definitions and specification of criteria for determining covered services, the importance of fair and efficient processes for developing prospective coverage rules and applying them cannot be overstated and is critical to restoring public confidence in the “system.” The next section of this paper examines current processes for making medical necessity determinations.

CURRENT PROCESSES FOR DETERMINING MEDICAL NECESSITY

The processes by which medical necessity determinations are currently made raise fundamental issues affecting the rationality, equity, and effectiveness of our healthcare system. Medical necessity determinations are complicated in practice by five factors:
Most diagnosis and treatment decisions are fundamentally subjective in nature; medical technology and treatment options change rapidly, and private health plans and government health programs need time to analyze medical advances and determine whether new services will be covered or excluded;

Government program payment contractors such as fiscal intermediaries and carriers and private health plans historically have emphasized post-payment review, applied ad hoc and post hoc administrative interpretations in adjudications, and provided little advance information to providers concerning which standards would be applied;95

Although private plans generally have straightforward appeals processes in place, providers and patients may not be familiar with a plan’s procedures or may have preconceptions about “bureaucratic red tape” that deter them from pursuing appeals; and

The non-precedential nature of appeal determinations resulting from the case-specific medical facts relevant to medical necessity inquiries means that little or no precedent is available to aid in subsequent decisions.96

While many patients are covered by private health plans and other government programs, the Medicare program covers the largest, and fastest growing, portion of the United States population. Accordingly, this paper summarizes Medicare’s approach to medical necessity policy-making and case adjudications as a basis for discussion of general issues and potential improvements in the process in the public interest. Obviously, there may be other issues specific to particular private health plans, and some issues may be of greater significance in the Medicare context. For illustrative purposes, however, Medicare’s processes for determining medical necessity illustrate issues and implications that have some degree of applicability to most plans and programs. As a starting point, it is necessary to recognize that decisions regarding medical necessity are made through two very different processes. Medical necessity determinations of general applicability are made through rulemaking, similar to “rulemaking” in administrative law terms, which is the development and publication of a standard of general applicability and prospective effect. Medical necessity determinations respecting individual claims are made through “adjudication,” the case-by-case application of the rules to reach a determination. Medical necessity rulemaking has historically been conducted without the benefit of extensive public discussion or debate and in many cases the resulting standards have been maintained in secrecy. Often, individual claims adjudications have been conducted with limited opportunity for the claimant (patient or provider) to participate effectively and with limited explanation provided for the result.

The next section addresses each situation or posture in turn.

**MEDICAL NECESSITY RULEMAKING**

The process of establishing medical necessity policy varies considerably between private plans and government programs, and within the multiplicity of plans that exist in each segment. Medical necessity rulemaking by private plans is generally viewed as less “open” than the rulemaking process for Medicare and other government programs, but that perception may reflect a difference in openness throughout society between public and private enterprises. This section of the issue paper discusses aspects of private plan policymaking and then focuses on the Medicare program coverage policymaking process, which has been the subject of much litigation and controversy and provides considerable matter for reflection.

**Private Plans**

Private plans develop their coverage policies through the use of medical research, practice guidelines, underwriting principles and market considerations. In many states, however, legislators have imposed content and process mandates. As a result, it is difficult to generalize about private plans. However, it is clear from ERISA case law that, where the courts do find jurisdiction, they will not uphold administrative aspects of plan coverage that are arbitrary or capricious.
The Medicare Program

For many years, Medicare’s processes for creating medical necessity policies were informal, operating within the general coverage parameters established by statute and rules. In a notice issued in 1995, HCFA described its existing national coverage decision-making process. National coverage determinations (NCDs), which are binding on all carriers and fiscal intermediaries, were to be developed and published by HCFA, but not as rules developed through the notice and comment rulemaking procedures of the Administrative Procedure Act. The Medicare program would continue to delegate the majority of medical necessity policymaking to individual payment contractors, who were authorized to develop “local medical review policies” (LMRPs), and subsequently local coverage determinations (LCDs), for use in conducting medical review of claims.

In response to continued litigation over medical necessity issues, Congress enacted new requirements for Medicare medical necessity determinations. Section 522 of BIPA established a process for appealing NCD and LCD policies themselves. The provision subjects NCDs and LCDs issued on or after October 1, 2001, to administrative and judicial review in specified circumstances independent of the submission or denial of any related claims.

National Coverage Determinations (NCDs)

A “national coverage determination” sets forth the extent to which Medicare will cover specific services, procedures, or technologies on a national basis. In 2003 CMS published a new Federal Register notice that provides for informal participation by anyone interested in a particular coverage issue, including physicians and other providers. However, only “aggrieved parties” have formal appeal rights with respect to initial NCD decisions. The Notice sets forth the process for requesting an NCD or reconsideration of an NCD and summarizes the review process that CMS will follow. Reconsiderations under the notice need not be requested by an “aggrieved party,” but are not technically appeals under the statute. This “informal” process allows participation by interested providers or members of the public.

Local Coverage Determinations (LCDs)

A “Local Coverage Determination” (LCD) is a decision by a fiscal intermediary or carrier to cover, or not cover, a particular service on an intermediary-wide or carrier-wide basis as reasonable and necessary. The LCD process is governed by instructions in Chapter 13 of the CMS Program Integrity Manual, CMS Pub. 100-8. According to these instructions:

- Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:
  - Safe and effective;
  - Not experimental or investigational (exception: routine costs of qualifying clinical trial services [under certain circumstances]); and
  - Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:
    - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient’s condition or to improve the function of a malformed body member;
    - Furnished in a setting appropriate to the patient’s medical needs and condition;
    - Ordered and furnished by qualified personnel;
    - One that meets, but does not exceed, the patient’s medical need; and
    - At least as beneficial as an existing and available medically appropriate alternative.

Contractors are to base LCDs on “the strongest evidence available,” defined as, “in order of preference:"

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and
- General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:
- Scientific data or research studies published in peer-reviewed medical journals;
Consensus of expert medical opinion (that is, recognized authorities in the field); or medical opinion derived from consultations with medical associations or other health-care experts.

This explication of the Medicare concept of medical necessity may be contrasted with the definitions described earlier in this paper.

The Government Accountability Office (GAO) has reported continuing problems with the Medicare coverage development process and has cited inequities in care provided to Medicare beneficiaries that result from variances among LMRPs. MMA requires the Secretary of Health and Human Services to develop a plan for achieving consistency among LCDs on a national basis and deciding which LCDs should be adopted nationally.

ADJUDICATION OF MEDICAL NECESSITY IN INDIVIDUAL CASES

The paper next discusses dispute processes available for private health plan claims, then reviews the appeal processes for Medicare claims.

Private Health Plan Claims

A medical necessity dispute between a private plan and its member is primarily contractual in nature. The plan makes an initial determination as to whether the requested service is expressly excluded by the terms of insurance contract, commonly called the “benefit document.” If the services is not excluded, the question becomes whether the service is medically necessary as that term is defined by the benefit document or applicable law. If a plan member disagrees with a plan’s denial based on medical necessity, the dispute may be resolved through internal plan appeals processes, independent medical review, or litigation.

Internal Appeals

A member must first look to the plan’s internal appeals processes as set forth in the benefit document. Failure to exhaust these administrative remedies inevitably precludes recourse to litigation. Plan appeal processes are heavily regulated to insure that appeals are both prompt and fair.

Independent Medical Review

If the plan’s internal appeal again results in a denial of coverage, health plan members have two alternatives. They can sue for relief or, as most choose to do, request an Independent Medical Review (“IMR”). IMR allows patients to appeal a health plan’s medical necessity denial to an independent third-party medical expert, often operating under state oversight. In response to the managed care backlash, some consumer organizations and health plans pushed for IMR, and, as of August 2004, forty-three states and the District of Columbia had enacted mandatory IMR requirements for private insured health plans.

Judicial Review

Judicial review is available when an individual claims that a plan has improperly denied coverage. These suits commonly claim that the plan has breached the insurance contract, and seek either damages are, as a general matter, not preempted by ERISA’s exclusive enforcement scheme, so long as the review is serving, effectively, as nothing more than a second medical opinion. If an IMR program appears more in the nature of an arbitration proceeding or a new cause of action, as opposed to a second medical opinion, it contravenes the exclusive remedy provision of ERISA, § 502, and is therefore preempted.

IMR holds the promise of prompt, inexpensive, and credible dispute resolution. IMR decisions typically resolve disputes within a few months, as opposed to years of litigation. Both the cost of the review process and the attorneys fees incurred (if any) are minimal. The credibility of IMR decisions derives from the selection of a neutral expert and conscientious application of applicable standards by that expert.

Despite these benefits, IMR mechanisms are used relatively infrequently by enrollees, possibly because health plans have historically denied relatively few claims (less than one-half of one percent of all claims) on medical necessity grounds. In the end, it may be that only a small number of cases are appropriate for IMR.
for injuries caused by the denial or an injunction compelling the plan to cover the care sought.

Congress has taken action to eliminate punitive or multiple damages and to limit recoveries to the actual dispute at hand, that is, whether the insurer is responsible for the cost of covering the treatment in question. With respect to ERISA employee benefit plans, which account for the vast majority of private healthcare insurance in this country, a member’s exclusive remedy is to sue for coverage of the benefit under federal law.118 State law claims for more expansive recoveries in coverage disputes are preempted with respect to employer-funded insurance programs.119 Congress created this exclusive remedy scheme as a balancing of the need for prompt and fair claims settlement procedures against the public interest in encouraging the formation of employee benefit plans. The policy choices reflected in the inclusion of certain remedies and the exclusion of others under the federal scheme would be completely undermined if ERISA-plan participants and beneficiaries were free to obtain remedies under state law . . . 120

Many have argued that the courts are not a good forum for medical care dispute resolution. The judicial process is notoriously slow, often taking years and years to resolve disputes. Further, commenters have suggested that neither judge nor jury is well equipped to resolve scientific medical disputes. Instead, having no background or education in the science at hand, they are expected to listen to hours of conflicting testimony from paid “experts” testifying for each side and then to adjudicate that “battle of the experts.” All too often, the results are ungrounded, sympathy-based, and conflicting.121

The ABMT scenario discussed earlier provides an example of problems that can occur in resolving scientific medical necessity disputes through the courts. Many cases sought coverage for ABMT as a breast cancer treatment or damages for the failure to cover such treatment.122 While some courts ruled in favor of the plans, a large number of decisions favored the plaintiff members, most prominent of which was Fox v. Health Net, in which the court awarded over $89 million, including $77 million in punitive damages, for a health plan’s denial of coverage for ABMT to a breast cancer patient who ultimately succumbed to the disease. 123 This litigation, as well as related government mandates discussed earlier, compelled plans to offer coverage for ABMT, an extraordinarily expensive treatment that ultimately proved ineffective and potentially harmful to patients. “Desperation- or sympathy-guided rulings”124 from untrained judges and juries do not appear to contribute to a fair and just system of resolution of medical necessity disputes.

Medicare Claims125

Claims Processing Determinations

If there is no statutory provision, regulation, NCD, or LMRP in place, local Medicare contractors have the discretion to determine whether a particular service is covered by Medicare.”126 The contractor decision may be based on the professional judgment of the contractor’s medical director, a physician advisor in a particular specialty, or a non-physician claims processor.

Appeals Processes

Prior to statutory amendments enacted under BIPA §521 and the MMA,127 there were separate appeal processes for Part A and Part B. These processes are described because as they have been used as models for many government and private plans appeals.

Part A128

Denied Part A claims were subject to reconsideration (desk review by the fiscal intermediary, based on the record and on additional information submitted by the beneficiary); a de novo administrative hearing (the ALJ was bound by statute, regulations, national coverage determinations, and CMS Rulings); Appeals Council review; and judicial review in federal court.

Part B

Denied Part B claims were subject to reconsideration (desk review by the carrier, based on the record and on additional information submitted by the beneficiary); a carrier fair hearing (conducted by a hearing officer employed or engaged by the carrier); an admin-
istrative hearing (conducted by an ALJ bound by statute, regulations, national coverage determinations, and CMS Rulings); Appeals Council review; and judicial review in federal court.

A variety of procedural, substantive and practical problems, including extensive delay, were reported by appellants in the Medicare appeal process.129 There were also limitations on the extent to which disputes involving “national coverage determinations” could be resolved by the Part A and Part B administrative appeals processes.

On March 8, 2005, CMS published an interim final rule incorporating changes required by statutory amendments.130 CMS also recently published final rules regarding appeals of determinations under Part C (Medicare Advantage) and Part D (Medicare Prescription Drug).131, 132

**Limitation of Liability**

Recognizing that physicians and patients would not always be able to know in advance whether a particular healthcare service would be found reasonable and necessary, Congress decided it would be unfair to hold patients or providers financially responsible when neither had a reason to anticipate an adverse determination. Congress enacted a protection, known as “limitation of liability” that provides that if neither the provider nor the beneficiary knew, or should have known, that the services in question would be considered not medically necessary, Medicare will pay for the services notwithstanding the adverse decision regarding medical necessity.

While the limitation of liability provision allows providers to recommend and provide services at the patient’s expense when Medicare has given notice that a specific treatment will not be covered, the process puts the patient in a difficult and confusing situation. The patient is told (1) that his or her physician believes that a particular service may be beneficial for their condition, (2) that Medicare probably will deny a claim for the services as not reasonable and necessary, and (3) that if Medicare denies the claim, he or she will be required to pay for the services personally. It is certainly reasonable to allow patients to choose to receive non-covered services (including services that are not considered reasonable and necessary) at their own expense. Otherwise, physicians who face medical necessity policies with which they disagree would face the ethical dilemma of withholding the services from Medicare patients based on the policies but against their medical judgment in the interest of the patient, or providing the service for free in the event Medicare ultimately denies the claim.

**Quality Improvement Organizations**

Formerly known as Peer Review Organizations, Quality Improvement Organizations (QIOs) make determinations concerning the medical necessity, quality, and appropriateness of care (for example, whether inpatient medical services could be provided more economically in a different setting) furnished to Medicare and Medicaid patients. In so doing, QIOs are required to “apply professionally developed norms of care, diagnosis, and treatment based upon typical patterns of practice within the geographic area served by the [QIO] as principal points of evaluation and review, taking into consideration national norms where appropriate.”134 Beneficiaries may appeal certain decisions directly to the QIO.

**Cost-Effectiveness Issues**

The original Medicare legislation did not include cost-effectiveness as a criterion for deciding whether claims should be paid or not. From time to time Congress has attempted to introduce consideration of the cost-effectiveness of government-reimbursed healthcare services.135 Indeed, Medicare and Medicaid providers have an obligation to ensure that healthcare services ordered for government patients are “provided economically and only when, and to the extent, medically necessary.” Congress has directed that professional standards of care be developed for use by government contractors charged with reviewing the quality of care furnished in the programs.136 The consideration of cost effectiveness of a given treatment is taken into account in medical necessity determinations made under some Medicaid programs and private plans.
IMPROVING THE PROCESS FOR DETERMINING MEDICAL NECESSITY

Both the efficacy and the utility of the medical necessity concept have been questioned by legal and medical/public health commentators because of ambiguities in the definition and interpretation/application in practice. Nevertheless, it appears clear that the concept of medical necessity will be with us for at least the immediate future. After an exhaustive review of the subject, researchers at Stanford University’s Center for Health Policy concluded that understanding and improving the process by which medical necessity decisions are made is more important than the terminology used to describe those decisions.137

The development of an approach to medical necessity policies and processes that appropriately considers the interests of the stakeholders would be an improvement in the current state of affairs. The challenge will be striking the right balance(s) and setting aside ingrained prejudices and fears regarding the motives, strategies, and forthrightness of the other stakeholders so that an open and productive discourse can occur.

To balance these competing interests and provide for the orderly and fiscally viable administration of healthcare, Health Lawyers’ Public Interest Committee believes that several important values should be considered. While there may be additional concepts that should be considered regarding the process for making medical necessity decisions, both at the policy and individual level, our research has identified the following as potential characteristics of a “better” system that we believe warrant consideration by the Colloquium panel:

- Transparent138 with respect to standards and processes;
- Predictable;
- Based, to the extent possible, on scientific research (that is, “evidence-based”);
- Fair/equitable;
- Applied uniformly across geographic regions and similarly situated patients;139
- User-friendly—for all users, patients, providers, and plans;
- Providing protection against “gaming” of the system;
- Timely for both policymaking and individual determination and appeals;
- Responsive to changes in medical research/technology/treatments;
- Financially sustainable/economical/fiscally responsible; and
- Incorporating consumer choice and responsibility.

Core Questions That Will Guide the Colloquium Discussion

Discussion at the 2005 Colloquium will be structured around five core questions:

**Question 1:** What are the key concerns of the following stakeholders with respect to public and private policymaking/rulemaking processes for medical necessity determinations as they are conducted today:

(a) Patients/consumers;
(b) Physicians and other healthcare practitioners;
(c) Institutional providers and healthcare systems;
(d) Payors and Risk-Pool Stakeholders: Government Healthcare Programs, Private Health Plans, Employers, and Individuals

**Question 2:** What are the key characteristics of an ideal system for public and private policymaking/rulemaking processes for medical necessity determinations? Is there a better rulemaking model?

**Question 3:** What are stakeholders’ key concerns with the public and private adjudication processes for challenges to medical necessity determinations, with an emphasis on the interpretation and application of medical necessity rules?

**Question 4:** What are the key characteristics of an ideal system for the public and private processes of adjudicating challenges to medical necessity determinations, with an emphasis on identifying better ways to interpret and apply the rules governing adjudications?

**Question 5:** What points of consensus and points of disagreement emerged from the overall discussion at Health Lawyers’ 2005 Colloquium, *Medical Necessity: Current Concerns and Future Challenges*?
ENDNOTES

1 Similar issues exist in other countries, of course. The Supreme Court of Canada recently addressed important issues related to the meaning of medical necessity within the context of the Canadian healthcare system and the provisions of the Canadian constitution (the Canadian Charter of Rights and Freedoms) guaranteeing equal protection, § 15(1), and due process, § 7. Auton v. British Columbia, 2004 SCC 78 (November 19, 2004) (concluding generally that, within the Canadian scheme, not all medically necessary health care services are covered).

2 Editor’s Note: This issue paper is designed to provide readers with substantive background on the concept and application of “medical necessity.” The American Health Lawyers Association researched, wrote, and distributed this issue paper to participants in its 2005 Public Interest Colloquium, Medical Necessity: Current Concerns and Future Challenges, as a briefing paper on the issue and to orient the expert panel to what AHLA judged would be the scope and objectives of the Colloquium discussion. Hence, the paper uses the future tense in sections that explain the scope and objectives of what was “the upcoming Colloquium” at the time the paper was distributed.

3 Medical necessity determinations are made not only with respect to payment of an individual claim, but also in connection with allegations of malpractice or fraud against a physician or a provider.

4 In addition to denial of payment, adverse findings regarding medical necessity can subject providers to administrative sanctions related to quality of care, as well as investigation by numerous government agencies that have become increasingly interested in cases involving medical necessity issues as a basis for false claims and fraud allegations.


6 As Paul Ginsberg explained to Congress:

   Over the long haul, advancements in medical technology are far and away the biggest factor in rising costs. And our current financing system facilitates the rapid diffusion of expensive new technologies by paying most of their cost — even in the absence of careful consideration of their clinical effectiveness relative to existing treatments. Fundamental change in this dynamic would require support for improved and more frequent evaluation of new technologies prior to decisions about coverage, as well as carefully differentiated incentives built into the financing system that encourage both providers and patients to evaluate the clinical effectiveness of a given course of treatment against its cost.

   House Committee on Ways and Means Statement of Paul Ginsburg, Ph.D., President, Center for Studying Health System Change Testimony Before the Subcommittee on Oversight of the House Committee on Ways and Means, June 22, 2004.

7 Healthcare technology advances have greatly extended the functional lifespan for Americans, increasing consumption of goods and services by those individuals, and therefore contributing substantially to the economy of the nation. See Kevin M. Murphy and Robert H. Topel, eds., “Measuring the Gains from Medical Research: An Economic Approach,” University of Chicago Press, a compilation of papers questioning whether investments in medical treatment and research are worthwhile. The editors conclude that they are: Growth in longevity since 1950 has been as valuable as growth in all other forms of consumption combined; medical advances producing 10 percent reduction in mortality from cancer and heart disease alone would add roughly $10 trillion (a year’s gross domestic product) to national wealth; and the average new drug approved by the FDA yields benefits worth many times its cost of development.


10 42 U.S.C. §§ 1395-1395ggg (2004). The Medicare program is administered by the Centers for Medicare and Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA) and the Bureau of Health Insurance (BHI).
Appendix A

Issue Paper to Establish a Common Basis for the Colloquium Discussion


17 Perhaps the most dramatic development has been the ability of attorneys to advertise and solicit clients more freely in the marketplace, which has contributed to an environment in which it seems that someone must be found at fault for every bad result, and in which the standards of practice are debated in courtrooms and effectively decided by juries. Some would argue that the result of this development has been the rise of “defensive medicine,” in which the ultimate standard against which a provider measures his or her decisions is not so much what is “medical necessary” as we use that term here, but rather what is necessary to avoid liability.


19 See GUIDE TO MEDICARE COVERAGE DECISION-MAKING AND APPEALS (Eleanor Kinney ed., 2002), which includes chapters that present the perspectives of patients, providers, drug and device manufacturers, and CMS regarding the coverage determination process and bibliography of suggested readings.


21 For example, see the changes made to the Medicare program’s coverage determination process by BIPA § 522.

22 The “moral hazard” problem in health care has been explained succinctly as follows: If individuals are free to spend as they will with the assurance that the insurance company will pay, the resulting resource allocation will certainly not be socially optimal. This makes perfectly reasonable the idea that an insurance company can improve the allocation of resources to all concerned by a policy which rations the amount of medical services it will support under the insurance policy.


24 Raising the stakes even higher is the fact that—in addition to lost practice revenues—by not pursuing payment from patients when Medicare denies a claim, or by simply providing but not billing for the service in question, a physician caring for Medicare patients could face fraud and abuse liability for “patient inducement.” 42 U.S.C. § 1320a-7a(a)(5) (violation to provide free services that physician knows or should know are “likely to influence” a beneficiary’s choice of provider.).

25 In the Medicare context, this is known as an advance beneficiary notice (ABN).


27 Id. at 2.

28 Id.

29 Condition of Participation: Medical Staff, 42 C.F.R. § 482.22 (2004). The OIG has suggested in its Compliance Program Guidance for Hospitals that the compliance officer should compile a clear comprehensive summary of applicable medical necessity criteria for dissemination within the organization. One commenter has suggested that even CMS has, to date, been unable to accomplish this task. See Publication of the OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8987 (1998); see generally Abuse of Discretion, supra note 30, at 117-21.

31 See generally Timothy P. Blanchard, Monitoring Medical Necessity In Hospitals: A Compliance Imperative and New Challenge in Hospital-Medical Staff Relations, CCH HEALTHCARE COMPLIANCE LETTER, Vol. 7, No. 15 (JULY 26, 2004). Difficult situations can arise when members of a medical staff or its executive committee disagree with hospital administration or the hospital’s governing body regarding questions of clinical competence, medical judgment, or indications of medical necessity. It is not uncommon for there to be significant differences of opinion among members of a medical staff (and organized medicine generally) regarding the appropriate treatment of certain conditions (medical versus surgical, conservative versus aggressive) and each perspective is typically supported by compelling professionally and ethically sound positions.

32 Since the hospital bills for the admission and ancillary services it provides, it has direct false claims exposure based on the submission of the claims if it knows or should know that the services it billed for were not reasonable and necessary. 42 U.S.C. §§ 1320a-7a(a) (1) (A), 1320a-7a(a)(1)(E); 31 U.S.C. § 3729.

33 According to then Acting Principal Deputy Inspector General, “[w]hen hospital quality review systems break down and unnecessary medical care is provided, we will use our authorities to remedy the problem.” See Press Release, Office of Inspector General, OIG and Tenet Healthcare Corporation Reach Divestiture Agreement to Address Exclusion of Redding Medical Center (Dec. 11, 2003), available at www.oig.hhs.gov/publications/docs/press/2003/121103release.pdf (last visited Nov. 21, 2004).

34 The concept of acting through medical staff processes to remove or limit privileges of physicians practicing inefficiently is known as “economic credentialing.” See, e.g., OIG Advisory Opinion 05-01, http://oig.hhs.gov/fraud/docs/advisoryopinions/2005/ ao0501.pdf.

35 In the 1980s and 1990s, various “managed care” models advanced with the goal of “rationing” medical services in this sense by substituting a knowledgeable care overseer with a financial stake in the outcome for the unavailable “knowledgeable” consumer paying for a service. These managed care approaches included selective provider networks, provider risk contracting, primary care gatekeeping and prospective and concurrent utilization review. The common theme to all of the approaches was that insurers would cover care only if it were truly medically appropriate as enforced by some mechanism other than a fee-for-service treating physician’s advice. See Mays, G. P., Claxton, G., and White, J. “Managed Care Rebound? Recent Changes in Health Plans’ Cost Containment Strategies.” Health Affairs Web Exclusive (August 11, 2004). Available at www.healthaffairs.org. See also, Rosenbaum, S., Kamoie, B., Mauery, D.R. and Walitt, B., Medical Necessity in Private Health Plans: Implications for Behavioral Health Care; DHHS Pub. No. (SMA) 03-3790, Rockville, MD: Center for Mental Health Services, Substance Abuse and Mental Health Services Administration (2003): 8.


38 Miller, R.H. and Luft, H.S. “HMO Plan Performance Update: An Analysis of the Literature, 1997-2001.” Health Affairs (Jul/Aug 2002): 63. In general, the Miller and Luft literature survey finds no harm to quality under a managed care system. With respect to the specific issue of underutilization, they find that: “five findings showed lower HMO quality with the same or lower utilization, while four findings showed higher HMO quality with the same or lower utilization.” Id. At 76.

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40 Miller, R.H. and Luft, H.S. “HMO Plan Performance Update: An Analysis of the Literature, 1997-2001.” Health Affairs (Jul/Aug 2002): 63. In general, the Miller and Luft literature survey finds no harm to quality under a managed care system. With respect to the specific issue of underutilization, they find that: “five findings showed lower HMO quality with the same or lower utilization, while four findings showed higher HMO quality with the same or lower utilization.” Id. At 76.

Appendix A  Issue Paper to Establish a Common Basis for the Colloquium Discussion


46 Two Wrongs, supra note 24, at 959-62.


48 Medicare 17 percent and Medicaid/SCHIP 15 percent.

49 These programs include workers’ compensation, public health, military healthcare, Veterans Administration, Indian Health Services, and school health.

50 Private programs include non-patient revenues and philanthropy.


56 Federal courts have allowed states to set across-the-board “utilization control” limits on the number of days that a beneficiary may spend in the hospital or see a physician per month. See, e.g., Curtis v. Taylor, 625 F.2d 645, 652 (5th Cir. 1980), see 42 C.F.R. § 440.230(d); These limits, which like benefit category determinations are permissible even though they will result in the denial of services that might otherwise be considered medically necessary.


58 42 U.S.C. § 1396a(a)(17).

59 Beal v. Doe, 432 U.S. 438, 444-45 (1977) (abortions not certified by a physician as “medically necessary”). The case did not raise the issue of how to distinguish between medically necessary and unnecessary services; it interpreted a statute that required a certificate of medical necessity from a physician.
53

60 42 C.F.R. § 440.230(d) (2004) (emphasis added); see also 42 U.S.C. § 1396a(a)(30) (requiring states to safeguard against unnecessary utilization). Organ transplants are a special case. For these services, Federal payments will not be made unless the state has written standards for coverage of such procedures providing that similarly situated individuals are treated alike, and that any restrictions on facilities or practitioners are consistent with the accessibility of high quality care. 42 U.S.C. § 1396b(i)(1). Some courts have interpreted this provision to mean that states have discretion over whether to fund organ transplants. See Dexter v. Kirschner, 984 F.2d 979, 983 (9th Cir. 1993) (holding that organ transplants may be limited even if medically necessary).

61 42 C.F.R. § 440.230(b) and (c).

62 See, e.g., Hern v. Beye, 57 F.3d 906, 911 and n. 3 (10th Cir. 1995); but see DeSario v. Thomas, 139 F.3d 80, 96 (2d Cir. 1998) (states need not provide all medically necessary durable medical equipment), citing Alexander v. Choate, 469 U.S. 287, 302-03 (1985), in which the Court explained:

But Medicaid programs do not guarantee that each recipient will receive that level of healthcare precisely tailored to his or her particular needs. Instead, the benefit provided through Medicaid is a particular package of services, such as 14 days of inpatient coverage. That package of services has the general aim of assuring that individuals will receive necessary medical care, but the benefit provided remains the individual services offered – not “adequate care.”

63 Preterm, Inc. v. Dukakis, 591 F.2d 121, 125 (1st Cir. 1979).

64 For example, the Eighth Circuit has held that a state cannot “interfere” with a physician’s judgment of medical necessity and applied a presumption in favor of the physician’s medical judgment. See, e.g., Weaver v. Reagen, 886 F.2d 194, 198, 200 (8th Cir. 1989).

65 See, e.g., Rush v. Parham, 625 F.2d 1150, 1155-56 (5th Cir. 1980) (holding that medical necessity can be defined to exclude experimental services).

66 For example, in Pinneke v. Preiser, 623 F.2d 546, 549 (8th Cir. 1980), the Eighth Circuit found Iowa in violation of the Medicaid statute by refusing to pay for sex reassignment surgery “[w]ithout any formal rulemaking proceeding or hearings.” After Iowa conducted formal rulemaking to exclude sex reassignment surgery from Medicaid coverage the court upheld the limitation, finding that Iowa had reasonably concluded that sex reassignment surgery was not medically necessary after engaging in a “rulemaking process and . . . consider[ing] the knowledge of the medical community.” Smith v. Rasmussen, 249 F.3d 755, 760-61 (8th Cir. 2001).


68 Summary of detailed requirements from, Schneider, Tennessee’s New Medically Necessary” Standard: Uncovering the Insured?, Kaiser Commission on Medicaid and the Uninsured Policy Brief (July 2004), available at http://www.kff.org/medicaid/7139.cfm. The only exception to the fourth criterion is for off-label uses of FDA-approved drugs that “can be shown to be widespread” and “to be generally accepted by the professional medical community as an effective and proven treatment in the setting and for the condition for which it is used.” Id.


71 HRS § 432E-1.4 (2000); see S. Rosenbaum, supra.


75 Mello and Brennan, supra, p. 110-111.

76 Case No. 219692, 1993 WL 794305 (Riverside Cty. Super. Ct./Central Cal. Dec. 23 1993). The court awarded over $89 million, including $77 million in punitive damages, for a health plan’s denial of coverage for ABMT to a breast
cancer patient who ultimately succumbed to the disease. Defendant in Fox was not helped by the fact that while denying ABMT for the deceased plaintiff, it had covered the treatment for a relative of its CEO. Mello and Brennan, supra, p. 108. See also cases cited in: Morreim, E. H. “From the Clinics to the Courts: The Role Evidence Should Plan in Litigating Medical Care” Journal of Health Politics, Policy and Law 26:2. (April 2001): 409, 411.

77 Mello and Brennan, supra, pp. 103-105.


79 Mello and Brennan, supra.

80 Mello and Brennan, supra, p. 110-111.

81 Blue Cross and Blue Shield Service Benefit Plan 2004 Brochure, p. 112. http://www.opm.gov/insure/04/brochures/pdf/71-005.pdf. “The fact that one of our covered providers has prescribed, recommended, or approved a service or supply does not, in itself, make it medically necessary or covered under this Plan.” Id.

82 See generally Linda A. Bergthold, Medical Necessity: Do We Need It?, 14 Health Affairs 4, 180 (Winter 1995).


87 Id.

88 Penalties under the False Claims Act, 31 U.S.C. § 3729, include treble damages plus a penalty of $5500 per false claim.


90 Id. at 5 (emphasis added).

91 The first is “coding and billing,” which includes submitting bills only for “reasonable and necessary” items and services. The second is described simply as “reasonable and necessary services.” OIG Compliance Program for Individual and Small Group Physician Practices, 65 Fed. Reg. 59434, 59438-39 (Oct. 5, 2000).

92 Id. at 59439. This requirement suggests that the OIG is referencing the “Medicare definition” of “reasonable and necessary”; in fact no such definition exists.

93 Id.

94 Id.

Precedential determinations are, of course, a two-edged sword. One who likes the precedent is happy, but one who disagrees with the precedent has more of an uphill battle. The problem with making medical necessity determinations or aspects thereof precedential is several fold. First, the numerous parties appealing adverse determinations do not all have the same abilities and interests, particularly when it comes to certain nuances, which may be or appear to be more important to some in the population than to others. A partial victory may be sufficient for some, but worse due to continuing uncertainty for others. Second, and more important, for a system of precedent to be fundamentally fair, there must at a minimum be a system of public notice regarding pending issues and an adequate opportunity for participation by others who, while not a party to the instant claims on appeal, have an interest in securing or avoiding a precedent that will affect them.


BIPA § 522 (codified at 42 U.S.C. § 1395ff(f)).


Id.

See BIPA, §522

CMS Program Integrity Manual, CMS Pub. 100-8, Chapter 13, § 13.5.1.


MMA § 731.

Nothing precludes other voluntary dispute resolution procedures, but these three are almost universally available.[authority]

See e.g., Makar v. Health Care Corp. of Mid-Atlantic, 872 F.2d 80 (4th Cir. 1989).


Rush, supra, at 386, n.17. See also, Hawaii Management Alliance Corporation v. Insurance Commissioner, 106 Hawaii 21, 100 P. 3d 952 (2004) (holding that Hawaii’s IMR law too closely resembles an adjudicatory proceeding and is therefore preempted).

See, e.g., Mass. G. L. c. 176O, §14(a) and 105 Code of Mass. Reg. 128.401, setting forth a 60 day decision period along with an opportunity for expedited review as necessary.

[authority] costs of review low


Aetna Health Inc. v. Davila, No. 02-185 (U.S. June 21, 2004); Hotz v. Blue Cross and Blue Shield, 292 F. 3d 57 (1st Cir. 2002).


While ERISA would preempt damages beyond the cost of the coverage with respect to ERISA health benefit plans, not all insureds (e.g. state and municipal employees, church employees, non-group members) are subject to ERISA. ERISA § 4(b); 29 U.S.C. § 1003(b).


Morreim, supra, at 413. Morreim advocates for better scientific decision-making within the judicial process.

This section addresses the process for regular fee-for-service Medicare claims. A separate system exists for Medicare + Choice, a form of HMO now known as “Medicare Advantage.” See 42 C.F.R. Part 422, Subpart F, and grievance procedures at 42 C.F.R. Part 422, Subpart E.

Medicare Program; Criteria and Procedures for Making Medical Services Coverage Decisions That Relate to Health Care Technology, 54 Fed. Reg. at 4305, 4311. (“Even when a claim for a new, or otherwise questionable, service is received, the contractor is authorized to make reasonable and necessary decisions with respect to the service, in the absence of applicable national policy.”).


In view of the Colloquium’s broad policy focus, Health Lawyers concluded that it would exceed the Colloquium’s anticipated scope of discussion to summarize in this paper the pending revisions to the Medicare appeals process and proposed changes to Part C and Part D rules governing appeals of medical necessity determinations.


See Testimony of Linda Bergthold, Ph.D., supra, n. 18.

In optics, a transparent physical object is one that can be seen through, and the term “transparency” has been used in politics, law, economics, and management as a metaphorical extension of that meaning. Transparency is the
opposite of privacy; an activity is transparent if all information about it is freely available. Thus, when courts of law admit the public, when fluctuating prices in financial markets are published in newspapers, those processes are said to be “are transparent;” when military authorities classify their plans as secret, transparency is absent. “Radical transparency” is a management method whereby nearly all decision making is carried out publicly: all draft documents, all arguments for and against a proposal, the decisions about the decision-making process itself, and all final decisions are made publicly archived. Wikipedia, www.wikipedia.com/

139 As Sean Tunis, MD, an emergency medicine physician and acting Chief Clinical Officer at CMS, has recognized: “It becomes problematic when a beneficiary is desirous of a service that somebody ten minutes away can get because they are covered by a different [Medicare claims processing] contractor.” Markian Hawryluk, Local Commotion: The Flip Side of National Medicare Policy-Making, AM. MED. NEWS, Aug. 5, 2002, at www.ama-assn.org/amed-news/2002/08/05/gvsa0805.htm (last visited Nov. 21, 2004).
Appendix B

Medical Necessity and Complementary and Alternative Medicine
(A Supplement to Health Lawyers’ Discussion Paper on Medical Necessity)

Introduction

The term “complementary and alternative medicine” (CAM) describes a group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine. As the terms “complementary” and “alternative” are used by the National Center for Complementary and Alternative Medicine (NCCAM), complementary medicine refers to treatments used with conventional medicine, and alternative medicine refers to those used in place of conventional medicine. NCCAM classifies CAM modalities as follows:

1. Alternative medical systems
2. Mind-body interventions
3. Biologically based treatments
4. Manipulative and body-based methods
5. Energy therapies

A recent Institute of Medicine report found that the diversity of practices within CAM is so great that there are few, if any, generalizations that apply equally to all systems, modalities and practices defined as CAM. The report defined CAM as “a broad domain of resources that encompasses health systems, modalities and practices and their accompanying theories and beliefs, other than those intrinsic to the dominant health system of a particular society or culture in a given historical period.” The report went on to note that boundaries within CAM and between the CAM domain and the domain of the dominant system are not always sharp or fixed. CAM interventions are increasingly being integrated with conventional medical therapies, which has given rise to use of the term “integrative” in place of the terms “alternative” and “complementary.”

Medical necessity decisions regarding medical interventions classified as complementary or alternative are complicated by several factors. The first are common criteria for determining medical necessity, which may rule out many forms of CAM, even if there is sound scientific evidence of their safety and efficacy. Another is the lack of scientific evidence concerning the efficacy of some forms of CAM. While there is a growing body of evidence from well-designed randomized, controlled trials demonstrating the safety and effectiveness of some CAM therapies, scientific evidence supporting other CAM interventions is lacking. Even if the safety and effectiveness of a particular complementary or alternate intervention have been scientifically demonstrated, there may be little or no information on the cost effectiveness of the intervention or how it compares in cost and effectiveness to one or more conventional medical treatments for the same condition. In addition, most health plans lack long-term experience in determining which CAM interventions are appropriate in particular clinical situations and which are not. These factors mean that the reasons for medical necessity decisions concerning CAM therapies often are even more obscure than they are concerning conventional medicine. They also mean that CAM interventions, which may in some cases be superior to those available in conventional medicine both in efficacy and cost, are not available to patients, unless they are willing to pay for them out of their own pockets.

A health policy discussion of the medical necessity of CAM is complicated by the fact that there is a striking level of consumer demand for CAM, despite the dearth of scientific knowledge about the effectiveness of some CAM interventions. This consumer demand has translated into employee demand for health plan coverage of CAM and, as a result, into employer demand for health plans that include some coverage for CAM.

Utilization and Costs of CAM

A survey conducted in 2002 by the National Center for Complementary and Alternative Medicine at the National Institutes of Health found that 36 percent of U.S. adults use some form of alternative remedies. Another survey conducted in 1997 pegged estimated annual U.S. spending on CAM at between $36 billion and $47 billion. Of this amount, an estimated $12 billion to $20 billion was paid out-of-pocket for the services of professional CAM health care providers. These fees represented more than the public paid out-of-pocket for all hospitalizations in 1997 and about half of what it paid for all out-of-pocket physician services. In addition, this survey found...
another $5 billion of out-of-pocket spending on herbal products.\(^6\) Estimated out-of-pocket expenditures on herbs and high-dose vitamins totaled $8 billion in 1997. Out of pocket expenditures in 1997 for CAM therapies were estimated to be $27 billion, which were comparable to the total out-of-pocket expenditures for all U.S. physician services. The total number of visits to CAM providers (629 million) exceeded the total number of visits to physicians’ offices in 1997.\(^7\)

Despite the high rates of CAM use, studies in both 1990 and 1999 found that fewer than 40 percent of individuals using CAM disclosed to their physicians that they had used such therapies.\(^8\) Patients’ failure to disclose CAM use to their physicians raises concerns about possible drug-herb interactions, including herbs that reduce the effectiveness of certain prescription drugs. In 1997, an estimated 15 million adults took prescription drugs concurrently with herbal remedies or high-dose vitamins.\(^9\)

Use of CAM is more prevalent among women (48.9%) than men (37.8%).\(^10\) The higher rates of CAM use among women correspond to women’s higher utilization of health care in general.\(^11\) Those with at least some college and those earning $50,000 or more per year use CAM more than those with less education or lower incomes.\(^12\)

A 1998 study found that predictors of CAM use include: more education; poorer health status; a holistic orientation to health; having had a transformational experience that changed the person’s world view; and classification in a cultural group identifiable by their commitment to environmentalism and feminism, and their interest in spirituality and personal growth psychology.\(^13\)

Studies have documented more frequent CAM use for treatment of health problems that lack definitive cures, have an unpredictable course and prognosis, or are associated with substantial pain, discomfort, or side effects from medication.\(^14\) Chronic conditions are associated with more frequent use of CAM, although an estimated one-third of CAM use is for purposes of wellness and disease prevention.\(^15\)

Results of the 2002 National Health Information Survey indicate that use of CAM increases with age. Prevalence of some use of CAM in the 18–29 age bracket was 53.5 percent, compared to a prevalence of 70.3 percent in the in the oldest age bracket (85 years and above).\(^16\)

The already-intense cost pressures on health plans would increase if CAM were covered by more health plans. Several studies have found that utilization of CAM services tends to increase as coverage of CAM increases.\(^17\) One survey found that health insurance coverage was the strongest correlate of frequent visits to alternative practitioners.\(^18\)

Paradoxically, the high cost of conventional medical treatment may drive at least part of the demand for CAM. The Center for Studying Health System Change recently released a report finding that nearly six million American adults turned to CAM in 2002 because conventional medical treatment was too expensive.

According to the report, herbal remedies were by far the most widely used form of CAM among the group that cited cost concerns as a reason for using CAM. Compared to the 38 million adults who used CAM to treat specific health conditions but did not cite the cost of conventional medicine as a reason for doing so, people using CAM because of costs concerns were four times more likely to be uninsured. They were almost twice as likely to have incomes below 200 percent of the federal poverty level ($36,200 for a family of four). In addition, those using CAM because of cost concerns were much more likely to report fair or poor health status and to lack a place where they usually receive medical care. This group was more likely to report overall unmet medical needs (i.e., mental health and prescription drug needs) because of costs.\(^19\)

There is growing integration of CAM with conventional medicine. The American Hospital Association began collecting information in 1998 about hospitals that provide CAM services. In 1998, only 6 percent of hospital reported offering CAM services. By 2001, the number of hospitals providing CAM services had increased to 15 percent, showing “a steadily growing interest by hospital to enter into this arena.”\(^20\) Cancer treatment centers frequently integrate CAM with
conventional cancer therapies. Well-known cancer centers integrating CAM with conventional treatment include the University of Texas M.D. Anderson Cancer Center, Memorial Sloan-Kettering Cancer Center, and Dana Farber Cancer Institute.21

**Third Party Payment for CAM**

The Medicare program provides very limited coverage for CAM. Currently, only manual manipulation by chiropractors for subluxation of the spine and religious nonmedical health care (e.g., Christian Science nursing care) are covered.22 Medicare will also conduct a two-year demonstration project mandated by Section 651(b) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 to evaluate the feasibility and advisability of covering chiropractic services under Medicare. The services in the demonstration project extend beyond the current coverage for manipulation to correct neuromusculoskeletal conditions, and include diagnostic and other services that a chiropractor is legally authorized to perform by the state or jurisdiction in which the treatment is provided. The demonstration project is slated to begin in April 2005. Physician approval would not be required for these services.23

Other CAM treatments, such as acupuncture, chelation therapy for atherosclerosis, colonic irrigation, and laetrile are not covered under Medicare.24 Biofeedback therapy, which used to be considered CAM, is approved under very limited circumstances.25 In response to findings about lifestyle interventions for prevention of cardiovascular disease, Medicare announced it would test a new (non-surgical) preventive heart program developed by Dean Ornish, M.D.26 One study showed that this preventive heart program reduced the need for surgery and cut patients’ medical costs by $10,000 a year.27

In recent years, numerous employer-sponsored health plans have begun to offer coverage for certain CAM services, although the prevalence of this coverage is still relatively low in comparison to coverage of conventional therapies.28 Coverage of CAM by health plans has been increasing. For example, an annual survey of employer-sponsored health plans found that, from 1998 to 2000, the percentage of respondents covering chiropractic services rose from 49 to 70. During the same period, coverage of acupuncture rose from 12 percent to 17 percent, with coverage of massage therapy increasing from 10 percent to 12 percent. The survey found that employers with more than 20,000 employees were more likely to offer CAM benefits than were medium and smaller employers. PPOs and indemnity insurers were more likely to offer CAM coverage than HMOs. Most respondents anticipated increasing their coverage of CAM in the future.29 A 2004 Kaiser Family Foundation survey found that acupuncture is covered by 47 percent of all employee health plans, and chiropractic is covered by 87 percent. Rates of healthcare coverage for large of firms with 200 or more workers were even higher, with 50 percent covering acupuncture and 91 percent covering chiropractic.30

A survey of Fortune 200 companies conducted in 2000 by PricewaterhouseCoopers found that more than 76 percent of respondents said they offer some form of complementary health care as part of their benefits package, and cited employee demand as the primary reason for doing so. In addition, 63 percent of the benefits managers surveyed believe that complementary health care is cost-effective, an important factor since many health care organizations remain skeptical about its therapeutic and cost-saving benefits.31

Where health plan coverage of CAM therapies exists, coverage nevertheless is often limited. Only certain CAM services may be covered, or there may be ceilings on the number of visits covered or restrictions on clinical applications. Coverage may vary depending on the qualifications of the practitioner providing the service. For example, a health plan may cover acupuncture for management of chronic pain if the acupuncture is performed and billed by a physician but may not cover acupuncture provided by a professionally trained acupuncturist, even if the acupuncturist is licensed.32

Private health plans may cover CAM in several different ways. These include:
1. As a rider, or supplement, to the basic benefit package, often with controls on usage, such as copayments, benefit limits (e.g., visit limits, annual limits), or use of an approved network of CAM providers.

2. As a discount program whereby covered employees (or members) pay out-of-pocket but are eligible for discounts off professional CAM fees and CAM products (discounted fees are usually tied to an approved network of CAM practitioners).

3. As a defined, core benefit. This benefit is managed by limiting the type of CAM services covered (e.g., only chiropractic, or only chiropractic and acupuncture), requiring a preauthorization or a referral by a primary care physician, or setting visit or dollar limits and higher co-payments than for routine physician visits.

4. As a CAM benefit account, typically an annual dollar amount.\textsuperscript{33}

Because the coverage of CAM by private health plans typically has built-in controls on utilization or the costs borne by the health plan, one would expect that disputes over medical necessity would not to arise as frequently with respect to CAM services as they would with respect to conventional medical services. This could change were CAM to be covered by health plans in the same way as conventional medical care is covered.

Some states have mandated that CAM benefits be included in private health insurance plans or that the services of CAM providers be covered. According to a recent report published by the Council for Affordable Health Insurance, 47 states have mandates covering chiropractors, eleven have mandates covering acupuncturists, four have mandates covering massage therapists, and four have mandates covering naturopaths.\textsuperscript{34}

The most far-reaching requirements are those of the state of Washington, which adopted a law effective at the beginning of 1996 requiring health plans to provide access to licensed providers of alternative health care. The Washington law requires that all categories of providers be given equal treatment by insurance companies.\textsuperscript{35} A partial list includes naturopaths, acupuncturists, licensed midwives, physician assistants, nurses, chiropractors, licensed massage therapists, and certified dietitians and nutritionists. The health care service they provide must be appropriate to the condition, covered by the plan, and fall within the provider’s scope of practice.\textsuperscript{36}

In response to a challenge by Washington’s 12 largest insurers, the Ninth Circuit held that ERISA does not preempt Washington’s “every-category” law. The three-judge panel unanimously held that the law does not “relate to” an employee benefit plan, and even if it did, it falls within the savings clause exception as a law regulating insurance. The court also noted that the state law operates only on health carriers and not on ERISA plans.\textsuperscript{37}

**CAM and Medical Necessity**

Under criteria used for determining medical necessity by some health plans, complementary and alternative medical therapies will be defined as not medically necessary, whether or not there is good scientific evidence of the safety and efficacy of such therapies. As an example, the Corporate Medical Policy of BlueCross BlueShield of North Carolina sets forth the following criteria for determining medical necessity:

1. The service, procedure, or supply must be provided for the diagnosis, treatment, cure, or relief of a health condition, illness, injury, or disease.

2. The service, procedure, or supply must not be experimental, investigational, or cosmetic in purpose.

3. It must be necessary for and appropriate to the diagnosis, treatment, cure, or relief of a health condition, illness, injury, or disease or its symptoms.

4. It must be within generally accepted standards within the medical community.\textsuperscript{38}

Many definitions of, or criteria for determining, medical necessity reference generally accepted standards within the medical community. If a service or procedure is still considered complementary or alternative, by definition, it would not be within generally accepted standards within the medical community. As therapies become generally accepted within the medical community, they generally cease to be defined as alternative.
or complementary therapies. If medical necessity determinations for CAM interventions depend on their acceptance by the medical community, then the intervention will probably never be considered medically necessary, as long as it has not been accepted by at least a substantial minority within the relevant medical community.

In addition, a therapy is generally not considered medically necessary if it is experimental. Many CAM therapies can legitimately be classed as experimental, because scientific validation of their safety and effectiveness is lacking.

For specific CAM therapies to be more widely accepted within the medical profession, they must first overcome the longstanding prejudice against complementary and alternative medicine within the profession. A 1993 article in the New England Journal of Medicine (NEJM) stated that a large proportion “of unconventional practices entail theories that are patently unscientific.” In 1998, while not classifying theories underlying alternative medicine are “patently unscientific,” NEJM editors, in the introduction to a special issue on alternative medicine, wrote: “It is time for the scientific community to stop giving alternative medicine a free ride. There cannot be two kinds of medicine—conventional and alternative. There is only medicine that has been adequately tested and medicine that has not, medicine that works and medicine that may or may not work.”

In its final report, the White Commission on Complementary and Alternative Medicine, which was convened by President Clinton, opined that conventional and CAM systems of health and healing should be held to the same rigorous standards of good science. A theme of several of its recommendations was that funding for research on CAM should be increased.

A recent Institute of Medicine report recommended that the same principles and standards of treatment effectiveness apply to all treatments, whether currently labeled as conventional medicine or CAM. While acknowledging characteristics of CAM that make performing scientifically valid treatment effectiveness studies difficult, the IOM committee, nevertheless, called for investigators to use and develop as necessary common methods, measures, and standards for generating and interpreting evidence necessary to make decisions about the use of CAM and conventional therapies. Although it identified randomized, controlled trials (RCTs) as the “gold standard” for treatment effectiveness research, the IOM committee called for other, innovative study designs to be used when RCTs cannot be done or where their results are not generalizable to the real world of CAM practice. Options include preference RCTs, observational and cohort studies, case control studies, studies of bundles of therapies, studies that specifically incorporate, measure or account for the placebo or expectation effect, and attribute-treatment interaction analysis.

The report states that a majority of CAM therapies reviewed in Cochrane reviews were found to have insufficient evidence of effect. Based on this finding, the committee stated that much more research on CAM is required.

If the approach recommended in the Institute of Medicine report were followed in making medical necessity determinations about CAM, more CAM therapies probably would be deemed medically necessary. The Institute of Medicine Committee on the Use of Complementary and Alternative Medicine by the American Public conducted a review of the evidence for CAM from Cochrane reviews. Cochrane reviews apply the same standards in evaluating both CAM and conventional therapies. Of the CAM treatments reviewed, the largest percentage (56.5) were classified as insufficient evidence of effect, with 24.8 percent classified as positive effect, and 12.4 percent as possibly positive effect. Only one review described a CAM treatment classified as harmful.

It is interesting to compare the results of the committee’s evaluation of Cochrane reviews of CAM therapies with an earlier study evaluating Cochrane reviews of conventional therapies. While insufficient evidence of effect was found for a larger proportion of CAM therapies (56.6 percent for CAM versus 21.3 percent for conventional medicine), fewer reviews of CAM classed the therapy as harmful (8.1 percent for conventional medicine versus 0.69 percent for CAM) or as having no effect (20.0 percent for conventional medicine versus 4.8 percent for CAM).
for CAM). The percentage of therapies classified as having positive or a possibly positive effect was approximately equal for both CAM and conventional medical therapies (41.3 percent for conventional medicine versus 38.4 percent for CAM). It is important to note here that the studies were conducted at different times and, thus, were based on different sets of Cochrane reviews. The study of conventional medicine includes only reviews published in The Cochrane Library in 1998, while the evaluation of CAM therapies by the IOM committee included reviews published in the 2004 issue, which has expanded and developed significantly since 1998.45

The definition of medical necessity recently adopted by state of Tennessee’s TennCare program is highly congruent with the recommendations of both the White House Commission on CAM and the Institute of Medicine report. To be medically necessary under the TennCare program, a therapy must:

- “be required in order to diagnose or treat an enrollee’s medical condition”;
- “be safe and effective” – i.e., “the reasonably anticipated medical benefits of the item or service must outweigh the reasonably anticipated medical risks based on the enrollee’s condition and scientifically supported evidence”; and
- “be the least costly alternative course of diagnosis or treatment that is adequate for the medical condition of the enrollee;” (including “where appropriate, no treatment at all”); and
- have “adequate...empirically-based objective clinical scientific evidence of its safety and effectiveness for the particular use in question.”46

There is some irony in the fact that more CAM interventions probably would be deemed medically necessary under the TennCare program’s definition of medical necessity than under definitions of medically necessity that require acceptance of a therapy within the medical community. This is especially true when the record of conventional medicine for safety and effectiveness is reviewed.

For example, FDA-approved prescription drugs have been found to have serious safety problems that become evident only after the drugs had been on the market for an extended period of time.47 Some experts estimate that more than 100,000 people in the U.S. die from adverse drug reactions resulting from routine prescription drug use each year. This number does not include deaths resulting from medication errors (i.e., avoidable adverse drug reactions).48 A study conducted by Oxford University scientists suggested that fatal adverse drug events rank from the fourth to the sixth leading cause of death in the USA after heart disease, cancer, and stroke, and similar to pulmonary disease and accidents. Costs associated with adverse drug events were estimated at up to $4 billion a year.49 In the last few years, important studies have challenged the effectiveness of high dose chemotherapy and bone marrow transplantation for breast cancer,50 arthroscopic surgery for osteoarthritis of the knee,51 and hormone replacement therapy during menopause.52 Furthermore, autologous bone marrow transplantation and hormone replacement therapy were found to entail significant risks to patients. In the case of hormone replacement therapy, the therapy increased risks for cardiovascular disease and other pathology it was touted as preventing.

There are several policy options in assessing the medical necessity of CAM. One commentator has suggested that health plans should not cover CAM, except for therapies that have been proved safe and effective (which are, presumably, medically necessary). Otherwise, valuable health care dollars will be diverted to pay for “interventions for which evidence of efficacy is either non-existent or merely anecdotal.” Furthermore, the fact that a health plan covers a therapy signals to the market that it has “a potential health benefit, that it is medically appropriate in the circumstances for which it is covered, and that it is medically necessary.” However, when reliable evidence becomes available that a particular CAM therapy is effective, compares favorably to the conventional alternatives, and is cost-effective, it should become the standard of care and should be covered by health plans.53 One potential criticism of this option is that it appears to contain an...
implicit presumption in favor of the medical necessity of conventional medical interventions, or at least implicit deference to prevailing opinion with the medical community. As is suggested by the discussion of the safety and effectiveness of conventional medical therapies above, such a presumption and such deference may not be warranted with respect to many conventional interventions.

A more even-handed approach to determining the medical necessity of both CAM and conventional therapies would be that embodied in the definition of medical necessity used by the TennCare program. If such a medical necessity standard were to be applied fairly, both CAM and conventional therapies would be evaluated under the same objective standards. While this more objective approach to determining medical necessity could result in improvements in the quality of the health care received by health plan participants, it does have weaknesses.

First, not all effective therapies have been scientifically validated, whether such therapies are currently classed as complementary, alternative, or conventional. We still live in an era of substantial medical uncertainty. Thus, the TennCare model may result in denial of reimbursement for care that is, in fact, medically necessary, based on its implicit assumption that no therapy is medically necessary until there is adequate science supporting the therapy. Another, more subtle problem with the TennCare model is that clinical research may provide scientific support for therapies that work for most of the participants in a clinical trial but are ineffective or even unsafe for other individuals. Mechanical application of the TennCare criteria may, thus, deprive individuals of care that is necessary for them or give them the Hobson’s choice of receiving inappropriate care or no care at all.

Though physicians have learned to recognize and respect drug allergies, they are still not able to predict drug allergies before a patient has ever taken a drug. Just as patients vary in their drug allergies, they also vary in their susceptibility to diseases and in their responses to treatments for those diseases. The same prescription drug may be highly effective in some patients and cause severe adverse reactions in others. Research in genomics and proteomics holds the promise that, in the future, practitioners will be able to choose among different types of treatment and different types and doses of drugs on the basis of individual differences. Another policy option concerning the medically necessity of CAM is based on the fact that a great deal of conventional care lacks scientific validation. One approach is to remove health plans from their current role as decision-makers. By using health savings accounts or similar mechanisms, the choice of therapies could be returned to patients. The recent trend of health plans toward health savings accounts, health reimbursement accounts, and consumer-directed health plans is designed to put decision-making concerning therapies back in the consumer’s hands. A cautionary note must be sounded here, since plan designs that combine high deductibles with health reimbursement accounts may still involve medical necessity determinations by health plans. Under such a plan, costs of health care that are determined not to be medically necessary would not count toward deductibles or, in some cases, not be payable from a health reimbursement account. Thus, depending on trends in health plan design, it may still be necessary to address the policy issues related to how and why health plans make medical necessity decisions. In addition, while promoting the autonomy of individuals with respect to their own health, putting medical necessity determinations in the hands of uninformed consumers may result in harm to them if they spend scarce health care dollars on care that is ineffective or harmful. For this model to succeed, consumers would need, at a minimum, concise and understandable information on the costs and efficacy of CAM and conventional therapies to help them make optimal use of their health care dollars.

Finally, one commentator has suggested that, given the uncertainty about the efficacy of many CAM and conventional therapies, the medical necessity standard be replaced with a standard of “reasonable necessity.” Under the reasonable necessity standard, if a licensed health care provider—whether a licensed acupuncturist, chiropractor, naturopath or...
massage therapist — treats a patient within the scope of the provider’s license, the treatment would be presumed reasonable to the same extent it would be so presumed if provided by a medical doctor.\(^5^7\) The problem with such an approach is that there is often not a presumption of medical necessity with regard to treatment recommended by a medical doctor. In addition, implementing this approach would simply expand the current system, with all its weaknesses, to additional therapies. Another weakness of this approach is that the politics of state licensure would control the types of providers to whom this standard would apply. Although there is still substantial uncertainty about the efficacy of many CAM and conventional therapies, setting clearer and more objective criteria and designing a more rational process for determining medical necessity would represent an improvement over the current system. However, it is important that whatever system is used, it not be too inflexible in design. In an era of medical uncertainty, some flexibility is still required.

ENDNOTES


4 Complementary Health Care: No Longer Just an Alternative. AHIP Coverage September/October 2004. Available at www.ahip.org/content/default.aspx?bc=31%7C130%7C136%7C5733%7C5735.

5 Barnes et al 2004, supra.


8 Institute of Medicine, CAM in the United States 2005, supra.

9 Institute of Medicine, CAM in the United States 2005, supra.

10 Eisenberg et al 1998, supra; see additional studies cited in Institute of Medicine, CAM in the United States 2005 supra, p. 42.

11 Institute of Medicine, CAM in the United States 2005 supra; Eisenberg et al 1998, supra.


14 Institute of Medicine, CAM in the United States 2005, supra.


16 Barnes et al 2004, supra.


24 Dep’t of Health and Human Servs. & Ctrs. for Medicare and Medicaid Servs., Pub. 100-3, National Coverage Determinations Manual, National Coverage Determination for Acupuncture (30.3); National Coverage Determination for Chelation Therapy for Atherosclerosis (20.21); National Coverage Determination for Ethylenediamine-Tetra-Acetic (EDTA) Chelation Therapy for Treatment of Atherosclerosis (20.22); National Coverage for Colonic Irrigation (100.7); National Coverage Determination for Electroacupuncture (30.4), National Coverage Determination for Hair Analysis (190.6.); National Coverage Determination for Laetrile and Related Substances (30.7); National Coverage Determination for Thermography (220.11); National Coverage Determination for Transcendental Meditation (TM) (30.5); National Coverage Determination for Vitamin B12 Injections to Strengthen Tendons, Ligaments, etc., of the Foot (150.6). Available at  http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd.
30 Kaiser Family Foundation and Health Research and Educational Trust, Employer Health Benefits, 2004 Annual Survey.
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32 White House Commission Report, supra.
33 White House Commission Report, supra.
41 White House Commission Report, supra.


43 The Cochrane Library is supported through the work of the Cochrane Collaboration, an international organization of more than 9,000 volunteers, who prepare up-to-date, reliable summaries or systematic reviews of every kind of health therapy. These are known as Cochrane reviews. Institute of Medicine, CAM in the United States 2005, supra.

44 Institute of Medicine, CAM in the United States 2005, supra.

45 Institute of Medicine, CAM in the United States 2005, supra. The earlier study of conventional medicine was Ezzo J, Bausell B, Moerman DE, Berman B, Hadhazy V. 2001. Reviewing the Reviews: How Strong is the Evidence? How Clear Are the Conclusions? Int. J. Technol. Assess. Health Care 17 (4):457-466. The Institute of Medicine report also notes that reviews of study quality have found significant variation in the quality of CAM studies, with the studies having the most positive findings generally being of lower quality. A fuller discussion of this issue is beyond the scope of this [paper/report?].


54 See the Lancet series on treating individuals cited in note 41, supra.


56 Morreim, E. Haavi. A Dose of Our Own Medicine: Alternative Medicine, Conventional Medicine, and the Standards of Science. 31 J.L. Med. & Ethics 222 (Summer 2003).

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