

REPORT 1 OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS (I-09)
Financial Relationships with Industry in Continuing Medical Education
(Reference Committee on Amendments to Constitution and Bylaws)

EXECUTIVE SUMMARY

Objective: To provide ethical guidance for physicians and the profession with respect to industry support for continuing medical education.

Methods: Literature review; ethical analysis of issues in professionalism raised by influence of financial relationships with industry in continuing medical education; and feedback from key stakeholders within and outside the AMA.

Results: Medicine's autonomy and authority to regulate itself depends on its ability to ensure that physicians acquire, maintain, and apply the values, knowledge, skills, and judgment essential for quality patient care. To fulfill that obligation, the profession must safeguard the independence and integrity of continuing medical education.

Conclusions: Relationships with industry—i.e., pharmaceutical, biotechnology, and medical device companies—can offer enormous benefit to the profession and the patients it serves. However, commercial funding for professional education can pose significant ethical challenges to medicine's ability to focus primarily on the needs of patients and ensure quality education for physicians.

Whenever possible, funding or in-kind support should be provided only by sources that have no direct financial interest in a physician's clinical recommendations. Those involved in CME should have no current, recent, or potential direct financial interest in the subject matter and should not currently be or recently have been involved in a compensated relationship with a commercial entity that has a financial interest in the educational subject matter.

When declining industry support would significantly undermine the capacity to ensure that physicians have access to appropriate, high quality professional education, funding or in-kind support from industry sources can be ethically justifiable if: the educational activity is planned by the provider based on needs identified independent of and prior to solicitation or acceptance of the funding; the CME provider can articulate compelling reason(s) to accept industry support; support is not conditioned on acceptance of advice or services concerning educational content, faculty or content developers, or other educational matters; the source and magnitude of support are clearly disclosed; and the CME provider routinely audits the level of industry support it receives to ensure that it maintains the independence and integrity of its educational mission and programs. CME providers may permit involvement of individuals with modest financial interests if the nature and magnitude of those interests are disclosed and steps are taken to eliminate or mitigate the potential influence of those interests. CME providers may permit involvement of a *uniquely qualified expert* who has a direct, substantial, unavoidable financial interest if: there is a demonstrated, compelling need for the educational activity in the professional community that cannot otherwise be met; the CME provider demonstrates that the individual has unique expertise in the relevant body of knowledge/skills; the CME provider takes steps to mitigate the potential influence of the unavoidable financial interest; and the nature and magnitude of the specific interest are clearly disclosed. CME activities that use such experts should contribute overall to the timely development a pool of qualified, independent experts in the relevant field.

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 1-I-09

Subject: Financial Relationships with Industry in Continuing Medical Education

Presented by: Dudley M. Stewart, Jr., MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws
(John W. Spurlock, MD, Chair)

1 The practice of medicine is inherently a moral activity, founded in a “covenant of trust” between
2 patient and physician.^{1,2,3} The respect and autonomy that medicine enjoys rest on the profession’s
3 commitment to fidelity and service in the patient-physician relationship. To sustain that
4 commitment, medicine must ensure that physicians acquire and maintain the knowledge, skills, and
5 values that are central to the healing profession. In return, society grants medicine considerable
6 authority to set the ethical and professional standards of practice and the autonomy to educate
7 practitioners.^{4,5}

8
9 In recent decades, relationships between medicine and industry—by which we mean
10 pharmaceutical, biotechnology, and medical device companies—have driven innovation in patient
11 care, contributed to the economic well-being of the community, and provided significant resources,
12 financial and otherwise, for professional education, to the ultimate benefit of patients and the
13 public. In the end, however, the interests and obligations of medicine and industry diverge in
14 important ways, rendering these relationships double edged. Where medicine’s overriding
15 responsibility is to put the needs of patients first, commercial entities must serve their shareholders
16 and other vested stakeholders even as they engage in efforts to improve health and health care.

17
18 An increasingly urgent challenge for both medicine and industry is to devise ways to preserve
19 strong, productive collaborations for the benefit of patients and the public at the same time they
20 take clear, effective action to prevent relationships that damage public trust and tarnish the
21 reputations of both parties. Medicine must address growing concern that financial ties to industry,
22 in particular, carry ethical risks for the independence and integrity of professional education.

23
24 Medicine-industry relationships occur in research, clinical care, and beyond, not just in education,
25 of course. The Council also recognizes that pharmaceutical, biotechnology, and medical device
26 companies are not the only entities—commercial or otherwise—with which financial relationships
27 can raise concerns. Yet to attempt to address the range of ethical questions that can arise across all
28 of these different domains and among all of the different stakeholders is too ambitious a goal for a
29 single analysis. Thus this report focuses on issues raised by financial relationships with industry for
30 continuing medical education (CME). This allows us to explore the complex considerations at
31 stake in a manageable context and to provide practical ethical guidance on issues that increasingly
32 challenge medicine as a profession. It can lay the foundation for future analyses that address
33 similar concerns as they arise in other domains and among other stakeholders.

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1 LIFELONG LEARNING & MEDICINE’S DUTY TO EDUCATE

2
3 *Publicly in his oath and privately in his encounter with the patient, the physician professes*
4 *two things—to be competent to help and to help with the patient’s best interests in mind.*
5 —Edmund Pellegrino
6

7 The special moral character of the interaction between patient and physician arises from the need—
8 illness—that brings the patient into the relationship. Physicians are granted extraordinary privileges
9 to intervene in patients’ lives, to impose harm in the service of healing, to gain access to sensitive
10 information, and to engage in intimate contact with patients that would otherwise be prohibited.
11 Educating current and future generations of physicians to fulfill the responsibilities that flow from
12 the patient-physician relationship is the foundation of medicine’s status as a caring and competent
13 profession. Therefore, medicine’s ethical duty to educate cannot be delegated to others.
14

15 Individual physicians have an ethical obligation to dedicate themselves to “continue to study,
16 apply, and advance scientific knowledge” and to “maintain a commitment to medical education.”⁶
17 As professionals, practicing physicians are expected to commit themselves to lifelong learning and
18 to maintain their clinical knowledge and skills through CME and other professional development
19 activities.⁷ That commitment is reflected not only in ethical expectations and standards, but also in
20 requirements for licensure and specialty certification, as well as hospital credentialing.
21

22 Given the wide array of diagnostic and therapeutic options available today, physicians and the
23 patients who rely on them must be confident that treatment recommendations and clinical decisions
24 are well informed and reflect up-to-date knowledge and practice. CME activities that are
25 pedagogically sound, scientifically grounded, and clinically relevant are essential to ensure that
26 physicians can provide the high quality of care their patients deserve. To achieve these goals,
27 medicine has an ethical obligation to ensure that the profession itself sets the agenda and defines
28 the goals of physician education; controls what subject matter is taught; determines physicians’
29 educational needs; and takes steps to ensure the objectivity of educational content and of those who
30 teach it.
31

32 Despite the clear potential for benefit from strong working relationships with industry, there is
33 concern that medicine’s reliance on industry support to CME providers, as well as individual
34 financial ties between content developers or faculty and industry, undermines this independence
35 and objectivity. The implications may extend well beyond continuing education—as one recent
36 commentary noted, “[w]hat is at stake is nothing less than the privilege of autonomy in our
37 interactions with patients, self-regulation, public esteem, and a rewarding and well-compensated
38 career.”⁸
39

40 CONTINUING MEDICAL EDUCATION

41
42 Continuing medical education today takes place in a complex, dynamic environment that hosts a
43 mix of “promotional,” “certified,” and other activities. As defined by the Food and Drug
44 Administration (FDA), promotional activities are those developed by or on behalf of a commercial
45 entity and under the substantive influence of that entity that are designed to market health care
46 products or services. Promotional activities, which provide information on the therapeutic use of a
47 product or service, are governed by the labeling and advertising provisions of the Food, Drug, and
48 Cosmetic Act.^{9,10} Promotional activities may constitute protected commercial speech. These
49 industry-developed, FDA-regulated activities lie outside the scope of the present analysis and
50 recommendations. Our immediate concern is with certified and other (nonpromotional) educational
51 activities.

1 “Certified CME” refers to educational activities developed and implemented in compliance with
2 the certification requirements of the American Medical Association Physician Recognition Award
3 (PRA) CME Credit System, or the accrediting policies of the American Academy of Family
4 Physicians or American Osteopathic Association.¹¹ Certified CME meets the requirements for
5 Category 1 credit under AMA’s PRA program, including compliance with Accreditation Council
6 for Continuing Medical Education (ACCME) standards and with relevant AMA ethics policy.¹²

7
8 Beyond these formal categories lie activities designed to inform and educate practicing physicians
9 that are neither certified CME nor “industry-developed, FDA-regulated activities.” These other
10 activities may or may not be commercially supported, may or may not voluntarily adhere to AMA
11 policy or ACCME Standards for Commercial SupportSM despite not being formally certified or
12 accredited, and may or may not be recognized by licensing bodies or credentialing boards as
13 fulfilling local CME requirements.

14 *Industry Support of CME Providers*

15
16
17 Over the past decade, medicine has come to rely significantly on commercial funding to support
18 professional education across the learning continuum. With respect to CME, industry support now
19 accounts for more than half of all income to CME providers accredited by ACCME. Between 1998
20 and 2006, commercial support of providers accredited by ACCME increased by 300 percent to
21 \$1.2 billion.¹³ There is some evidence that the rate of growth in industry support of CME may be
22 leveling off, or even declining slightly.^{14,15}

23
24 Commercial funding is not uniformly distributed across the community of diverse CME providers,
25 which includes medical professional groups (such as state and local medical associations, as well as
26 national specialty societies), hospitals, academic medical centers, and commercial providers (such
27 as medical publishing/communication companies). In 2007 (the most recent year for which data are
28 publicly available), medical schools, which accounted for 46 percent of all certified CME hours,
29 received 20 percent of the overall total of commercial funding; publishing/education companies,
30 which accounted for nine percent of overall certified CME hours, received 49 percent of all
31 commercial funding.¹⁶ Because ACCME has not yet established a uniform reporting protocol for
32 nationally accredited providers, it is impossible to know with any real accuracy what proportion of
33 CME providers’ annual budgets derive from commercial entities.

34
35 Industry support for CME helps to meet the costs of programs and activities in the face of uncertain
36 funding from other sources.¹⁷ By helping to reduce costs to individual attendees industry support
37 may make CME more accessible, especially for physicians in resource poor communities. Along
38 with lower costs, by providing amenities that make participation attractive, industry support may
39 encourage greater participation than would otherwise be the case, although there is no evidence
40 either to support or to refute this hypothesis.¹⁸ For some medical specialties that rely on high cost,
41 sophisticated, rapidly evolving technology or devices, industry engagement in and support of CME
42 may be essential. At the same time, however, there is growing concern within and outside medicine
43 that industry funding can have undesired effects on CME.

44
45 At present there is no clear evidence to settle the question whether such concerns are borne out
46 empirically. Studies suggesting a link between industry-funded educational activities and
47 prescribing practices predate the ACCME Standards for Commercial SupportSM. Cervero and He
48 concluded from their review of the relevant literature that “to date there is no empirical evidence to
49 support or refute the hypothesis that CME activities are biased.”¹⁹ They note that while there is
50 ample evidence that CME affects physicians’ prescribing practices, no studies have looked

1 specifically at the impact of prescribing changes on patient outcomes and thus cannot answer the
2 important question of whether observed changes in practice were or were not in patients' interest.

3
4 However, there is evidence to suggest that industry support can influence the overall topics,
5 speakers, and educational content of CME. Companies make educational grants consistent with
6 their business strategies and therapeutic areas of interest,^{20,21} which may tend to shift education
7 toward benefiting funders and away from serving patient interests.²² Industry-supported CME
8 programs tend to address a narrower range of topics,²³ focus more on drug therapies,²⁴ and give
9 more favorable treatment to company products²⁵ than do programs that are not funded by industry.

10
11 The available data by no means demonstrate conclusively that commercial funding unduly biases
12 continuing professional education. They do suggest, however, that in addition to its primary *ethical*
13 commitments, medicine has reason to be concerned about possible unintended and undesirable
14 effects of industry support and should take steps to address the potential for industry funding to
15 undermine—or be perceived to undermine—the quality and credibility of CME.

16 17 *Individual Relationships with Industry*

18
19 In addition to concerns about the effects of industry funding for CME providers, there are concerns
20 about how financial ties with industry may affect the objectivity of individual physicians and others
21 who develop content for or teach in CME activities. We must be clear: Our concern is not with
22 egregious lapses of judgment or with corruption, but with the subtle bias that financial ties create.
23 Research indicates that relationships in which benefits—financial compensation, gifts, favors, or
24 other perceived benevolent gestures—are bestowed on one party by another introduce unconscious
25 bias favoring the giver. This occurs independent of the magnitude of the perceived benefit and even
26 when individuals are alert to the possibility of bias and strive to be objective.^{26,27,28} Emerging
27 neurobiological data confirm that such influence operates below the level of conscious awareness.²⁹
28 As Cervero and He note, the majority of physicians “may not be aware of how industry support of
29 a CME activity may influence their clinical decisions.”³⁰

30
31 What has not been as clearly demonstrated is to what extent the amount of a financial interest may
32 influence perception and judgment. Although clear evidence is lacking, most policies on conflict of
33 interest at least tacitly assume that the greater the financial interest, the more problematic that
34 interest is. Yet different institutions set the threshold of concern at significantly different amounts.
35 For example, the University of Massachusetts–Worcester requires faculty members involved in
36 nonclinical research to disclose financial interests in commercial entity of more than 5 percent
37 equity or \$100,000, while faculty involved in clinical research must disclose all equity interests and
38 nonequity interests over \$1,000.³¹ Northwestern University, meanwhile, requires reporting of
39 external income above \$10,000 a year.³² Trying to define any specific threshold is essentially an
40 arbitrary exercise.

41 42 *New Trends in Institutional Policy*

43
44 As relationships between medicine and industry have come under greater public scrutiny in recent
45 years, many academic medical centers, state and medical specialty societies, and health care
46 organizations have moved toward policies that more vigorously address the potential for conflict of
47 interest and bias with respect to physicians' interactions with industry. While many of these
48 policies focus particularly on gifts, consulting arrangements, and other specific physician-industry
49 relationships, several also address CME. For example, since September 2008 Stanford School of
50 Medicine has prohibited direct commercial support for individual CME activities, requiring that
51 (unrestricted) support from commercial funders be made to its Center for CME for broadly defined

1 areas of interest.³³ The University of Pittsburgh similarly requires that industry support of CME be
 2 negotiated through the university's Center for Continuing Education in the Health Sciences.³⁴

3
 4 State medical societies have begun adopting similar policies with respect to industry support for
 5 their CME activities. The nonprofit Physicians' Institute for Excellence in Medicine, affiliated with
 6 the Medical Association of Georgia (MAG) serves as an intermediary between state CME
 7 providers and industry funders not only for the MAG, but for 11 other state medical societies as
 8 well.³⁵ The Wisconsin Medical Society's newly updated policy on conflict of interest maintains
 9 that a CME provider should not accept industry support directly, but should create a fund to which
 10 commercial supporters may make unrestricted donations, with funding subsequently dispersed to
 11 CME programs according to publicly disclosed policies adopted by the fund.³⁶

12
 13 Medical specialty societies at the local and national level are also taking a new stance toward
 14 commercial supporters of their educational programming. Under policy adopted in 2006, the North
 15 American Spine Society (NASS) requires disclosure not only by speakers, faculty, and moderators
 16 in NASS educational activities, but also by audience members who offer comments or questions.
 17 NASS members are expected to encourage disclosure when they believe there has been a lapse and
 18 report ongoing failure to disclose. Members who fail to disclose their financial interests are subject
 19 to discipline through the organization's Professional Conduct and Ethics Committee.³⁷ In
 20 November 2007, the Oregon Academy of Family Physicians (OAFP) discontinued accepting
 21 industry support for OAFP-sponsored CME activities.³⁸ The Academy also seeks to evaluate
 22 industry's role in developing third-party programs it considers offering to its membership.

23 24 ENSURING THE INDEPENDENCE, OBJECTIVITY & INTEGRITY OF CME

25
 26 Financial relationships inevitably create conditions for conflict of interests that can undermine—or,
 27 just as important, *appear* to undermine—independence and objectivity. There are three options to
 28 address such undesired consequences: avoid the possibility altogether by not permitting conditions
 29 that give rise to potential bias or influence; implement strategies to mitigate actual or perceived
 30 bias or influence; or both. Each option has ethical and practical advantages and disadvantages.

31 32 *Avoiding Conditions that Can Compromise the Integrity of CME*

33
 34 The ethical aspiration should be to avoid potential bias altogether. In the context of CME, this
 35 would mean declining to accept or seek support for professional education activities from
 36 commercial funders who have significant financial interests in physicians' clinical decisions.
 37 Avoiding the potential for influence entirely has the virtue of ethical clarity and practical
 38 simplicity. Doing so would strongly underscore medicine's defining professional commitment to
 39 independence, objectivity, and fidelity to patients. Eliminating industry funding would have the
 40 further practical advantage of eliminating the administrative and resource costs that must otherwise
 41 be devoted to mitigating influence.³⁹ These costs may be particularly challenging for smaller CME
 42 providers, notably at the state and local level.⁴⁰

43
 44 CME providers, content developers, and faculty should strive to avoid financial relationships with
 45 industry. In testimony to the U.S. Senate Special Committee on Aging, ACCME indicated that as
 46 of July 2009 some 20 percent of nationally accredited CME providers no longer accept commercial
 47 support.⁴¹ The Institute of Medicine has called for development of a new system of funding CME
 48 that is free of industry influence.⁴² Medicine should cultivate alternative sources of support, should
 49 design and conduct educational activities so as to reduce costs, and should identify content
 50 developers and faculty members who do not have problematic ties with industry, to ensure

1 independent, unbiased, high quality educational programming that best meets physicians' needs
2 and is accessible and affordable for all practitioners.

3
4 Yet it is not always feasible, or necessarily desirable, for professional education to disengage from
5 industry completely. Thus we must also define conditions under which maintaining financial
6 relationships with industry can be ethically justifiable. Such conditions involve implementing
7 strategies to mitigate the potential for bias or influence when not accepting support from a
8 commercial source would significantly undermine medicine's capacity to ensure that physicians
9 have access to appropriate, high quality CME.

10
11 *Mitigating Potential Influence That Cannot Be Avoided*

12
13 While there should be a strong presumption that CME providers, content developers, and faculty
14 members should not have concurrent financial ties to industry, it is important to recognize that not
15 all relationships with industry are equally problematic. A relationship that is only indirectly related
16 to an educational activity, modest in scope, or distant in time is not likely to adversely affect—or
17 be perceived to affect—the activity in question. For example, having once conducted sponsored
18 research or accepted a modest honorarium for speaking on behalf of a company would not
19 necessarily create such clear potential for bias as to preclude an individual with the appropriate
20 expertise developing content or serving as a faculty member for a given CME activity.⁴³

21
22 Financial relationships that are direct or substantial, however, have significant potential to
23 undermine the independence and objectivity of educational activities. Examples of direct and/or
24 substantial financial interests include ownership or equity interest in the industry funder, royalties,
25 ongoing compensated relationships (e.g., consulting arrangements or service on scientific advisory
26 bodies or speakers bureaus),⁴⁴ or relationships that involve fiduciary responsibilities on behalf of
27 the funder (such as service on a corporate board of directors) or decision-making authority in
28 financial matters.⁴⁵ Similarly, some essential educational activities may not be feasible without
29 financial or in-kind support from industry—for example the provision of cadavers or high-cost,
30 sophisticated equipment to train physicians in new surgical procedures or the use of new
31 technologies. Such support may be vital to the professional community, but, like individual
32 financial ties, also creates potential for bias. When commercial funding, in-kind support, or
33 participation in CME by individuals or organizations that have direct, substantial financial ties with
34 an industry funder cannot reasonably be avoided, ethically strong practice requires that strategies
35 be implemented to mitigate the possible influence of such ties on educational activities.

36
37 Transparency is essential in mitigating the potential of financial relationships to create bias (or the
38 appearance of bias). As the ACCME Standards for Commercial SupportSM recognize, disclosing
39 the existence of a financial relationship is a necessary first step,⁴⁶ but it is not sufficient and may
40 even have perverse effects. Disclosure places the burden on those to whom it is made—in our
41 context, it requires learners themselves to determine how skeptical they should be about the
42 objectivity of an educational activity.⁴⁷ To the extent that disclosure fosters the impression that the
43 presenter is particularly honest and trustworthy, it can encourage false confidence in the objectivity
44 of the activity.⁴⁸ To the extent that the presenter believes disclosing a financial relationship is
45 adequate to mitigate its potential influence, the individual may not strive as hard to ensure
46 objectivity.⁴⁹ Disclosure plays an important role in mitigating the potential influence of financial
47 relationships, one whose value may be enhanced when both the existence and the magnitude of a
48 financial relationship is disclosed,⁵⁰ but it cannot be the only strategy relied on.

49
50 Creating a “firewall” between industry funders and decisions about educational goals, content,
51 faculty, pedagogical methods and materials, and other substantive dimensions of CME activities is

1 also an important strategy for mitigating the influence of financial relationships. Both ACCME and
2 the Inspector General of the Department of Health and Human Services have recommended clearly
3 separating decisions about funding from substantive decisions about CME activities. ACCME
4 standards require that a CME provider ensure the independence of key decisions, although the
5 standards do not provide specific guidance about how to do so.⁵¹ (HHS guidance for industry
6 requires that manufacturers clearly separate their sales and marketing functions from their grant-
7 making functions.⁵²) Emerging strategies to create strong firewalls include pooling monies from
8 multiple commercial sources and disbursing support to individual activities through a “blind trust”
9 model. In such models, funders have no knowledge of which programs their grants or gifts
10 supported,⁵³ nor are CME providers, content developers, or faculty aware of which funder
11 supported their activities. Where it is not feasible to create a blind trust to manage industry support,
12 one strategy to help protect the independence and integrity of CME would be to have activities
13 routinely supported by multiple, competing funders.

14
15 Another way to mitigate the influence of financial relationships when they cannot be eliminated is
16 to change the terms of those relationships. A CME provider, for example, could set an upper limit
17 on how great a proportion of its income derives from industry support to avoid becoming overly
18 reliant on commercial funding. Among individuals who develop content for or teach in CME
19 activities, strategies must be tailored to the nature and magnitude of their varying individual
20 relationships. For example, physicians participating as content developers or faculty in a CME
21 activity could be required to desist from speaking on behalf of the activity's industry supporter for a
22 defined period before and after the activity. Similarly, an individual could forgo royalties or other
23 compensation from the company for a defined interval following his or her participation (whether
24 as content developer or faculty) in an industry-funded CME activity. It will be important, of course,
25 that in seeking to change the terms of problematic relationships decisions be made fairly and
26 consistently across individual cases.

27 28 *Exceptional Cases: Conflicted But Essential Expertise*

29
30 Sometimes a financial interest cannot be avoided and is extraordinarily difficult or even impossible
31 to mitigate. In most cases, participation in CME by providers, content developers, or faculty
32 members who have direct, and unavoidable financial interests would not be ethically acceptable.
33 However, in certain compelling circumstances, it may be justifiable to allow such participation—
34 for example, when an individual who has a significant financial interest to participate in a CME
35 activity has unique expertise. In the earliest stage of adoption of a new medical device, technique,
36 or technology, the only individuals truly qualified to train physicians in its use are often those who
37 developed the innovation. Yet these are the very individuals who often have the most substantial
38 and direct interests at stake, whether through employment, ongoing relationships with
39 manufacturers, or other direct financial interests in the adoption and dissemination of the new
40 device, technique, or technology.

41
42 Criteria for determining when it is ethically justifiable to permit participation by someone who has
43 a direct, substantial, unavoidable, and irreducible financial interest in a CME activity might include
44 a variety of considerations. For example, that the dissemination of the device, technique or
45 technology will be of significant benefit to patients, and to the public and the professional
46 community; that the individual is uniquely qualified as an expert in the relevant body of knowledge
47 or skills; that disclosure includes the nature and magnitude of the specific financial interest at stake;
48 that there is demonstrated, compelling need for the specific CME activity; and that all feasible
49 steps are taken to mitigate influence.⁵⁴

1 *Understanding Key Ethical Criteria*

2
3 Current guidelines for CME do not distinguish among financial relationships based on their
4 different potential to undermine the independence and objectivity of educational activities. Nor do
5 they provide specific guidance for how to manage potential conflicts of interest when such
6 conflicts are disclosed. At present there are no specific, publicly agreed on understandings of key
7 criteria proposed above: “substantial interest,” “significant benefit,” “uniquely qualified,” or
8 “compelling need.” Attempting to provide specific, concrete delineations of these criteria would be
9 an essentially arbitrary exercise—what is a “substantial” interest for one practitioner may not be for
10 another. Inevitably, these criteria must be interpreted case by case, based on knowledge of the
11 particular circumstances and on the exercise of judgment. In other contexts, physicians routinely
12 make similar judgments under conditions of uncertainty.

13
14 Judgments about some criteria, such as “significant benefit,” will be reasonably familiar; others are
15 more challenging. While we cannot offer precise definitions, it is possible to suggest considerations
16 that might come into play. For example, current standards require CME providers to design
17 activities to address demonstrated educational needs;^{55,56} a “compelling need” for a particular
18 educational activity may be present when a new therapy becomes available to treat a disease that is
19 prevalent in the local community for which there is otherwise no satisfactory treatment.

20
21 Similarly, an individual might be considered “uniquely qualified” when he or she is the only expert
22 (or one of only a very few) who has significant knowledge about or experience in treating a rare
23 disease or who was involved in the early development or testing of a new treatment, device, or
24 technology. To some extent, the need to rely on conflicted expertise may be dictated by local
25 conditions—CME providers in small or rural communities, for example, may not always be able to
26 obtain the services of experts who do not have problematic ties to industry. In any event, it will no
27 longer be appropriate to speak of an expert being “uniquely qualified” when a substantial body of
28 peer-reviewed evidence has evolved in a given subject area, or when a cohort of individuals who
29 do not have direct, substantial, unavoidable, and irreducible financial interests have become
30 experienced in using a new medication, device, or technology and are available to teach others.

31
32 CME providers should be transparent about what considerations led them to decide to permit an
33 individual with a problematic financial interest to participate as a content developer or faculty
34 member in a particular CME program or activity. The goal is to ensure that decisions are made
35 objectively and are justifiable based on considerations the CME provider believes will be
36 persuasive to the professional community at large. As the community gains experience in working
37 with these criteria it is to be expected that consensus will coalesce around core interpretations. As
38 Harvard Medical School notes in its conflict of interest policy:

39
40 These classifications are not intended to serve as a rigid or comprehensive code of conduct or
41 to define “black letter” rules with respect to conflict of interest. It is expected that the
42 guidelines will be applied in accordance with the spirit of the mission of Harvard Medical
43 School in education, research and patient care. By this process, it is expected that a common
44 institutional experience in the application of these guidelines will gradually evolve.⁵⁷

1 RECOMMENDATION

2
3 The Council on Ethical and Judicial Affairs recommends that the following be adopted and the
4 remainder of this report be filed:

5
6 The respect and autonomy that medicine enjoys rest on the profession's commitment to fidelity
7 and service in the patient-physician relationship. To sustain that commitment, medicine must
8 ensure that physicians acquire and maintain the knowledge, skills, and values central to the
9 healing profession. With that comes an ethical obligation to ensure that the profession itself sets
10 the agenda and defines the goals of physician education, decides what subject matter is taught,
11 determines physicians' educational needs, and takes steps to ensure the objectivity of
12 educational content and of those who teach it.

13
14 Financial and in-kind support of continuing medical education (CME) by pharmaceutical,
15 biotechnology, and medical device companies puts that ethical obligation at risk by creating
16 conditions for conflict of interest. Medicine's ethical aspiration should be to avoid this potential
17 for bias.

18
19 In some circumstances, however, refusing support from industry entirely could significantly
20 undermine the profession's capacity to ensure that physicians have access to appropriate, high
21 quality CME. Medicine should seek to minimize such occasions; when they cannot be avoided,
22 medicine must act vigorously to protect the interests of patients and the integrity and
23 independence of the educational enterprise.

24
25 The following considerations define an ethical framework to guide professional practice with
26 respect to industry support for CME:

- 27
28 1. Funding or in-kind support should be provided only by sources that have no direct
29 financial interest in a physician's clinical recommendations; and
30
31 2. Individuals who develop content for or teach in CME activities should:
32
33 a. have no current, recent (within the preceding 12 months), or potential direct
34 financial interest (e.g., royalties or ownership interest) in the educational subject
35 matter; and
36
37 b. not currently be and not recently have been (within the preceding 12 months)
38 involved in a compensated relationship (e.g., direct employment, service on a
39 speakers bureau, service as a consultant or expert witness) with a commercial entity
40 that has a financial interest in the educational subject matter.
41
42 3. When adhering to guidelines (1) and (2) above would significantly undermine the
43 capacity to ensure that physicians have access to appropriate, high quality professional
44 education, funding or in-kind support may be provided by industry sources under the
45 following conditions:
46
47 a. the educational activity is planned by the provider based on needs identified
48 independent of and prior to solicitation or acceptance of the commercial support;
49 and
50 b. the CME provider can articulate a compelling reason(s) to accept industry support
for the educational activity or activities; and

- 1 c. the CME provider declines industry support that is conditioned on the provider's
2 acceptance of advice or services concerning educational content, faculty or content
3 developers, or other educational matters; and
- 4 d. the source and magnitude of the funding or in-kind support are clearly disclosed;
5 and
- 6 e. the CME provider routinely audits the level of industry support it receives to ensure
7 that it maintains the independence and integrity of its educational mission and
8 programs.
- 9
- 10 4. When necessary to ensure that physicians have access to appropriate, high quality
11 professional education, individuals who currently have *modest* financial interests in the
12 educational subject matter may develop content for or teach in CME activities if the
13 following conditions are met:
14
 - 15 a. the existence and magnitude of any financial interests are clearly disclosed; and
 - 16 b. steps are taken to eliminate or mitigate the potential influence of those interests.
- 17
- 18 5. It can be ethically justifiable for an individual who currently has a *direct, substantial,*
19 *and unavoidable* financial interest in the educational subject matter (e.g., as the inventor
20 of a new device) to develop content for or teach in a CME activity if the following
21 conditions are met:
22
 - 23 a. there is a demonstrated, compelling need for the specific CME activity in the
24 professional community that cannot otherwise be met; and
 - 25 b. the CME provider demonstrates that the individual is *uniquely qualified* in the
26 relevant body of knowledge or skills; and
 - 27 c. the CME provider takes steps to mitigate the potential influence of the unavoidable
28 financial interest; and
 - 29 d. participants are clearly informed about the nature and magnitude of the individual's
30 specific financial interest in the subject matter; and
 - 31 e. CME activities that use such experts contribute overall to the timely development of
32 a pool of qualified, independent experts in the relevant field.
- 33
- 34
- 35

(New HOD/CEJA Policy)

Fiscal Note: Staff cost estimated at less than \$500 to implement.

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REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 2-I-09

Subject: Physician Responsibilities for Safe Patient Discharge
(Resolution 4, I-08)

Presented by: Dudley M. Stewart, Jr., MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws
(John W. Spurlock, MD, Chair)

1 Resolution 4 (I-08) was referred. It asked the Council on Ethical and Judicial Affairs (CEJA) to
2 address the ethical concerns surrounding “the forced repatriation” of immigrant patients from
3 hospitals in the U.S. to facilities in the patients’ countries of citizenship. Incidents of “forced
4 repatriation” of immigrant patients have been a consequence, in large part, of the limited insurance
5 and treatment options available to immigrant patients with long-term health care needs. These
6 circumstances can test a physician’s ability to carry out his or her duty to discharge patients safely.
7 For physicians, this is fundamentally an issue of the ethics of safe patient discharge. Therefore, this
8 report first addresses physicians’ ethical responsibilities for discharging patients safely, and then
9 explores implications for discharge practices in contexts of severely limited options.

10 PHYSICIANS’ ETHICAL RESPONSIBILITIES IN DISCHARGING PATIENTS

11
12
13 When a patient discharge from a health care facility is planned, the physician must evaluate its
14 appropriateness. Therefore, a patient discharge should not occur without the physician’s prior
15 order. In patient discharge, the following statement by Pellegrino holds true: “No order can be
16 carried out, no policy observed, and no regulation imposed without the physician’s assent.... The
17 physician is therefore de facto a moral accomplice in whatever is done for good or ill to patients.”¹

18
19 In considering and making discharge decisions, physicians should be guided by a framework that
20 prioritizes the well-being of patients. The physician’s fundamental purpose is to help alleviate the
21 impact of illness on human persons.² Therefore, dedication to patients’ well-being is not only a
22 basic tenet of a physician’s professional ethic,³⁻⁶ it is a physician’s primary ethic. Principle VIII of
23 the AMA Principles of Medical Ethics affirms, “A physician shall, while caring for a patient,
24 regard responsibility to the patient as paramount.”⁵

25
26 With regard to a patient discharge decision, this primary ethic requires that the physician first try to
27 ensure that the discharge plan appropriately meets the individual patient’s needs and is safe for the
28 patient. A safe discharge requires an ethical standard acknowledging that discharge arrangements
29 are often complex,⁷ involving numerous stakeholders and concerns that are beyond a physician’s
30 control.^{8,9} By way of example, a model discharge may arguably require a professional caretaker
31 who is available 24 hours a day, but in reality the only available caretaker may be obligated
32 elsewhere, and be able to only meet the patient’s minimum needs for having a caregiver available.

* Reports of the Council on Ethical and Judicial Affairs are assigned to the Reference Committee on Amendments to Constitution and Bylaws. They may be adopted, not adopted, or referred. A report may not be amended, except to clarify the meaning of the report and only with the concurrence of the Council.

1 Safe discharge requires that physicians weigh such practical realities in light of the patient's best
2 interests, and take reasonable steps to prevent foreseeable harm to the patient during and after the
3 discharge.

4
5 The safety of patients depends on physicians (and supporting staff) anticipating and addressing (or
6 delegating others to address) risks before authorizing a discharge, which is when physicians have
7 some control over the process. Many risks will be clinical in nature, but physicians should
8 anticipate and address psychosocial and situational risks as well. Regardless of clinical stability at
9 the time of discharge, risks of harm can escalate if patients are, for instance, socially isolated, left
10 without appropriate caretakers, or forced to live in an unsuitable environment after discharge.^{8,9}
11 Therefore, to ensure safety, physicians, in partnership with other health care professionals, should:
12 confirm the patient's clinical readiness for discharge, confirm the receiving environment's ability
13 to meet the patient's needs, respect caretakers' concerns and patients' preferences, and be sensitive
14 to societal interests to the extent possible.

15
16 *Confirm the patient's clinical readiness for discharge*

17
18 Consistent with his or her expertise, the physician should carefully assess the patient and confirm
19 that the individual is medically stable enough to leave the hospital setting and to travel distances (if
20 the planning anticipates this) before authorizing a discharge.¹⁰ Whether a patient is medically stable
21 for discharge may depend on specific discharge arrangements. Physicians should be satisfied that
22 aspects of discharge arrangements such as transportation, care during transportation and
23 appropriate sustainable care at the destination have been reasonably verified. While discharge
24 coordinators or others may be better equipped to make these arrangements,^{7,11} the physician should
25 clarify expectations regarding a patient's needs, and the minimum technological capabilities as well
26 as provider expertise necessary to deliver an appropriate level of care. Expectations regarding
27 accountability for execution of the plan should also be stipulated.

28
29 *Confirm the receiving environment's ability to meet the patient's needs*

30
31 As a condition of participation in Medicare and Medicaid services, hospitals are required to
32 discharge patients to "appropriate facilities" that can meet the patient's medical needs.¹² In terms of
33 ethics, once a physician voluntarily enters into a patient-physician relationship, the physician
34 cannot neglect the patient.¹³ The physician has an ongoing responsibility to ensure that patients
35 have appropriate continuity of care before they terminate an established patient-physician
36 relationship.^{14,15}

37
38 As such, physicians should not discharge a patient to an environment in which the patient's health
39 could reasonably be expected to deteriorate simply because of inadequate resources at the intended
40 destination. Before discharging a patient, the physician should be assured that both the professional
41 and material resources at the receiving facility are adequate to the patient's medical needs.^{7,11}
42 While a discharging physician may have no control over the care provided at the destination, he or
43 she is nonetheless well placed to decide whether the described standard of care at the destination is
44 likely to be appropriate for the patient's post-discharge care needs. To do so, the physician should,
45 if possible, coordinate with caretakers at the receiving facility or appropriately delegate the task to
46 another qualified professional.

47
48 In an effort to secure appropriate continuity of patient care, physicians may also request that
49 discharge plans stipulate follow-up progress reports on a discharged patient. Such follow-up may
50 be effective in preventing unplanned rehospitalizations.¹⁶ It may also allow the physician and
51 others to consider corrective steps when the new care setting belatedly proves to be unsafe for the

1 patient. At the very least, such follow-up may help prevent harm to future patients who may be
2 discharged to the same facility under similar conditions.

3
4 *Respect caretakers' concerns and patients' preferences*

5
6 Physicians should actively seek the input of the patient's future caretakers and respect their
7 concerns when possible. Discharge is by nature a complex process that involves multiple
8 concerned individuals making negotiated arrangements for the patient's care.⁸ Not only are future
9 caretakers, such as family members, significantly affected by the changes that a patient's discharge
10 often entails,⁸ but their availability to provide care is vital to the patient's long-term safety. A
11 discharge is more likely to serve the future well-being of the patient if it accounts for others'
12 ability, availability and willingness to provide long-term care. Future caretakers' knowledge of the
13 financial and community resources may also be helpful to physicians as they consider the patient's
14 post-discharge care needs.

15
16 Similarly, individual patients' own informed preferences regarding discharge and post-discharge
17 care arrangements should be respected by physicians whenever possible. In so doing, physicians
18 help to mitigate harms that arise from an undue constraint on one's ability to exercise self
19 determination. This respect is, in fact, a physician responsibility that is widely affirmed in various
20 opinions of the AMA Code of Medical Ethics.^{15, 17, 18}

21
22 The physician's responsibility to respect a patient's right to self determination acknowledges that
23 the right is not absolute,¹⁹ but that it is appropriately constrained, in some measure, by the options
24 afforded by a multiplicity of other social factors. Physicians should consider the wishes of the
25 patient to the extent that respecting a patient's right to self-determination contributes to a safe
26 discharge. Discharge often marks a significant medical and social transition for patients. While
27 some patients fully recover and return to the normalcy of home, many with ongoing care needs
28 enter a new phase of care at home or another health care facility. For this group in particular,
29 discharge is often marked by the stresses of adjusting to new care and living arrangements.⁸ By
30 providing patients with a degree of control over this process, physicians can help patients better
31 prepare for a safer transition.

32
33 *Be sensitive to societal interests*

34
35 Physicians should be sensitive to the interests of society in discharge practices, but without
36 compromising the individual patient's safety, which must remain a physician's primary
37 commitment. The patient-physician interaction necessarily exists within a nexus of specific policies
38 and limited resources. This reality shapes what a physician is or is not able to do in regards to
39 patient discharge. For example, the unsustainable costs of health care in the U.S. have made the
40 prudent use of health care resources increasingly important. Many health care institutions
41 incentivize reducing a patient's length of stay, for instance, in an effort to constrain costs.²⁰ Such
42 incentives, while legitimate, may increase the risk of patients being discharged before they are
43 clinically ready or before post-discharge care can be adequately arranged. Physicians should be
44 wary of such possibilities, because they can compromise the safety of patients.

45
46 **IMPLICATIONS FOR DISCHARGE TO RESOURCE POOR SETTINGS ABROAD**

47
48 Ensuring a safe discharge for patients can be extremely challenging for physicians when adequate
49 post-discharge options are severely limited. For instance, homeless patients may have limited
50 options due to a lack of insurance or caretakers,²¹ while a patient in a rural setting may be limited
51 by logistic barriers. The issue of limited options is starkly illustrated by recent reports alleging

1 forced discharge of noncitizen immigrant patients from U.S. hospitals to resource poor facilities in
2 their countries of origin.

3
4 These practices usually involve noncitizen immigrants who are residing in the U.S. illegally or
5 have legally resided in the country for less than five years. When such noncitizen immigrants
6 experience a major illness or injury, their initial emergency medical needs are met regardless of
7 their immigration or insurance status under the provisions of the Emergency Medical Treatment
8 and Active Labor Act (EMTALA).²²⁻²⁴ However, uninsured noncitizen immigrant patients, who
9 have been stabilized, but require long-term care, often cannot access appropriate facilities or
10 caregivers in the United States.^{24, 25} They frequently lack the financial means to purchase private
11 insurance for long-term care, and their immigration status disqualifies them from Medicaid or
12 Medicare. Such patients may alternatively qualify for a patchwork of local resources or allowances
13 from the Immigration and Naturalization Services (INS), but these plans apply to only a few
14 qualified groups.^{25, 26}

15
16 Millions of legal and illegal noncitizen immigrants are potentially at risk of being unsafely
17 discharged across U.S. borders. As of March 2007, an estimated 37.9 million noncitizen
18 immigrants were living and working in the U.S.²⁷ Of these, more than 33.8 percent (or 12.8
19 million) lacked any public or private health insurance for the entire year of 2006.²⁷ The risks are
20 particularly high among certain immigrant groups, such as those from Mexico, 56.9 percent of
21 whom did not have any insurance in 2006.²⁷ According to preliminary inquiries made by
22 journalists, this risk has translated into physician authorizations for hundreds of patient discharges
23 to facilities in other countries each year, with little formal oversight.^{22, 25, 28}

24
25 Immigration status is clearly a reality that can limit the options available to patients and their
26 physicians.^{29, 30} However, these limitations should not diminish the physician's ethical commitment
27 to seek a safe discharge for all patients. Physicians should not discriminate in the care that they
28 provide.³¹ "The existence of a genuine medical need," and not the patient's immigration or social
29 status, "constitutes a moral claim on those equipped to help."¹ Physicians should negotiate even
30 difficult limitations with the patient's safety in mind.

31
32 Physicians should, of course, assess the patient's medical stability and readiness for discharge to
33 another care environment and for a long international trip (during which patients may be prone to
34 dehydration or respiratory illness³²). Likewise, physicians should not authorize a discharge unless
35 they have confirmed that the intended destination has adequate human and material resources for
36 the patient's medical needs. Relative to a local discharge, an international discharge may require
37 additional efforts to coordinate care effectively, such as speaking with the receiving physician
38 through an interpreter or seeking reliable information about the standard of care at the facility in
39 question. For patients with extensive care needs, the physician should keep in mind that many
40 countries throughout the world are struggling to provide even basic medical care for their citizens,
41 and are unlikely to be able to provide resource intensive care with public funds.²⁵ Regardless of
42 whether or not the discharging hospital is the best environment for the patient's needs,²⁴ the
43 physician should not discharge the patient to care conditions that are inadequate to his or her needs.

44
45 Throughout the discharge process, physicians should listen to the concerns of future caretakers and
46 to the preferences of the patient. The physician should consider the caretakers and patients'
47 understanding of the standards of care in their country of citizenship and the social attachments that
48 the patient may have in the U.S., for example. These considerations may be important when
49 physicians assess the adequacy of future care arrangements for the patient. Moreover, the
50 caretakers and patients' involvement in the discussions may lead to a helpful consensus for what
51 ought to be done.

1 Given that uncompensated care is at issue, physicians may need to be sensitive to administrators'
2 concerns about the hospital's financial viability. The costs for hospitals to provide uncompensated
3 long-term care for even "a few" patients can be significant, reaching up to \$2 million a year
4 according to one New York City hospital.²⁴ Hospital administrators have used such costs and their
5 duties to stewardship to justify potentially unsafe discharge practices in the past.^{24, 25} To be sure,
6 physicians should consider that the hospital's existence benefits other patients and often the
7 economy of an entire community.³³ So physicians should not prescribe medically unnecessary or
8 futile interventions,^{34, 35} or interventions that would unfairly deny care to other patients.³⁶ However,
9 unless an uninsured noncitizen immigrant's care at the hospital meets either criteria, a physician
10 should maintain the primacy of the patient's safety over the hospital's resource concerns.

11
12 Therefore, when asked by hospital administrators to discharge an uninsured noncitizen immigrant
13 patient to an inadequate facility on the basis of limited resources, physicians should carefully
14 examine the arguments for potential harm to the hospital. Ideally, physicians should request that
15 the current treating facility demonstrate a causal link between continuing to provide resource
16 intensive care for one or a few patients and the likelihood of disproportionate harm to other
17 patients. But physicians should be aware that this is often difficult, if not impossible, for hospital
18 administrators to show. A patient's care is likely to be absorbed by the broader operations of the
19 hospital and is unlikely to affect the care provided to other patients in a direct or clearly identifiable
20 manner. Nonetheless, the case for overriding an individual patient's safety with the concerns of the
21 hospital must be objective, defensible and ethically compelling.

22
23 Despite efforts to fulfill all the responsibilities of a safe discharge practice, in the end, physicians
24 may be unable to make an ethically satisfying decision. Even if a patient is medically ready for
25 discharge and administrators insist that an adequate facility is available, patients and their families
26 may continue to object, thereby creating a stalemate situation. Physicians should then support the
27 patient's right to seek input from an ethics committee that is independent from the hospital's
28 administrative functions. Should consensus fail even after such input, a physician should support a
29 patient's right to seek arbitration before a legal body.²² Forcing an immigrant to leave the U.S. is a
30 prerogative of the federal government, and should only occur following due process, in which the
31 immigrant's legal options are exhausted.^{22, 37} Physicians should not allow hospital administrators to
32 use their significant power and the current lack of regulations on medical repatriations to
33 unilaterally discharge patients abroad.²² Such patient advocacy is consistent with the physician's
34 pledge to seek the patient's safety.

35 36 RESPONSIBILITY TO SUPPORT SAFE DISCHARGE ENABLING POLICIES

37
38 The challenges associated with discharging uninsured immigrant patients with long-term post-
39 hospital needs are complex. Physicians cannot expect hospitals to provide costly uncompensated
40 care to an indefinite number of patients for indefinite lengths of time. But neither should physicians
41 allow hospitals to arbitrarily determine the fate of an uninsured noncitizen immigrant patient.
42 Resolving this issue will require the collective involvement of various stakeholders in health care,
43 including physicians, health care facilities, insurers, policymakers, and the public.³⁸ Physicians
44 should participate in the policy development process by supporting proposals that will benefit
45 patients and are consistent with the ethical principles on which the medical profession is
46 established. They should work to ensure that societal decisions about discharge and long-term care
47 safeguard the interests of all patients,³⁹ including noncitizen immigrant patients who are socially,
48 politically, and economically disadvantaged.

1 RECOMMENDATION

2

3 The Council on Ethical and Judicial Affairs recommends that the following be adopted in lieu of
4 Resolution 4 (I-08) and that the remainder of this report be filed:

5

6 Physicians' primary ethical obligation to serve their patients' needs encompasses an obligation
7 to help ensure a discharge that is safe for the patient, without regard to socioeconomic status,
8 immigration status, or other clinically irrelevant considerations. However, physicians should
9 also use health care resources responsibly and can ethically consider compelling arguments
10 made by hospital administrators to discharge a patient whose continued hospitalization is likely
11 to compromise the care of other patients. As advocates for their patients, physicians should
12 resist any discharge requests that could compromise a patient's safety.

13

14 To ensure a patient's safe discharge, including discharge to caregivers outside the U.S.,
15 physicians should:

16

17 (a) Determine that the patient is medically stable and ready for discharge from the treating
18 facility;

19

20 (b) Develop a plan for any medically needed post-discharge care;

21

22 (c) Ascertain—individually or through the treating facility or other intermediary—that the
23 receiving facility or caregiver has the capacity to provide care adequate to meet the
24 patient's needs;

25

26 (d) Take reasonable steps to ensure the patient's safe transit;

27

28 (e) Assist a patient who is unwilling to accept the discharge plan to seek independent ethics
29 consultation or other means of resolving ongoing disagreement; and

30

31 (f) Refrain from signing a discharge order that would result in involuntary discharge of a
32 patient who is not a U.S. citizen to his/her country of origin and advocate for the patient's
33 opportunity to seek formal review of the proposed involuntary removal from the U.S. by
34 appropriate government authorities.

35

36 (New HOD/CEJA Policy)

Fiscal Note: Staff cost estimated at less than \$500 to implement.

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REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 3-I-09

Subject: Physicians with Disruptive Behavior

Presented by: Dudley M. Stewart, Jr., MD, Chair

1 At the 2008 Interim Meeting of the American Medical Association (AMA) House of Delegates
2 (HOD), the HOD adopted Resolution 1 (I-08), “Disruptive Behavior by a Physician.” Introduced
3 by the Florida Delegation, the Resolution requested in part that the Council on Ethical and Judicial
4 Affairs (CEJA) update Policy E-9.045, “Physicians with Disruptive Behavior.” Consequently, the
5 Council has undertaken a careful review of this Opinion.

6
7 CEJA believes that E-9.045 and the AMA’s Model Medical Staff Code of Conduct adequately
8 address the concerns raised by Resolution 1 (I-08) and related testimony to the Reference
9 Committee on Amendments to Constitution and Bylaws. Therefore, CEJA has chosen to prepare
10 this informational report in lieu of a revised Opinion on disruptive behavior by a physician.

11
12 This informational report examines existing policy with respect to concerns articulated in
13 Resolution 1 (I-08) and testimony. In particular, this report examines policy relevant to good faith
14 criticism that is wrongly labeled “disruptive” by a hospital administration and the role of an
15 organized medical staff in dealing with disruptive behavior by a physician.

16 17 BACKGROUND

18
19 At the 1999 Annual Meeting of the AMA House of Delegates, the HOD adopted Resolution 9
20 (A-99), “Addressing the Disruptive Physician.” Introduced by the Resident and Fellow Section,
21 Resolution 9 (A-99) requested that the AMA “identify and study behavior by physicians that is
22 disruptive to high quality patient care,” and that the AMA “define the term ‘disruptive physician’
23 and disseminate guidelines for managing the disruptive physician.” In response to Resolution 9
24 (A-99), the Council on Ethical and Judicial Affairs wrote CEJA Report 2-A-00, “Physicians With
25 Disruptive Behavior.” In developing its report, CEJA contacted the AMA’s Governing Councils of
26 the Resident and Fellow Section and the Organized Medical Staff Section, as well as the American
27 Psychiatric Association, the Federation of Medical State Boards, and the American College of
28 Legal Medicine. CEJA Report 2-A-00 was adopted at the 2000 Annual Meeting, and its
29 recommendations formed the basis for Policy E-9.045.

30
31 In July 2008, the Joint Commission published Standard LD.03.01.01. In recognition of disruptive
32 physicians’ ability to intimidate others and affect morale or staff turnover that can be harmful to
33 patient care, Standard LD.03.01.01 requires accredited health care organizations to create a code of
34 conduct that defines “acceptable,” “disruptive,” and “inappropriate” behaviors and to establish a
35 formal process for managing unacceptable behavior.¹ A related “Sentinel Event Alert” noted that

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1 “disruptive and intimidating behaviors” undermine a culture of safety and can contribute to medical
2 errors and preventable adverse outcomes.²

3
4 Concerns about the possible pernicious effect of LD.03.01.01 led to Resolution 1 (I-08). The
5 Resolution reflected a concern that hospitals could misuse the term “disruptive physician” if there
6 was no clear definition of what acts by a physician rise to the level of truly disruptive behavior.
7 CEJA was thus asked to consider updating E-9.045, for further clarification and consideration of
8 issues raised in reference committee hearing testimony, such as the need to address further the
9 inappropriate use of allegations of “disruptive behavior” by institutions to retaliate against
10 members of the medical staff, or by members of the medical staff against their peers. The Council
11 has undertaken a careful review of this Opinion.

12 13 DEFINING DISRUPTIVE BEHAVIOR

14
15 Disruptive behavior by a physician, sometimes called “abusive” behavior, generally refers to a
16 style of interaction by physicians with others, including hospital personnel, patients, and family
17 members, that interferes with patient care or adversely affects the health care team’s ability to work
18 effectively.^{3,4} It encompasses behavior that adversely affects morale, focus and concentration,
19 collaboration, and communication and information transfer, all of which can lead to substandard
20 patient care.^{2,3,5-7} Disruptive behavior by a physician can also increase apprehension and anxiety
21 among patients, both those being treated by the physician as well as other patients who may
22 witness outbursts or other inappropriate behavior.⁷

23
24 The frequency of disruptive behavior is relevant, as a pattern of behavior may be considered
25 disruptive when a single instance of such behavior would not.³ As the Federation of State Medical
26 Boards (FSMB) has observed, “[d]isruptive behavior in physicians is characteristically a chronic or
27 habitual pattern of behavior” that creates a hostile environment, the effects of which have serious
28 implications on the quality of patient care and patient safety.⁷ The AMA’s *Code of Medical Ethics*
29 and the OMSS Model Medical Staff Code of Conduct both provide further insight on appropriate,
30 inappropriate, and disruptive behavior by physicians.

31 32 *AMA Ethics Policy*

33
34 Opinion E-9.045, “Physicians with Disruptive Behavior,” defines disruptive behavior as “personal
35 conduct, whether verbal or physical, that negatively affects or that potentially may negatively affect
36 patient care.”⁴ Disruptive behavior by a physician does not include “criticism that is offered in
37 good faith with the aim of improving patient care.”⁴ E-9.045 provides that each medical staff
38 should develop and adopt bylaw provisions or policies for intervening in situations where a
39 physician’s behavior is identified as disruptive.^{4,8} These bylaw provisions or policies should
40 contain procedural safeguards that protect due process and facilitate prompt and fair
41 intervention.^{3,4,8}

42 43 *OMSS Model Medical Staff Code of Conduct*

44
45 The Model Medical Staff Code of Conduct developed by the Organized Medical Staff Section
46 encourages organized medical staffs to adopt bylaws containing a three-tiered approach to
47 identifying physicians with disruptive behavior. The model code distinguishes appropriate,
48 inappropriate, and disruptive behavior and makes clear the difference between truly disruptive
49 behavior and good faith criticism wrongly labeled disruptive.

1 Appropriate Behavior

2
3 It is entirely appropriate for physicians to “advocate for patients, to recommend improvements in
4 patient care, to participate in the operations, leadership or activities of the organized medical staff,
5 or to engage in professional practice including practice that may be in competition with the
6 hospital.” Physicians who speak about quality concerns within their hospital or take other steps in
7 an attempt to improve patient care and safety should be protected from retribution.^{8,9}

8
9 AMA’s Model Medical Staff Code of Conduct provides the following examples of appropriate
10 physician behavior:

- 11
- 12 • Criticism communicated in a reasonable manner and offered in good faith with the aim of
 - 13 improving patient care and safety;
 - 14 • Encouraging clear communication;
 - 15 • Expressions of concern about a patient’s care and safety;
 - 16 • Expressions of dissatisfaction with policies through appropriate grievance channels or
 - 17 other civil non-personal means of communication;
 - 18 • Use of cooperative approach to problem resolution;
 - 19 • Constructive criticism conveyed in a respectful and professional manner, without blame or
 - 20 shame for adverse outcomes;
 - 21 • Professional comments to any professional, managerial, supervisory, or administrative
 - 22 staff, or members of the Board of Directors about patient care or safety provided by others;
 - 23 • Active participation in medical staff and hospital meetings (i.e., comments made during or
 - 24 resulting from such meetings can not be used as the basis for a complaint under this Code
 - 25 of Conduct, referral to the Health and Wellbeing Committee, economic sanctions, or the
 - 26 filing of an action before a state or federal agency);
 - 27 • Membership on other medical staffs; and
 - 28 • Seeking legal advice or the initiation of legal action for cause.⁹
- 29

30 The model code identifies the following as types of physician behaviors—inappropriate and
31 disruptive—that a medical staff should not tolerate.

32
33 Inappropriate Behavior

34
35 Inappropriate behavior is conduct that is unwarranted and is reasonably interpreted to be
36 demeaning or offensive. This behavior can have a detrimental effect on relationships between
37 healthcare practitioners. Inappropriate behavior includes such things as belittling or berating
38 statements, use of profanity or disrespectful language, inappropriate comments written in the
39 medical record, deliberate failure of cooperation without good cause, and refusal to return phone
40 calls, pages, or other messages concerning patient care or safety.⁹ Persistent, repeated inappropriate
41 behavior can become a form of harassment and thereby rise to the level of disruptive behavior.⁹

42
43 Disruptive behavior

44
45 In keeping with E-9.045, the OMSS model code defines disruptive behavior as any abusive
46 conduct, including sexual or other forms of harassment, or other forms of verbal or nonverbal
47 conduct that harms or intimidates others to the extent that quality of care or patient safety could be
48 compromised.⁹ Disruptive physician behavior includes, but is not limited to:

- 1 • Physically threatening language directed at anyone in the hospital including physicians,
2 nurses, other medical staff members, or any hospital employee, administrator or member
3 of the Board of Directors;
- 4 • Physical contact with another individual that is threatening or intimidating;
- 5 • Throwing instruments, charts or other things;
- 6 • Threats of violence or retribution;
- 7 • Sexual harassment; and,
- 8 • Other forms of harassment including, but not limited to, persistent inappropriate behavior
9 and repeated threats of litigation.⁹

10
11 Because of the detrimental effects on patient care and the ability to work with other members of the
12 health care team, disruptive behavior by a physician should not be tolerated.

13
14 AMA policy is consistent in providing that an organized medical staff, not a hospital's
15 administrative body, is the proper entity to deal with disruptive behavior by physicians.^{4,9} OMSS
16 supports tiered, nonconfrontational intervention strategies, starting with informal discussion of the
17 matter and escalating to the use of summary suspension when the disruptive physician behavior
18 presents danger to the health of any individual.⁹ Both E-9.045 and the model code of conduct hold
19 that policies should allow for self-correction and a means of monitoring change in behavior, with
20 the focus on restoring trust, placing accountability on and rehabilitating the offending medical staff
21 member, and protecting patient care and safety. When there is reason to believe that inappropriate
22 or disruptive behavior is due to illness or impairment, the matter should be evaluated and managed
23 confidentially according to the established procedures of the medical staff's health and well-being
24 (or equivalent) committee.^{4,9}

25
26 **CONCLUSION**

27
28 Disruptive physician behavior is undoubtedly a serious issue that organized medical staffs must
29 address. CEJA believes, however, that Policy E-9.045 and AMA's Model Medical Staff Code of
30 Conduct adequately address the concerns raised by Resolution 1 (I-08) and related Reference
31 Committee hearing testimony.

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REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 4-I-09

Subject: Update: Modernizing the AMA *Code of Medical Ethics*

Presented by: Dudley M. Stewart, Jr., MD, Chair

1 As noted in CEJA Report 5-I-08, “Modernizing the AMA *Code of Medical Ethics*,” the Council on
2 Ethical and Judicial Affairs (CEJA) has embarked on a project to critically review and update the
3 *Code*. The goal is to ensure that the *Code* continues to provide timely, relevant, cogent guidance for
4 the profession of medicine and its individual physician and medical student members.
5

6 Staff and consultants completed a preliminary review of all Opinions in the *Code* as re-organized
7 under the new, more intuitive taxonomy identified in CEJA’s previous report. Each Opinion was
8 scored with respect to the continued importance of the topic the Opinion addresses; the quality of
9 ethical analysis; and the quality, timeliness, and usefulness of the specific ethical guidance the
10 Opinion offers. This first round of review also sought to identify topic gaps that should be
11 addressed in new CEJA reports and recommendations; opportunities to combine two or more
12 existing Opinions on related issues into an overarching report and recommendations; and opinions
13 that are outdated and should be replaced (or, where appropriate, sunsetted).
14

15 The Council is currently reviewing initial proposals from staff and consultants for refining how the
16 Opinions of the *Code* are organized within each topical chapter. The first round of review
17 suggested that bringing together “clusters” of Opinions on closely related concerns within a general
18 topic area would enhance the value of the *Code* not only for the practicing physicians who are its
19 primary audience, but also for medical educators and others. For example, bringing together
20 Opinions in clusters on confidentiality, privacy, and medical records within an overall chapter on
21 privacy and confidentiality would help make it easy to find guidance about physicians’
22 responsibilities with respect to particular questions while also indicating the broader range of
23 relevant ethical issues.
24

25 The Council is also considering the potential value for users of presenting the content of the *Code*
26 in a uniform format across all Opinions. As the *Code* has evolved to meet new challenges in
27 medical science and the delivery of health care, Opinions have been presented in a variety of
28 formats. This can present a challenge for interpreting the ethical guidance provided in different
29 Opinions. One proposal under discussion is to present the substantive content of all Opinions in a
30 three-part form: a “preamble” that identifies the fundamental ethical and professional values and
31 obligations at issue; a brief description of the context of the ethical concern(s) the Opinion
32 addresses; and finally, concrete, practical guidelines for physicians’ professional ethical conduct.
33

34 Building on these foundations, in the coming months the Council will work with staff and
35 consultants to begin developing specific proposals for revision of each chapter in a systematic,
36 iterative process. As this process goes forward, CEJA will solicit additional review and feedback
37 from stakeholders, including representatives from AMA Councils, Sections, Special Groups,
38 members, and the Federation.

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OPINION OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Opinion 1-I-09

Subject: Quality

Presented by: Dudley M. Stewart, Jr., MD, Chair

1 INTRODUCTION

2
3 At the 2009 Annual Meeting, the American Medical Association House of Delegates adopted the
4 recommendations of Council on Ethical and Judicial Affairs Report 5-A-09, "Quality." This report
5 outlined the ethical obligations of physicians in providing quality care and provided guidance to
6 help physicians better understand that quality is not just a technical, systems concern; it is an
7 ethical and hence a professional one as well. The Council issues this Opinion, which will appear in
8 the next version of PolicyFinder and the next print edition of the Code of Medical Ethics.

9
10 E-9.14 Quality

11
12 As professionals dedicated to promoting the well-being of patients, physicians individually and
13 collectively share the obligation to ensure that the care patients receive is safe, effective,
14 patient centered, timely, efficient, and equitable.

15
16 While responsibility for quality of care does not rest solely with physicians, their role is
17 essential. Individually and collectively, physicians should actively engage in efforts to improve
18 the quality of health care by:

- 19
20 (1) Keeping current with best care practices and maintaining professional competence.
21
22 (2) Holding themselves accountable to patients, families, and fellow health care professionals
23 for communicating effectively and coordinating care appropriately.
24
25 (3) Monitoring the quality of care they deliver as individual practitioners—e.g., through
26 personal case review and critical self-reflection, peer review, and use of other quality
27 improvement tools.
28
29 (4) Demonstrating a commitment to develop, implement, and disseminate appropriate, well-
30 defined quality and performance improvement measures in their daily practice.
31
32 (5) Participating in educational, certification, and quality improvement activities that are well
33 designed and consistent with the core values of the medical profession. (I, V, VII, VIII)

34
35 Issued November 2009 based on the report "Quality," adopted June 2009.

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OPINION OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Opinion 2-I-09

Subject: Financial Barriers to Health Care Access

Presented by: Dudley M. Stewart, Jr., MD, Chair

1 INTRODUCTION

2
3 At the 2009 Annual Meeting, the American Medical Association House of Delegates adopted the
4 recommendations of Council on Ethical and Judicial Affairs Report 2-A-09, "Financial Barriers to
5 Health Care Access." This report examined financial barriers that prevent individuals from getting
6 care and the ethical responsibility that physicians, individually and as a profession, have to ensure
7 that all individuals can access needed care regardless of their economic status. The Council issues
8 this Opinion, which will appear in the next version of PolicyFinder and the next print edition of the
9 Code of Medical Ethics.

10
11 E-9.0651 Financial Barriers to Health Care Access

12
13 Health care is a fundamental human good because it affects our opportunity to pursue life
14 goals, reduces our pain and suffering, helps prevent premature loss of life, and provides
15 information needed to plan for our lives. As professionals, physicians individually and
16 collectively have an ethical responsibility to ensure that all persons have access to needed care
17 regardless of their economic means. In view of this obligation:

- 18
19 (1) Individual physicians should take steps to promote access to care for individual patients.
20
21 (2) Individual physicians should help patients obtain needed care through public or charitable
22 programs when patients cannot do so themselves.
23
24 (3) Physicians, individually and collectively through their professional organizations and
25 institutions, should participate in the political process as advocates for patients (or support
26 those who do) so as to diminish financial obstacles to access health care.
27
28 (4) The medical profession must work to ensure that societal decisions about the distribution
29 of health resources safeguard the interests of all patients and promote access to health
30 services.

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1 (5) All stakeholders in health care, including physicians, health facilities, health insurers,
2 professional medical societies, and public policymakers must work together to ensure
3 sufficient access to appropriate health care for all people. (VI, IX)

4

5 Issued November 2009 based on the report "Financial Barriers to Health Care Access,"
6 adopted June 2009.

OPINION OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Opinion 3-I-09

Subject: A Physician's Role Following a Breach of Electronic Health Information

Presented by: Dudley M. Stewart, Jr., MD, Chair

1 INTRODUCTION

2
3 At the 2009 Annual Meeting, the American Medical Association House of Delegates adopted the
4 recommendations of Council on Ethical and Judicial Affairs Report 3-A-09, "A Physician's Role
5 Following a Breach of Electronic Health Information." This report examined physicians' ethical
6 responsibilities in the event of a breach of electronic health information. The Council issues this
7 Opinion, which will appear in the next version of PolicyFinder and the next print edition of the
8 Code of Medical Ethics.

9
10 E-5.10 A Physician's Role Following a Breach of Electronic Health Information

11
12 When used with appropriate attention to security, electronic medical records (EMRs) promise
13 numerous benefits for quality clinical care and health-related research. However, when a
14 security breach occurs, patients may face physical, emotional, and dignitary harms.

15
16 Dedication to upholding trust in the patient-physician relationship, to preventing harms to
17 patients, and to respecting patients' privacy and autonomy create responsibilities for individual
18 physicians, medical practices, and health care institutions when patient information is
19 inappropriately disclosed. The degree to which an individual physician has an ethical
20 responsibility to address inappropriate disclosure depends in part on his or her awareness of the
21 breach, relationship to the patient(s) affected, administrative authority with respect to the
22 records, and authority to act on behalf of the practice or institution.

23
24 When there is reason to believe that patients' confidentiality has been compromised by a
25 breach of the electronic medical record, physicians should:

- 26
27 (1) Ensure that patients are promptly informed about the breach and potential for harm, either
28 by disclosing directly (when the physician has administrative responsibility for the EMR),
29 participating in efforts by the practice or health care institution to disclose, or ensuring that
30 the practice or institution takes appropriate action to disclose.

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- 1 (2) Follow ethically appropriate procedures for disclosure, which should at minimum include:
2
3 (a) carrying out the disclosure confidentially and within a time frame that provides
4 patients ample opportunity to take steps to minimize potential adverse consequences;
5 and
6
7 (b) describing what information was breached; how the breach happened; what the
8 consequences may be; what corrective actions have been taken by the physician,
9 practice, or institution; and what steps patients themselves might take to minimize
10 adverse consequences.
11
12 (3) Support responses to security breaches that place the interests of patients above those of
13 the physician, medical practice, or institution.
14
15 (4) To the extent possible, provide information to patients to enable them to mitigate potential
16 adverse consequences of inappropriate disclosure of their personal health information,
17 such as credit monitoring services or identity theft hotline. (IV, VIII)
18

19 Issued November 2009 based on the report "A Physician's Role Following a Breach of
20 Electronic Health Information," adopted June 2009.

OPINION OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Opinion 4-I-09

Subject: Physician Employment by a Nonphysician Supervisee

Presented by: Dudley M. Stewart, Jr., MD, Chair

1 INTRODUCTION

2
3 At the 2009 Annual Meeting, the American Medical Association House of Delegates adopted the
4 recommendations of Council on Ethical and Judicial Affairs Report 4-A-09, "Physician
5 Employment by a Nonphysician Supervisee." This report discussed the arrangement where a
6 physician is employed by a nonphysician whom the physician is also charged with supervising. The
7 Council issues this Opinion, which will appear in the next version of PolicyFinder and the next
8 print edition of the Code of Medical Ethics.

9
10 E-3.05 Physician Employment by a Nonphysician Supervisee

11
12 Physicians' relationships with midlevel practitioners must be based on mutual respect and trust
13 as well as their shared commitment to patient well-being. Health care professionals recognize
14 that clinical tasks should be shared and delegated in keeping with each practitioner's training
15 and scope of practice. Given their comprehensive training and broad scope of practice,
16 physicians have a professional responsibility for the quality of overall care that patients
17 receive, even when aspects of that care are delivered by nonphysician clinicians.

18
19 When nonphysicians employ physicians to supervise the employer's clinical practice,
20 conditions are created that can lead to ethical dilemmas for the physician. If maintaining an
21 employment relationship with a midlevel practitioner contributes significantly to the
22 physician's livelihood, a physician's personal and financial interests can be put at odds with
23 patient care interests. Similarly, the administrative and financial influence that employer status
24 confers creates an inherent conflict for a physician who is simultaneously an employee and a
25 clinical supervisor of his or her employer.

26
27 Physicians in such arrangements must give precedence to their ethical obligation to act in the
28 patient's best interest by always exercising independent professional judgment, even if that
29 puts the physician at odds with the employer/supervisee. (II, VI, VIII)

30
31 Issued November 2009 based on the report "Physician Employment by a Nonphysician
32 Supervisee," adopted June 2009.

* Opinions of the Council on Ethical and Judicial Affairs will be placed on the Consent Calendar for informational reports, but may be withdrawn from the Consent Calendar on motion of any member of the House of Delegates and referred to a Reference Committee. The members of the House may discuss an Opinion fully in Reference Committee and on the floor of the House. After concluding its discussion, the House shall file the Opinion. The House may adopt a resolution requesting the Council on Ethical and Judicial Affairs to reconsider or withdraw the Opinion.

REPORT 1 OF THE COUNCIL ON LONG RANGE PLANNING AND DEVELOPMENT (I-09)
The Experience of International Medical Associations with Universal Coverage

EXECUTIVE SUMMARY

In light of current proposals to reform the US health system, the Council on Long Range Planning and Development (CLRPD) sought to explore the experiences of a sample of national medical associations in countries that have implemented universal coverage in order to provide information that might be useful to our American Medical Association (AMA) as a key player in health system reform. This informational report describes the experiences of seven national medical associations.

CLRPD selected the medical associations of Canada, France, Singapore, Thailand, the United Kingdom, Taiwan, and Australia because these countries implemented universal coverage at different points since World War II. Telephone interviews were conducted with one or more spokespersons for each medical association to explore four major topics of interest:

1. The role of the medical society in the design and ongoing functioning of the system of universal coverage;
2. The impact of universal coverage on patient demand for services;
3. The impact of universal coverage on the day-to-day practice of medicine; and
4. What advice would they give to the AMA as the US considers implementing universal coverage.

The interviews revealed that the general feeling of physicians toward their country's forms of universal coverage was more positive than initially expected. According to the association spokespersons, physicians seemed to adapt fairly well following the implementation of health system reform and increasingly accepted it while pointing out components that could be improved. Association representatives generally cited the positive aspects of health system reform, including increased patient access to care, improved national health indicators, and better predictability for reimbursement for their services. Their common recommendations were that, where possible, medical associations should be involved in the planning and implementation of reform and be advocates for their patients.

REPORT OF THE COUNCIL ON LONG RANGE PLANNING AND DEVELOPMENT

CLRPD Report 1-I-09

Subject: The Experience of International Medical Associations with Universal Coverage

Presented by: Neil Brooks, MD, Chair

1 INTRODUCTION

2
3 The current US health care system is perceived by many to be unsustainable, and pressure has been
4 mounting for the US to adopt reforms. While there is significant information about the health
5 delivery systems and the history of reform in other countries, there is very little information about
6 the role of national medical associations in the health system reforms that have taken place in their
7 countries. Accordingly, the Council on Long Range Planning and Development (CLRPD) has
8 prepared this informational report to share the experiences of a sample of national medical
9 associations in countries that have implemented universal coverage for their citizens.

10 11 METHODOLOGY

12
13 In March, 2008, CLRPD identified several nations and sought to assess the experience of their
14 national medical associations before, during and post adoption of universal coverage. The Council
15 selected seven countries which had adopted health system reform at different times from immediate
16 post-World War II to relatively recent times. These included Canada, France, Singapore, Thailand,
17 the United Kingdom, Taiwan, and Australia. Interviews were conducted with association
18 leadership between March, 2008 and June, 2009. The American Medical Association (AMA) pre-
19 arranged international telephone connections and undertook single, one-hour interviews with up to
20 five individuals from each association.

21
22 This study focuses on the role of the seven national medical associations in the evolution of
23 universal health care in their countries and the impact of reform on patient care. Hopefully, the
24 information derived from these interviews will provide perspectives that our AMA can utilize as
25 our association plays a key role in the current US health system reform debate.

26
27 In preparation for the interviews, the Council reviewed published and online resources related to
28 each country's medical association, the nation's health issues, and its health care system. This
29 research provided background and context for the discussions and helped frame relevant and
30 individualized questions pertaining to four major topics which were covered in all seven
31 interviews:

- 32
- 33 1. The role of the medical society in the design and ongoing functioning of the system of
34 universal coverage;
 - 35 2. The impact of universal coverage on patient demand for services;
 - 36 3. The impact of universal coverage on the day-to-day practice of medicine; and
 - 37 4. What advice would they give to the AMA as the US considers implementing universal
38 coverage.

1 In examining the experiences of national medical associations, interviews focused on the activities
2 of the national medical associations and impacts on physicians' everyday practices rather than
3 components of the plans that were developed per se. While it would have been desirable, for
4 example, to inquire about the public's expectations of the new health care system pre- and post-
5 reform and to delve into the mechanisms used by the health systems of these countries to manage
6 health resources within budgetary limits, including price controls, those matters were not the aim of
7 the Council's study. Given the brevity of the interviews and differences in the experiences of the
8 various association representatives, variations existed in the extent to which each key area was
9 covered in the interviews.

10
11 This informational report is based entirely on responses provided by spokespersons to questions
12 related to these four key areas of interest. However, it is important to note that comments made by
13 interviewees were their perspectives and may not reflect official policies of their associations.

14 15 OVERVIEW OF EACH COUNTRY'S EXPERIENCE

16 17 *Canada*

18
19 Prior to the final adoption of universal coverage at the national level in 1966, individual provinces
20 initiated reform between 1948 and 1962, starting with hospital coverage and in some cases
21 incorporating physicians' services. In anticipation of a surge in demand, Canada doubled its
22 hospital capacity and expanded medical education to increase physician supply. To further avoid
23 abrupt changes, Canada intentionally controlled residency training slots, resulting in a 51/49 split
24 between primary care and specialists.

25
26 Consequently, the demand for care, especially physicians' services, did not increase sharply
27 following the nationwide implementation of the Canadian Universal Coverage system in 1966. In
28 fact, the surge in demand did not materialize as expected in part because of the provincial systems
29 that had been developing over the years. Over-preparation for the expected surge in demand led to
30 the unintended consequence of creating a surplus of physicians. According the spokesperson for
31 the Canadian Medical Association (CMA), this resulted in a supplier-induced increase in the
32 number of services.

33
34 The CMA, which currently has an 85% membership market share, was not originally a key player
35 as the various provinces adopted universal coverage reforms. However, 1986 proved to be a
36 turning point as CMA mounted a constitutional challenge to the 1984 Canada Health Act which
37 banned balance billing. Even though four years later the challenge was dropped, CMA's
38 spokesperson believes it became the basis for CMA being viewed by physician members as a real
39 leader in advocacy.

40
41 Since that time, the CMA has been credited with increases in physician income and addressing
42 issues important to physicians. The provincial medical associations, which are divisions of CMA,
43 have substantial autonomy as well as influence within CMA and serve as the formal bargaining
44 agents for physicians.

45
46 Implementation of universal coverage presented many benefits including a substantial increase in
47 physicians' incomes due to the virtual disappearance of bad debts. Incomes leveled off in the
48 1990s as government funding for the overall system was reduced in response to rising costs.
49 Starting in 2000, funding began to increase again, with some positive impact on physicians'
50 incomes.

1 Even though the payer is a public entity (primarily provincial), about two-thirds of Canadian
2 physicians are reimbursed on a fee for service basis. The provincial associations negotiate the fee
3 schedules on behalf of the physicians. Provinces with physician workforce shortages try to pay
4 higher fees as an incentive to attract physicians from other provinces.

5
6 Waiting lists for some procedures remain a problem in Canada and are high priority for
7 government and the Canadian Medical Association. While the wait for some procedures has been
8 reduced, it has been offset by an increase in wait time for others.

9
10 *France*

11
12 Universal coverage was initially implemented in 1947, shortly after World War II, as a social
13 service. In 1974, the health system was adapted to provide universal coverage for all salaried
14 employees. Employee salaries were used to finance the system with employers assuming some
15 financial responsibility for providing such coverage.

16
17 In France the medical association exists alongside several physician unions. While membership in
18 the medical association is mandatory, membership in a union is not. Though separate, the medical
19 association, physician unions, and government work collaboratively. For example, the
20 development of a system similar to CPT has been identified as a key necessity and is an issue that
21 the medical association, unions, and government are working on together.

22
23 The medical association focuses mainly on working conditions, education, and professional issues,
24 but has become somewhat involved in recent years in financial issues as well. Since the universal
25 coverage system is state run, the medical association is not directly involved in its management.
26 The unions focus mainly on financial issues, including negotiations for physician payment which
27 are conducted every five years.

28
29 The demand for physicians' services gradually increased as universal coverage was implemented.
30 However, because the increase was not immediate, it did not unduly burden physicians.

31
32 At the time of implementation of universal coverage, there was a predominance of general
33 practitioners over specialists. Subsequently, the mix has changed and now is approximately equal.

34
35 The big change for physicians that came with universal coverage was an "equalization" of
36 payment. Physicians were assured of the same payment regardless of the patient, compared to
37 before when some paid in cash and on a timely basis, while others paid "in kind" and/or when they
38 could afford to pay.

39
40 *Singapore*

41
42 Due to Singapore's small population and the existence of an already developed medical system, the
43 implementation of universal coverage in 1983 did not have a major impact on private, community-
44 based practice. However, a maldistribution of work developed which left physicians in the
45 government "polyclinics" more burdened than private, community-based physicians. Further, there
46 was a shortage of physicians in some specialty areas.

47
48 Physicians in Singapore are considered upper middle to upper class and medicine is a well
49 respected profession. Physicians in Singapore are either in private practice or work for the
50 government. Among specialists, about half work in government hospitals and half in community-
51 based private practice. Private practice specialists earn 30-50% more than government hospital-

1 based specialists. Among physicians in private practice, specialists earn about twice what primary
2 care physicians earn.

3
4 Seventy percent (70%) of physicians in Singapore are members of the Singapore Medical
5 Association (SMA) which focuses on assisting physicians with regulatory matters, including
6 representation with managed care and various workforce issues.

7 The medical society is working to address maldistribution and shortages by outsourcing certain
8 services to other countries. It is also working toward making Singapore an international hub for
9 medical care in the region by importing medical professionals. The SMA has played a role in the
10 expansion of health services to attract more patients and ensuring that quality assurance measures
11 are in place.

12
13 In addition, the SMA has been active in health care financing. For many years, the SMA had a set
14 of “fee guidelines” but recently discontinued the guidelines in response to new government
15 regulations similar to US antitrust laws that are designed to promote more vigorous competition.
16 The representatives from the SMA expressed concern over what will happen in the market as a
17 result.

18
19 One aspect of the system in Singapore that could have an impact in the future is its “medical
20 savings account” system, which is used only to pay for hospital care. Unlike the HSAs or MSAs in
21 the US, participation in the medical savings account system is mandatory, and may serve more as a
22 tax than a savings mechanism. The Singapore MSA program has proven to be quite successful and
23 has generated a very substantial balance of funds. However, there is continuing pressure to ease
24 restrictions so that the money can be used for other services, not just hospital care. Should this
25 restriction be lifted, the result could be a sudden movement of funds to pay for physician services
26 and a subsequent increase in supplier-induced demand.

27 28 *Thailand*

29
30 The Thai representatives noted that there was a distinct increase in demand for physician services
31 even though universal coverage was phased in between 1990 and 2006 for different segments of
32 the population. Outpatient visits increased from 103 million in 2002 to 116.5 million in 2007.
33 Outpatient care constituted 96% of total medical visits in 2007. For in-patient care, Thailand
34 transitioned from a capitation to a DRG system between 2003 and 2007. In hospitals, demand
35 increased approximately 10% annually during the first two years and the hospitals had inadequate
36 budgets for hiring more physicians and nurses. To compensate, they used capital funds to hire
37 medical professionals instead of investing in equipment and supplies. Overall, inadequate funding
38 at the implementation of the system along with an increase in covered people compounded the
39 problem of being able to add capacity to the system.

40
41 The Thailand Medical Association (TMA) has about 2000 members out of a total population of
42 about 12,000 (16.7%). Physicians are also a part of other medical organizations, especially rural
43 physicians’ organizations and patients’ organizations. Because many of the rural physicians
44 indicated that they wanted a stronger voice and more involvement, the TMA has had more success
45 in working with organizations representing rural physicians and patients in recent years.

46
47 The TMA was not consulted on the design of the universal coverage system, which association
48 representatives believe may have stemmed from its disjointed relationship with the other medical
49 organizations and its low membership market share. This disjointed relationship contributed to a
50 missed opportunity where the medical association could have helped anticipate and address issues,
51 especially those related to the initial inadequacy of overall funding of the system.

1 Physicians are seeking more support from the medical association to expand primary care, so that
2 fewer people go to the hospitals for routine care. More primary care in rural areas is especially
3 needed. There was a shift from public clinics to private physicians' offices, and in some areas,
4 especially rural areas, there were not enough physicians and some did not have the supplies they
5 needed. Adding to the problem, language barriers deter physicians from moving to Thailand to
6 supplement capacity.

7
8 When first implemented, the Thai system was inadequately funded. Physicians lost income (some
9 substantially – up to 50%), but adjustments have been made in the funding base and physicians'
10 incomes are improving along with increased resources for other components of the medical system.

11 *Great Britain*

12
13
14 When the British government implemented universal coverage in 1948, there was pent up demand
15 in the system which led to a considerable surge in the patient flow to physicians' offices. Primary
16 care physicians constituted about 60% of the physicians but grew to a high of 80% around 2000
17 and are now at about 70%. Moreover, in the 1940s, there was not a nursing shortage and medicine
18 did not utilize technology to the extent that it is used now.

19
20 Demand for health services increased due to universal access and freedom of choice and resulted in
21 an increase in the number of patients treated. The surge in demand was expected, but what was not
22 anticipated was that it did not subside. It continued to grow as medical technology, increased
23 public expectations, and post-war economic growth continued to feed it.

24
25 To accommodate this increase, a wait list initiative was implemented. The British Medical
26 Association (BMA) spokesperson stated that the UK has largely resolved the waiting list problems
27 in recent years due to excess hospital and physician capacity, with the wait times now down to less
28 than six weeks. Currently, the only major area of backlog is for services related to reproductive
29 endocrinology. Since the issue of waiting lists is politically sensitive, if a backlog of services were
30 to begin to build again, the system is now authorized to pay for care in other countries.

31
32 The BMA spokesperson characterizes the association as a very participatory organization.
33 Approximately 2000 members serve on various committees, some of which are very active and
34 meet monthly. Physicians' expectations of BMA today are to achieve change to improve the
35 system. The BMA spokesperson indicated that the association is focusing on what it considers
36 "sensible" change. Most general practitioners are not government employees but contract with the
37 government to provide services. There is some effort to localize negotiations by districts, but
38 physicians are reluctant about this since they have more confidence in collective negotiations at the
39 national level.

40
41 The BMA has played the role of a negotiating agent for collective pay and working conditions for
42 physicians. The spokesperson for the BMA indicated that over the years, the association's
43 negotiations have been fairly successful on behalf of physicians. This role in negotiations allowed
44 the BMA to play a significant role in the initial functioning of the universal coverage system. This
45 role was formalized in 1971 to meet regulatory requirements.

46
47 The BMA has been presented with another opportunity to negotiate on behalf of UK physicians. In
48 2004, the government proposed a very substantial payment increase for physicians (60% for GPs
49 and 25% for specialists). On the other hand, the BMA proposed more moderate increases for
50 physician salaries while ensuring that there would be adequate funding for the provision of health
51 services. However, the government proposal was approved. Currently, reform measures are being

1 proposed by the government in response to cost increases associated with providing various health
2 services.

3
4 Some physician income is from private insurance, which has been a stable 9-12% of the health
5 economy for many years. The amount of income from private insurance varies by physician.
6 Physicians in the UK are considered upper middle class to upper class and consistently rate very
7 high in public satisfaction surveys. However, the spokesperson for the BMA commented that
8 physicians themselves are not comfortable with their place in society as a result of media attacks on
9 professionalism over the past decades. There is a sense that the government and media are trying
10 to “de-professionalize” medicine, especially the general practitioners, in order to promote
11 delegation of responsibilities to non-physician groups.

12
13 *Taiwan*

14
15 A system of universal coverage was adopted in 1995 during a time when popular demand,
16 economic conditions, and the agenda of the government administration favored a move towards
17 universal coverage. The short lead time prior to the implementation of universal coverage and
18 other factors precluded participation in the planning process by the Taiwan Medical Association.

19
20 The Taiwan Medical Association (TMA) obliges all physicians to be members. The Association
21 has jurisdiction over specialty societies. After registering with the TMA, a physician may join a
22 specialty society, which supports credentialing and various academic interests.

23
24 According to TMA spokespersons, the government is receptive to recommendations from
25 organized medicine only on a limited basis. Physician influence is not expected to increase since
26 the government considers the small and more conservative physician community less important
27 politically than the general public. The Department of Health is staffed with practicing physicians
28 (virtually all of whom were trained in the US) who also serve as consultants. These physicians
29 typically help develop the majority of health directives, e.g., experiments with pay-for-performance
30 and quality measures, before the TMA is even consulted.

31
32 Overall, Taiwan has seen some surge in demand as patients now have total freedom to access,
33 sometimes excessively, any physician (primary or specialist) or hospital with their “smart-cards.”
34 However, because of this generous government policy of open unfettered access, physicians are
35 frustrated about their lack of ability to coordinate patient care.

36
37 According to the spokespersons for the TMA, physicians are pleased that patients have access to
38 care and that there are both declines in overall mortality and improved management of chronic
39 diseases. However, these physicians expressed concern that the system does not include some sort
40 of a gate-keeper provision to address patients who tend to over use access to care and abuse the
41 freedom of choice of providers. Physicians are not able to appropriately monitor and improve
42 quality of care but hope to be able to influence public policy on this issue.

43
44 The TMA representatives also expressed that they believe physicians are generally pleased with
45 professional fees they receive. Their incomes have increased due to expanded coverage for
46 patients seen after the implementation of universal coverage. Physicians receive their revenues
47 from fee-for-service payments through the Bureau of National Health Insurance (BNHI) and direct
48 payment by patients in the form of user fees and co-payments. The TMA representatives
49 acknowledged that the BNHI has been very efficient in keeping its administrative costs at less than
50 2% and Taiwan spends approximately 6.23% of its GDP on health care, but noted that funding is
51 not always available to cover services offered.

1 The health system is financed through a global budget, which entails universal coverage for dental,
2 traditional Chinese medicine, clinic, and hospital budget systems. The TMA had limited input into
3 the negotiated fee schedules under the global budget.

4
5 *Australia*

6
7 In the 1970s and 1980s, the Australian Medical Association actively opposed government reforms
8 and feared a British-style National Health Service (NHS) system which might dictate terms of
9 practice and salary. The Australian Medical Association spokesperson indicated that in response,
10 the government totally closed the association out of negotiations about the implementation of
11 reform.

12
13 However, once universal coverage was implemented, the association became its greatest supporter.
14 Physicians saw a marked reduction in bad debt and those in private practice gained added security.
15 The new mixed private/public system also yielded benefits for patients in the form of a government
16 subsidy for fees along with improved quality and access to care.

17
18 Approximately 50% of physicians in Australia are in primary care and half of all Australian doctors
19 belong to the Australian Medical Association. However, association membership fluctuates
20 depending on how urgently physicians perceive challenges and the ability of the association to
21 address them.

22
23 With the first wave of health system reform, the demand for services did not increase due to the
24 dual system of government and private health insurance being equally accessible to patients,
25 regardless of age or health status. Over 45% have private insurance, which frees up an estimated
26 three billion dollars for public care and the waiting period for services in the public sector. The
27 Australian Medical Association spokesperson indicated that over utilization is not a major issue
28 with regulatory oversight of practice guidelines and potential penalties for physicians.

29
30 The spokesperson for the Australian Medical Association indicated that the new association
31 leadership is more supportive of collaboration with the government. The association sees this as
32 essential in order to resolve key issues, such as scope of practice, health information technology,
33 practice management, public health, mental health services, and increasing the number of medical
34 schools. However, residual effects of negative interactions with the government during the first
35 round of health system reform still impact relations between the association and the government.

36
37 **SUMMARY OF FINDINGS AND ADVICE FROM OTHER INTERNATIONAL MEDICAL**
38 **ASSOCIATIONS**

39
40 The interviews revealed that the general view of physicians toward their countries' form of
41 universal coverage was more positive than initially expected. According to the associations'
42 representatives, physicians seemed to adapt fairly well following implementation of reforms and
43 increasingly accepted those changes even though they pointed out certain components that could be
44 improved. Spokespersons for the associations generally cited the positive aspects of health system
45 reform, including increased patient access to care, improved national health indicators, and better
46 predictability for reimbursement for their services. Their common recommendation is that, where
47 possible, medical associations should be involved in the planning and implementation of reform
48 and be advocates for patients. Responses pertaining to the four key interview topics are
49 summarized in this section.

1 *Role of Medical Society in Design and Implementation of Universal Coverage*

2
3 Medical associations perform a range of functions, from general advocacy to formalized
4 negotiating agents. Even where there are formal negotiating roles, the importance of keeping
5 professional considerations in the forefront of discussions seems to be high. Many of association
6 representatives said that ensuring that the interests of patients (i.e. access to and quality of care) are
7 a priority that all the medical associations share.

8
9 In countries where there are formal negotiations separate from the medical association, there is
10 some working relationship between the medical society and the negotiating organizations. Medical
11 society involvement in the design of universal coverage is considered necessary and important.

12
13 *Summary of the Impact of Universal Coverage on Demand for Service*

14
15 There was a considerable range of experiences related to the demand for physicians' services
16 across the various countries. Some saw substantial and sustained increases in demand while others
17 saw increases that subsequently subsided, and still others did not experience problematic surges in
18 demand.

19
20 The extent of a surge in demand for physicians' practices depended in part on how recently and
21 how suddenly or incrementally universal coverage was implemented. In general, developed
22 countries that implemented universal coverage more recently and more incrementally saw less of a
23 surge in demand, whereas less developed countries and countries that implemented universal
24 coverage longer ago saw relatively more impact on demand. The gradual introduction of
25 employer-based insurance in developed countries in the post-WWII era made adoption of universal
26 coverage a less dramatic change.

27
28 Another issue on demand is the relative distribution of services across the country. Areas of
29 substantial deprivation will likely see a more dramatic impact as universal coverage is
30 implemented. Moreover, the proportion of primary care to specialists and whether primary care
31 has a gatekeeper role also predict the impact on the initial demand for physician services.

32
33 *Summary of the Impact of Universal Coverage in the Day-to-Day Practice of Medicine*

34
35 When spokespersons discussed the impact of reform on practice, they responded with comments on
36 the impact on physicians and reimbursement. In the countries studied, physicians remain among
37 the upper middle to upper class, as measured by income, and are consistently considered to be
38 among the most respected professions. It is important to note that when formal negotiation of
39 physicians' fees and/or salaries occurs, there have been periodic substantial increases in income.
40 The UK in 2004 is a notable recent example. Conversely, in countries where medical association
41 involvement was missing or very limited, financing of the system (and thus physicians' incomes)
42 was lower and in some cases inadequate. Thailand is an example of this.

43
44 In countries where some form of coverage existed prior to the implementation of universal
45 coverage, physicians' incomes were more likely to remain stable and predictable. In addition,
46 physicians were able to benefit from reduced collection issues as well as lowered administrative
47 costs and burden.

1 *Advice to the AMA as the US Considers Health System Reform*

2
3 In response to a question about what general advice each interviewee had for the AMA and the US
4 as our nation negotiates universal coverage, some interesting observations were made. The
5 responses were categorized into key areas:

6
7 Approach to universal coverage:

- 8 • Focus first on the most common clinical conditions and where there is the most need.
9 (Singapore)
- 10 • Incremental change is better than the “big bang” approach. This may be best achieved through
11 local demonstration projects to see what really works. (Canada)
- 12 • Keep in mind three key areas: insurance, private pay, and delivery. All three are important.
13 Experiment to get the right mix. (Canada)
- 14 • Keep the medical association and negotiating organization separate so the medical association
15 does not lose focus on professional matters. (France)
- 16 • Universal coverage is not that difficult to achieve, but no plan will please everyone.
17 (Singapore)
- 18 • Make sure the medical society is involved in the design phase or there will be important
19 aspects that are overlooked and will have to be corrected later. (Thailand and Taiwan)
- 20 • “Be the agent of change rather than the object of change” meaning that active involvement in
21 the reform process more likely assures that the association can influence change. Otherwise,
22 decisions may be made that are not advantageous to the profession, the association, or patients.
23 (Canada)
- 24 • Make sure everyone is aware of the difference between health and health care, and make sure
25 the system addresses each according to its specific nature and needs. (United Kingdom)
- 26 • The AMA should continue to be at the table with reasonable positions and to stand for the
27 interests of patients. Be part of the debate and don’t be afraid of the debate. (Australia)

28
29 Finance:

- 30 • The system may lose money and miss some people initially so make sure there is a good safety
31 net. (France)
- 32 • Adequate quality of care requires adequate funding of the system. (Singapore)
- 33 • Design the system so that each generation pays for its own health care. Do not create inter-
34 generational subsidies. (Singapore)
- 35 • Promote the development of a mechanism for community rating that will make universal
36 coverage affordable for all patients. (Taiwan)
- 37 • In developing universal coverage, Taiwan modeled their system after our Medicare system and
38 applied it to their entire population. In turn, the TMA representatives encourage the
39 development of a global budget system, which may entail a private health delivery or partial
40 single payer system. Further, they urged the US to develop a mechanism for community rating
41 that will make universal coverage affordable for all patients. (Taiwan)

42
43 **CONSIDERATIONS FOR THE US**

44
45 Experience from other countries suggests that major reform that covers all and effectively restrains
46 costs will have to embrace price restraints, set spending targets and aggressively address the
47 administrative costs of insurance and regulation. However, many of the association representatives
48 noted that after implementation of universal coverage in their countries, overall health care
49 spending was low while improvements in national health indicators were realized. Moreover, even
50 though the design and outcome of reforms were not always perfect, physicians were generally

1 pleased that their patients benefited. Significantly, too, in the countries in our report, physician
2 social status remained high. Incomes have been good and generally became more stable and
3 predictable.

4
5 All seven associations interviewed indicated that medical association involvement in the reform
6 process was desirable even though it was not often achieved. Spokespersons indicated that the
7 design and implementation of system reform without physician input is less than ideal and runs the
8 risk of not working well for either patients or physicians. In addition, the representatives expressed
9 the opinion that it is important for the medical association to have a distinct role in protecting the
10 professional dimensions of medical practice and being an active patient advocate. A key lesson
11 from this report is that as the debate continues for reform in the US, it is important for our AMA to
12 be involved in the planning and implementation of reform and to be the advocate for patients.

REPORT OF THE COUNCIL ON MEDICAL EDUCATION

CME Report 1-I-09

Subject: Physician Reentry to Practice: Data to Guide Program Development

Presented by: Susan Rudd Bailey, MD, Chair

1 INTRODUCTION

2
3 Recommendation 6 of Council on Medical Education (CME) Report 6 (A-08), on physician reentry
4 states: “That our AMA, as part of its Initiative to Transform Medical Education (ITME) strategic
5 focus and in support of its members and Federation partners, develop model program standards
6 utilizing physician reentry program system Guiding Principles with a report back at the 2009
7 Interim Meeting.”

8
9 Ten recommendations for change in the system of medical education have been identified as part of
10 the ITME. One recommendation aims to make physician career paths more flexible.

11
12 “Consider creating alternatives to the current sequence of medical education continuum,
13 including introducing options so that physicians can re-enter or modify their practice.”¹

14
15 The CME has been working for the past several years to develop policies and strategies in support
16 of this recommendation. A CME Task Group on Career Paths has been addressing the overlapping
17 issues of physician reentry and retraining. (The issue of physician remediation, also addressed by
18 the Task Group is the topic of CME Report 3 (A-09.) The Task Group has created the following
19 definitions to facilitate discussion and action on these areas:

- 20
21 • Physician reentry: A return to clinical practice in the discipline in which one has been trained
22 or certified following an extended period of clinical inactivity not resulting from discipline or
23 impairment.
24 • Physician retraining: The process of updating one’s skills or learning the necessary skills to
25 move into a new clinical area (CME Report 6 (A-08).)

26
27 This informational report presents findings from two surveys on physician reentry. Information
28 from these surveys is being used to guide planning for model programs, as requested in CME
29 Report 6 (A-08.)

30 31 THE EVOLUTION OF THE CONCEPT OF “REENTRY”

32
33 Historically, the term “retraining” was used in reference to preparing physicians to reenter practice
34 after an absence (CME Report 5, I-94.) For example, in 1966, a pilot project was undertaken by
35 the Pacific Medical Center in San Francisco to “retrain” inactive physicians. The project,
36 supported by a contract with the Public Health Service, retrained nineteen physicians during a two-
37 year time period. Interest in retraining prompted the AMA to survey 1,874 inactive physicians
38 under 55 to explore interest in retraining among the participants and potentially, identify a need for

1 future programs. Fifty-seven percent (n=1,075) of respondents “indicated an interest in
2 retraining.”²

3
4 Between 1982 and 1992, 234 physicians enrolled in a Medical College of Pennsylvania (MCP)
5 retraining program to prepare clinically inactive physicians to return to practice. Although the
6 original stated purpose of the program was to help physicians reenter practice, a large percentage of
7 participants used it as an aid to change specialties.

8
9 More recently, a study of physicians in Arizona found that among 604 physicians who reported
10 returning to clinical practice between 2003-2006, about 45 (7%) returned to a specialty different
11 from the one they left.³ Many of the programs related to specialty change were either discontinued
12 or never came to fruition due in part to lack of funding and disinterest in retraining among
13 physicians.⁴

14
15 In order to enhance clarity of purpose, the term reentry came to be used specifically for physicians
16 desiring to resume practice after an interval, while retraining came to be applied to physicians
17 wishing to learn the skills necessary to move into another area of practice (CME Report 6, A-08.)

18 19 SUMMARY OF FINDINGS FROM TWO SURVEYS ON PHYSICIAN REENTRY

20
21 Two surveys inform this report: 1) 2010 Physician Licensure Survey – Questions on Physician
22 Reentry to Practice and 2) the Physician Reentry Program Questionnaire. The first was prompted
23 by inquiries from state medical boards seeking direction from the AMA on developing physician
24 reentry policy. The second was developed to address Recommendation 6 of CME Report 6 (A-08)
25 and to gain a better understanding of physician reentry from the perspective of reentry programs.
26 Questions for both surveys evolved from many physician reentry-related activities: The AMA-
27 AAP Physician Reentry into the Workforce conference, the Coalition for Physician Enhancement
28 Conference on reentry, discussions with stakeholders in medical education, discussions with
29 physician reentry program directors, and literature review.

30 31 *Survey 1: 2010 Physician Licensure Survey – Questions On Physician Reentry Into Practice*

32
33 The AMA annually publishes the *State Medical Licensure Requirements and Statistics*. The
34 process of compiling information for this annual publication includes sending a questionnaire
35 (*Physician Licensure Survey*) to state medical boards. In 2009, two questions on physician reentry
36 were added to the survey: 1) Does your board have a policy on physician reentry for physicians
37 who have left the active practice of medicine and want to reenter practice? and 2) What is the
38 length of time away from practice after which a reentry program is required? In an effort to further
39 explore the issue of physician reentry among state medical boards, additional questions on reentry
40 were added to the 2010 edition. The questions on physician reentry were sent, along with the 2010
41 *Physician Licensure Survey*, to 68 Boards of Medicine. Fifty-three boards responded (78% of the
42 total). A summary of the aggregate findings is presented here. The findings represent a “snapshot”
43 of specific physician reentry-related regulations and procedures among state medical boards.

44 45 Physician Reentry Policy, Length of Time Out of Practice, and Reentry Program Referral

46
47 Respondents were asked if the board has a policy on physician reentry (as defined by the AMA) for
48 physicians who have left the active practice of medicine and want to reenter practice. Just under
49 half (49%) of medical boards responded that they have a policy on physician reentry while 51%
50 have no formal policy. Among the medical boards without a physician reentry policy, about two-
51 fifths (41%) are either currently developing or planning to develop a reentry policy.

1 Among medical boards with a physician reentry policy, the average length of time out of practice
2 after which they require reentering physicians to complete a reentry program is 3.2 years and
3 ranges from 1 to 5 years. Almost two-thirds (64%) of these medical boards recommend specific
4 physician reentry programs to the reentering physicians.

5 6 Patient Care Requirements for Relicensure

7
8 The majority of medical boards (79%) do not require a physician to engage in a certain amount of
9 patient care for relicensure.

10 11 *Survey 2: Physician Reentry Program Questionnaire*

12
13 The survey was sent to physician reentry program directors as well as to directors of programs that
14 provide physician reentry services, but are not strictly as reentry programs. The survey includes
15 questions on demographics, program processes, and program outcomes. The survey also included
16 a section that asked program directors to rank the importance of the AMA's 10 guiding principles
17 for a physician reentry program system. The survey was sent to the directors of 10 programs and 6
18 program directors responded. (Program directors were promised confidentiality, therefore, names
19 of the programs are not listed in this report.) Findings are presented in aggregate.

20 21 Program Demographics

22
23 All of the programs started between 1996 and 2007. The length of time it takes physicians to
24 complete a reentry program varies, but generally takes between 6 weeks and 12 months. The cost
25 to attend a program, not including living or travel expenses, depends on the type and duration of
26 the program; however, all programs cost at least \$6,000.

27
28 In general, programs do not serve a large number of physicians. For the four programs that had
29 these data available, the average number of reentering physicians since the programs' inception
30 was 24. The average number of physicians who made inquiries to these same four programs in
31 2008 was 51; on average 13 physicians entered one of the programs during that year.

32 33 Program Participants

34
35 The average age of program participants is approximately 51 years. The majority of programs
36 indicated that they served a higher percentage of male (than female) physicians. The percentage of
37 program participants who lived locally ranged from 0 to 70. The majority of program participants
38 had an active medical license. Between 54 and 100 percent of the reentering physicians
39 successfully completed their programs.

40 41 Finding Programs and Referrals

42
43 Program directors were asked to indicate how reentering physicians found their programs.
44 Seventeen percent of program directors said "medical association;" 33% stated "colleague;" 67%
45 stated that physicians found them through the internet/program web site; 83% stated medical board
46 and 33% replied "other." Program directors stated that "hospital medical staff office" and
47 "physician's attorney" were other ways physicians found out about reentry programs.

48
49 Program directors were also asked to identify how physicians are referred to the program. All 6
50 programs stated that physicians were referred to them from hospital credentialing committees, state

1 medical boards, or from self-referrals. One program director listed “referral from other assessment
2 programs” as another way reentering physicians are referred to the program.

3
4 Criteria for Program Acceptance

5
6 Program directors gave a variety of criteria for acceptance into the physician reentry programs. For
7 example, physicians must: be in good standing, return to the same area/scope of practice, have a
8 medical license or a permit from their board, and be out of practice for a limited time period (e.g.,
9 no longer than 10 years).

10
11 Final Assessment of Program Participants

12
13 About two-thirds (67%) of programs have a final assessment at the completion of the programs; all
14 programs document successful program completion through a letter or summary document.

15
16 Barriers to Program Access

17
18 Program directors were asked, “What barriers do you think exist for physicians trying to access the
19 physician reentry program?” Two-thirds (67%) stated that money/financial issues were a barrier.
20 Other barriers program directors’ reported were: lack of guidelines/standards of regulation,
21 licensure, lack of confidence, travel and being away from family, and ability to obtain a local
22 preceptor.

23
24 Remediation Services

25
26 The AMA defines physician remediation as: The process whereby deficiencies in physician
27 performance identified through an assessment system are corrected (CME Report 3, A-09.)
28 Program directors were asked two questions with regard to remediation: 1) Does the program
29 provide services to physicians who need remediation? and 2) If yes, are these services the same as
30 or different from the services provided to physicians seeking reentry?

31
32 All of the programs provided remediation services as well as reentry services. Half of the
33 programs provided remediation services that were the same as services for reentry while the other
34 half provided remediation services that were different from their reentry services. Differences
35 included individualized curricula and competence assessment.

36
37 AMA Guiding Principles

38
39 The AMA CME developed the 10 guiding principles for a physician reentry program system
40 (included in the Appendix). Program directors were asked to rank the importance of each guiding
41 principle to the physician reentry program. The Appendix shows the number of program directors
42 who selected each option and the percent of the total program directors who selected each option.

43
44 At least half (50% – 87%) of program directors indicated that all of the guiding principles were
45 either “Very Important” or “Important.” The two guiding principles which garnered the largest
46 support were: Flexible-to maximize program relevancy and usefulness (87%) and Innovative-to
47 meet the diverse and changing needs of reentering physicians (87%).

48
49 A main implication of the perceived importance of the guiding principles by program directors is
50 that these guiding principles can be used by future physician reentry programs as a basis for
51 developing model program standards.

1 DISCUSSION

2

3 Facilitating physician reentry to practice continues to be an important issue for the medical
4 profession. However, the surveys described in this informational report indicate that there are
5 many barriers to physician participation.

6

7 *Lack of Information About Need*

8 There is a lack of data on the number of physicians who would participate in a reentry program if
9 the barriers described below were removed. This lack of information about need limits the ability
10 to plan for program development.

11

12 *Ease of Access*

13 Programs are not geographically accessible to many physicians, who would have to travel to
14 participate. The availability of regional training sites could ease this barrier.

15

16 *Liability and Credentialing Issues*

17 In order for physicians to participate fully in reentry programs, they need access to clinical training
18 sites. This access can be hampered by credentialing issues, as well as by lack of access to liability
19 protection for themselves and their supervisors.

20

21 *Funding Constraints*

22 The major source of funding for reentry programs is fees paid by participants. These costs may be
23 prohibitive for physicians without a source of income. In addition, lack of convenient access to
24 programs requires that physicians travel or re-locate, which adds costs.

25

26 *Lack of Consistency in Regulatory Guidelines*

27 Many state medical licensing boards now either have a reentry policy or are in the process of
28 planning or developing one. However, states are independently developing these regulations and
29 processes. The lack of consistency across geographic boundaries may make reentry harder for
30 physicians.

31

32 States also vary in their definition and criteria for maintaining an active medical license. While
33 some physicians who have taken a hiatus from clinical practice may seek opportunities to update
34 their skills before caring for patients, there is evidence that others with active medical licenses may
35 return to practice without obtaining reentry services.⁵ While not all physicians may need to update
36 their skills before reentering practice, the current structure of the licensure system may be
37 preventing medical regulatory bodies from making that assessment.

38

39 *Lack of Certification Related to Program Completion*

40 While reentry programs typically document program completion, not all include a final assessment
41 that would assure that physicians completing the program have achieved the expected outcomes.
42 The lack of a documented outcome may make credentialing the physician more difficult as he/she
43 attempts to return to practice.

44

45 In collaboration with other stakeholder groups, for example, our long-standing relationship with the
46 American Academy of Pediatrics, our AMA will continue to maintain visibility and leadership in
47 the area of physician reentry. This includes supporting the creation of consistent regulatory
48 guidelines for reentry and assisting programs in adopting the AMA's 10 guiding principles for a
49 physician reentry program system.

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APPENDIX
Importance of Guiding Principles to Physician Reentry Programs

Guiding Principles	Very Important	Important	Moderately Important	Of Little Importance	Unimportant
Accessible (by geography, time and cost)	1 17%	3 50%	1 17%	1 17%	0 0%
Collaborative (to improve communication and resource sharing)	2 33%	2 33%	1 17%	0 0%	1 17%
Comprehensive (to maximize program utility)	3 50%	1 17%	0 0%	1 17%	1 17%
Ethical (based on accepted principles of medical ethics)	4 67%	0 0%	0 0%	0 0%	2 33%
Flexible (to maximize program relevancy and usefulness)	3 50%	2 33%	0 0%	0 0%	1 17%
Modular (tailored to the learning needs of reentering physicians)	3 50%	1 17%	1 17%	0 0%	1 17%
Innovative (to meet the diverse and changing needs of reentering physicians)	2 33%	3 50%	0 0%	0 0%	1 17%
Accountable (has mechanisms for assessment and open to evaluation)	3 50%	1 17%	0 0%	0 0%	2 33%
Stable (to ensure financial stability over the long term)	2 33%	2 33%	1 17%	0 0%	1 17%
Responsive (able to make refinements and updates as well as address systemic changes including regulatory)	3 50%	2 33%	0 0%	0 0%	2 33%

The Appendix shows the number of program directors who selected each option and the percent of the total program directors who selected each option.

COUNCIL ON MEDICAL EDUCATION REPORT 2-I-09
Resident/Fellow Duty Hours, Quality of Physician Training, and Patient Safety
(Resolution 327, A-09, and Resolution 330, A-09)
(Reference Committee K)

EXECUTIVE SUMMARY

In December 2008, the Institute of Medicine (IOM) released *Resident Duty Hours: Enhancing Sleep, Supervision, and Safety*, a report that calls for, in part:

- Reducing the maximum number of hours that residents can work without time for sleep to 16
- Allowing overnight call only with a required 5-hour sleep/nap period
- Increasing the number of days residents must have off
- Restricting moonlighting during residents' off-hours

In addition, the report calls for continued research and more data on duty hours and patient safety. The report notes that the biggest barriers to implementing these changes are cost (an estimated \$1.7 billion per year) and an insufficient health care workforce to substitute for the time of residents.

Reaction from physicians and the public has been mixed, with strong opinions both for and against additional restrictions. The AMA's initial response was mixed as well, and further consideration of the IOM report's potential ramifications led to objections to particular recommendations.

The Accreditation Council for Graduate Medical Education (ACGME) is charged with the task of responding to the IOM's recommendations by December 2010. In February 2009, the ACGME solicited feedback from medical organizations on the IOM's recommendations as well as the ACGME's current duty hours standards. In March, the ACGME held a symposium that focused on a five-year review of its duty hour standards, implemented in July 2003. In June, the ACGME invited medical organizations to attend a duty hours congress to provide formal feedback on the ACGME standards and the IOM recommendations. Currently, the ACGME is conducting three comprehensive reviews of the literature on duty hours and related topics and is planning a consultation with leading ethicists of the issues of professionalism surrounding duty hours.

In measuring the quality of the graduate medical education learning environment and the quality of patient care delivered by resident physicians, duty hours is only one metric. Beyond duty hours are other fundamental and vexing issues affecting both the learning environment and patient safety/quality of care, including physician preparedness for practice, supervision, workload, handoffs, scheduling, enforced sleep periods, flexibility for different specialties, professionalism, personal responsibility, moonlighting, at-home call, and the cost ramifications of any fundamental change.

Among its recommendations, this report calls for reaffirmation of current ACGME duty hour standards, with any proposed changes to be based on the results of additional research. It also recommends that the ACGME allow for appropriate flexibility in duty hour standards for different disciplines and different training levels, and urges the ACGME to include external moonlighting hours in the calculation of duty hours. Further, the report urges that the AMA reject the IOM report's call for a protected sleep period and to advocate against any outside involvement in GME accreditation. It also calls for communication to the GME community on the importance of accurate reporting of resident duty hours. Finally, it encourages educating the public about the many contributions of residents/fellows to high-quality patient care and the importance of trainees' realizing their limits (under proper supervision) so they can learn to competently and independently practice under real-world medical situations.

REPORT OF THE COUNCIL ON MEDICAL EDUCATION

CME Report 2-I-09

Subject: Resident/Fellow Duty Hours, Quality of Physician Training, and Patient Safety
(Resolution 327, A-09, and Resolution 330, A-09)

Presented by: Susan Rudd Bailey, MD, Chair

Referred to: Reference Committee K
(Peter C. Amadio, MD, Chair)

1 This report is a follow-up to Council on Medical Education (CME) Report 5 (A-08), “Enforcement
2 of Duty Hours Standards and Improving Resident, Fellow and Patient Safety,” which asked, in
3 part, that our American Medical Association “continue to monitor the enforcement and impact of
4 the Accreditation Council for Graduate Medical Education duty hour standards, as they relate to the
5 larger issue of the optimal learning environment for residents, and monitor relevant research on
6 duty hours, sleep, and resident and patient safety.” In addition, the report asked that our AMA, “as
7 part of its Initiative to Transform Medical Education strategic focus, utilize relevant evidence on
8 patient safety and sleep to develop a learning environment model that optimizes balance between
9 resident education, patient care, quality and safety.” The report also called for future reporting on
10 the progress of these two recommendations.
11

12 This report also addresses the following items:
13

- 14 • Resolves 3 through 6 of Resolution 327 (A-09), “Resident Duty Hours: A Review of the
15 Institute of Medicine Recommendations,” which asked that our AMA “oppose the
16 involvement of outside organizations, including CMS and The Joint Commission, in the
17 monitoring of duty hours (Resolve 3); support the development of specialty-specific
18 guidelines for duty hours (Resolve 4); support the development of procedures to be used in
19 transferring patient care (Resolve 5); and urge the ACGME to include external
20 moonlighting hours in the calculation of duty hours (Resolve 6).” Because of the
21 considerable complexity of these issues, and their high visibility among medical students,
22 trainees, physicians, and the public (from both an educational and patient safety
23 perspective), the AMA House of Delegates (HOD) called for further consideration and
24 referred Resolves 3 through 6 of the resolution. Resolves 1 and 2 were adopted.
25
- 26 • Resolution 330 (A-09), “Opposition to Protected Sleep Time,” introduced by the Medical
27 Student Section, which asked our AMA to support the evaluation and improvement of duty
28 hours reform that does not include protected sleep time and to also support additional study
29 of the issues raised in the 2008 Institute of Medicine report on duty hours, and to consider
30 further modifications of the current duty hours requirements based on the results of this
31 inquiry. In light of testimony before Reference Committee C that a protected sleep period
32 may have significant ramifications for continuity of patient care and safety, as well as
33 being difficult to implement and monitor, this resolution was referred by the AMA HOD
34 for further study.

- 1 • CME Report 8 (A-07), “Intern and Resident Burnout,” which asked that our AMA
2 “continue to monitor this issue and track its progress, including publication of peer-
3 reviewed research and changes in accreditation requirements, with a report back at the
4 2009 Interim Meeting of the AMA House of Delegates.”
- 5
- 6 • CME Report 5 (I-08), “Use of At-Home Call by Residency Programs,” which asked that
7 the Council “incorporate a review of at-home call issues in the duty hours follow-up report
8 due at the 2010 annual meeting.”
- 9

10 THE ACGME DUTY HOURS STANDARDS AND THEIR MONITORING AND 11 ENFORCEMENT

12
13 The ACGME duty hour standards went into effect in July 2003 and require:

- 14
- 15 • An 80-hour weekly limit, averaged over 4 weeks, inclusive of all in-house call activities.*
- 16 • A 10-hour rest period between duty periods and after in-house call.
- 17 • A 24-hour limit on continuous duty, with up to 6 additional hours for continuity of care and
18 education.
- 19 • No new patients to be accepted after 24 hours of continuous duty.
- 20 • One day in 7 free from patient care and educational obligations, averaged over 4 weeks,
21 inclusive of call.
- 22 • In-house call no more than once every 3 nights, averaged over 4 weeks.
- 23

24 * Note: Programs in some specialties (neurological surgery, for example) may apply to the
25 ACGME for an 8-hour increase in weekly duty hours.

26
27 At the September 2008 ACGME meeting, chief executive officer Thomas J. Nasca, MD, MACP,
28 provided an update on duty hour violations and the recommendations of the ACGME Monitoring
29 Committee to address the problem. He noted that duty hour violations are unacceptable, regardless
30 of specialty or sponsoring institution, because they are a risk to the safety of residents and
31 potentially to patients, a risk to the accreditation authority of the ACGME, and a threat to
32 professional self-regulation. In addition, Dr. Nasca reported “a significant correlation between
33 resident-reported violations of duty hours with deficits in other important areas of the learning
34 environment.” Dr. Nasca reported that 101 programs out of 2,865 had been identified as potential
35 outliers in the ACGME’s 2007-2008 resident survey; 30 of these programs had also been identified
36 during the previous survey cycle as having significant duty hour issues. Twenty-one programs
37 were sent warning letters and nine had shortened site visits scheduled in 2007.

38
39 As noted in the CME Report 5 (A-08), the issue of confidentiality for and protection of
40 residents/fellows who report program violations of duty hour regulations continues to be a concern.
41 Some residents may face intimidation and pressure by attending physicians and senior
42 residents/fellows to under-report actual duty hours; this, combined with residents’ fears of negative
43 consequences for programs, program directors, and their own careers in the event of program
44 probation or withdrawal, are powerful disincentives to honest and accurate reporting. Furthermore,
45 many residents are reluctant to leave tasks undone or to shift care for sick and unstable patients to
46 their colleagues. In addition, true anonymity is hard if not impossible to ensure for residents in
47 smaller programs.

1 THE INSTITUTE OF MEDICINE REPORT ON DUTY HOURS

2
3 In September 2007, the Institute of Medicine (IOM) appointed the Committee on Optimizing
4 Graduate Medical Trainee (Resident) Hours and Work Schedules to Improve Patient Safety, at the
5 request of Congress and the Agency for Healthcare Research and Quality. The Committee's two
6 primary objectives were to:

- 7
8 • Synthesize current evidence on medical resident schedules and healthcare safety; and
9 • Develop strategies for implementing optimal work schedules to improve safety in health care.

10
11 The Committee held five meetings and two conference calls between December 2007 and August
12 2008, with presentations from invited experts and opportunity for questions/comments from the
13 public at three of the five meetings. The Committee heard from presenters representing the
14 perspectives of the accreditation and certification community, organized medicine, medical students,
15 residents, patient safety advocates, and researchers on sleep and patient outcomes, as well as program
16 directors in primary and surgical specialties; specific organizations included the following:

- 17
18 • Accreditation Council for Graduate Medical Education
19 • AMA Medical Student Section
20 • AMA Resident and Fellow Section
21 • American Board of Medical Specialties
22 • American Hospital Association
23 • American Medical Students Association
24 • Association of American Medical Colleges
25 • Centers for Medicare and Medicaid Services
26 • Committee of Interns and Residents
27 • The Joint Commission
28 • Public Citizen

29
30 The Committee's report, *Resident Duty Hours: Enhancing Sleep, Supervision, and Safety*
31 (available at: www.iom.edu/residenthours) was released on December 2, 2008. It does not
32 recommend further reducing residents' work hours from the ACGME's current 80-hour limit but
33 calls for:

- 34
35 • Reducing the maximum number of hours that residents can work without time for sleep to 16.
36 • Allowing overnight call only with a required 5-hour sleep/nap period.
37 • Increasing the number of days residents must have off.
38 • Restricting moonlighting during residents' off-hours.

39
40 The Committee's recommendations also call for greater supervision of residents, limits on patient
41 caseloads based on residents' experience and specialty, increased interdisciplinary teamwork, and
42 overlap in schedules during shift changes to reduce the chances for error during handoffs. In
43 addition, the Committee calls for continued research and more data on duty hours and patient
44 safety. The report notes that the biggest barriers to implementing these changes are cost (an
45 estimated \$1.7 billion per year) and an insufficient health care workforce to substitute for the time
46 of residents. Nonetheless, the report indicates that "action on all recommendations should be taken
47 within 24 months," that is, by December 2010.

1 ACGME, IOM, AND AMA POSITIONS ON DUTY HOURS

2

3 A chart comparing the current (2003) ACGME standards to the IOM recommendations (and
 4 existing AMA policy) may aid in more fully understanding some of the major points of concord
 5 and discord.

Duty Hours Limits	2003 ACGME Standards	IOM Recommendations	AMA Policy
Maximum hours of work per week	80 hours averaged over 4 weeks	No change	Supports current ACGME policy
Maximum shift length	30 hours, with 24 hours for admitting new patients and then 6 hours to complete work, transfer care and education	30 hours with 16 hours for admitting new patients, then 5 hour protected sleep, then remaining time for completing work and education. Alternative: 16 hours with no protected sleep	Supports original ACGME policy but recommends additional study
Maximum in-hospital on call frequency	Every 3 rd night, on average	Every 3 rd night, no averaging	Supports current ACGME policy
Minimum time off between scheduled shifts	10 hours	10 hours after shift 12 hours after night 14 hours after 30 hours	Supports current ACGME policy
Maximum frequency of in-hospital night shifts	Not addressed	4 consecutive night maximum 48 hours off after 3 or 4 night on	Supports current ACGME policy (which does not address this aspect)
Moonlighting	Internal moonlighting counted in 80 hours	All moonlighting counted in 80 hours All other restrictions apply to moonlighting in combination with scheduled work	Supports current ACGME policy
Limit on hours for exceptions	88 hours for select programs with educational rationale	No change	Supports current ACGME policy
Emergency Room Limits	12 hours shifts with 12 hours off between shifts; 60 hour work week with additional 12 hours for education	No change	Supports current ACGME policy

1 REACTION TO THE IOM REPORT

2
3 It has been said that the true test of any good law on a controversial subject is whether it makes no
4 one entirely happy—in that, the IOM report seems to have succeeded. Some are pleased with the
5 limit in shift length to 16 hours but have questioned the feasibility and practicality of the five-hour
6 protected sleep period. Some are pleased that the 80-hour limit was maintained; others, such as
7 Public Citizen, wanted to see a reduction to move the US closer to European standards. Residents (or
8 “junior doctors”) in Europe are limited to 48 duty hours per week under the European Working Time
9 Directive.

10
11 Within the graduate medical education (GME) community, varying viewpoints were quickly
12 expressed. Although most residents favor duty hour limits and most program directors decry the
13 rigidity of their implementation, some trainees and many attending physicians (especially in
14 surgical specialties) believe residents’ education is being shortchanged by the 80-hour weekly
15 limit. Although evidence is anecdotal, it appears that a number of attending physicians and
16 program directors feel that the current generation of trainees is being inadequately prepared for the
17 rigors of practice post-training. Also, work not completed by residents/fellows during shifts often
18 falls to attendings, who are not subject to duty hour limits, although a recent article in *Pediatrics*
19 calls for just such regulation to end “unnecessary and unjustified risk to patients.”¹

20
21 Anecdotal comments, such as the following received via the AMA’s monthly *GME e-Letter*, are an
22 additional indication of the skepticism that greeted the IOM report: “Several of us see problems
23 with inpatient continuity and follow-up, growing resident knowledge-base deficits, declining sense
24 of ownership of patient outcomes, and (anecdotally) an increase rather than decrease in medical
25 errors.”

26
27 The general public and public advocates (Public Citizen, for example) continue to compare
28 residents’ schedules to workers in other industries with regulated work hours, such as truck drivers
29 and airline pilots, and call for reduced hours to increase patient safety and reduce medical error.
30 Program directors and educators counter that shorter shifts mean more handoffs and transfers of
31 care, which are associated with their own risk for adverse events, and that educational goals (and
32 service needs) are already being compromised under the current standards.

33
34 AMA RESPONSE TO THE IOM REPORT

35
36 The AMA’s initial response to the IOM report was mixed. The AMA welcomed the IOM’s support
37 for the 80-hour weekly limit, which has been reflected in AMA policy since 2002. Further
38 consideration of the report and its potential ramifications, however, particularly by medical student,
39 resident/fellow physician, and academic physician members of the association, led to objections to
40 particular elements of the IOM recommendations (as reflected, for example, in Resolutions 327 and
41 330 noted above).

42
43 At the AMA’s annual meeting in June 2009, the issue of resident/fellow duty hours was a key
44 topic, with two separate educational sessions on the issue. One session focused specifically on the
45 IOM report, with presentations from two members of the IOM committee:

- 46
47
- Jordan J. Cohen, MD, Professor, Medicine and Public Health, George Washington University, Washington, DC
 - David F. Dinges, PhD, Professor and Chief, Division of Sleep and Chronobiology, Department of Psychiatry, University of Pennsylvania School of Medicine, Philadelphia
- 48
49
50

1 Among the items covered was one of the IOM's more controversial recommendations—a five-hour
2 nap period during extended shifts (longer than 16 hours). As noted in Resolution 330, described
3 above, overly prescriptive solutions to a complex problem may have unintended negative
4 consequences for both resident education and quality of care and may cause more problems than
5 they solve. Naps would be difficult to implement and monitor, and would in effect result in a 12
6 percent reduction in the work week, according to a representative of the Association of Program
7 Directors in Surgery who testified at the ACGME duty hours congress in June 2009.

8 In addition, a joint educational program of the Council on Medical Education and the Section on
9 Medical Schools featured a vigorous, interactive discussion of the intended and unintended
10 consequences of the current regulations and addressed the following questions:

- 11
- 12 • What is the impact of duty hour limits on the workload and learning of residents and on
13 medical students?
- 14 • How have duty hour limits changed the workload and teaching of attendings?
- 15 • In terms of patient-care safety and quality, and resident learning, what is the relative
16 importance of duty hour limits compared with: 1) appropriate supervision, 2) hand-overs,
17 3) patient continuity, 4) attending rounds, 5) teaching conferences, 6) sleep/rest or 7) other
18 factors?
- 19 • Are residency training lengths still adequate—especially in procedural specialties? If not,
20 are some specialties considering extending the length of training programs?
- 21 • How is the transition into practice (where there are no duty hour limits) changing?
- 22 • Are residents getting more sleep? If so, are they learning and/or performing better with
23 more sleep?
- 24 • Has the professionalism of residents changed and if so, in what way?
- 25 • Looking forward, what additional data do we need to improve the learning environment of
26 residents while striving to improve patient safety and quality?
- 27

28 These and other major issues that were identified are discussed fully in “Discussion and Future
29 Direction,” below.

30 31 ACGME RESPONSE TO THE IOM REPORT

32
33 As the recognized accrediting body for allopathic graduate medical education programs in the US,
34 the ACGME (and its constituent organizations, including the AMA) is charged with the task of
35 responding to the IOM's recommendations by December 2010. At its February 2009 meeting, the
36 ACGME Board of Directors endorsed a systematic review of duty hours and the learning
37 environment, with a goal of creating more appropriate, flexible standards that recognize the
38 challenges presented in the training of each specialty. In an “Open Letter to the GME Community”
39 sent later that month, Dr. Nasca noted:

40
41 In our well meaning attempt to limit resident duty hours to improve their education and
42 diminish the effects of acute and chronic sleep deprivation, we have placed many of our
43 residents all too often in [an] ethical quandary. We force them to choose between caring for
44 their patients the way they know they should, or satisfying a well meaning standard. In other
45 words, we compel them to lie if they do the right thing for their patients. I posit to you that this
46 is unacceptable. We must find a way to both assure proper and timely transitions in care (for
47 both resident and patients' sake), while respecting and nurturing the effacement of self interest
48 that is at the core of the trust between our patients and their physicians. And, in those
49 programs where the culture needs to be changed, or institutions where residents are abused
50 rather than nurtured in the profession, change must, and will, happen.²

1 Also in February, the ACGME began to solicit feedback from organizations responsible for or
2 participating in the education of physicians, and organizations representing various aspects of the
3 physician community (including the AMA). The request included a call for formal positions on the
4 IOM's recommendations as well as the ACGME's current duty hours standards, including an
5 analysis of costs and impact of implementation. In addition, organizations were invited to attend
6 an ACGME duty hours congress in June 2009 (described in more detail below).

7
8 In March, prior to its annual educational conference, the ACGME held a duty hours symposium,
9 "Promoting Good Learning and Safe, Effective Care: A Five-Year Review of the ACGME's
10 Common Duty Hour Standards." The symposium was convened to help the ACGME obtain input
11 from multiple perspectives and stakeholders and reconcile these viewpoints to design of standards
12 that promote an optimal learning environment as well as patient safety and quality. Presenters
13 covered such topics as fatigue and its effects on performance; continuity of care and patient safety;
14 the duty hours research agenda; and US duty hour standards versus those of Canada and the United
15 Kingdom. Some key points from the symposium:

- 16
- 17 • Mitigating fatigue is the real issue—not duty hours per se. Towards this end, uniform
18 regulation is not an appropriate response.
- 19 • Since 2003, work/life balance has improved for residents/fellows, but more patient care
20 handoffs are occurring (to the detriment of patient safety) and the shiftwork mentality has
21 become more prevalent.
- 22 • Without adequate funding, implementation of the IOM's recommendations would be
23 difficult.
- 24 • An additional "transition to practice" year of residency may be helpful for some trainees.
25

26 In June, the ACGME convened the duty hours congress to help determine the best strategy for
27 responding to the IOM's recommendations. Testimony was heard from 44 of the more than 120
28 professional associations, program director organizations, and other groups that submitted formal
29 position papers to the ACGME on this topic. Organizations that provided testimony were divided
30 into groups:

- 31
- 32 • Group 1—Internal Medicine
- 33 • Group 2—Surgery and Surgical Specialties
- 34 • Group 3—Pediatrics and Pediatric Subspecialties, and Women's Health
- 35 • Group 4—Hospital Based Specialties (emergency medicine, radiology, anesthesiology,
36 pathology)
- 37 • Group 5—Psychiatry, Neurology, Allergy and Immunology, and Family Medicine
- 38 • Group 6—Medical Students, Residents, and Resident Unions (AMSA, CIR, ORR,
39 Resident and Associate Society of the American College of Surgeons)
- 40 • Group 7—National Organizations with Major Involvement in American Graduate Medical
41 Education (AHME, AIAMC, VA, AAMC, ABMS, AHA, AMA, CMSS)
42

43 One emphatic message was shared by all speakers: "One size does not fit all"; that is, flexibility in
44 duty hour standards is a must. This invited the question, however, "How many different sizes do
45 we need?" Further, "What are the criteria for determining an appropriate grouping?" In addition,
46 too much flexibility may be as problematic as too little. Both the AHA and AMA speakers, in
47 particular, cautioned against letting the pendulum swing too far towards flexibility, which could
48 lead to a negative response in the press and the "court of public opinion" as well as renewed calls
49 for federal legislation of duty hours. Another challenge would be for institutional officials to
50 operationalize the requirements and monitor adherence for a wide variety of programs.

1 Nonetheless, consensus was expressed for different solutions for different fields and individuals
2 with varying levels of experience, from interns through to chief residents.

3
4 Other issues of note:

- 5
- 6 • The GME community needs to move beyond duty hours to more essential (if less easily
7 measured) concerns, such as resident supervision, patient safety, and quality improvement.
- 8 • More research and data are needed on the effects of duty hours, both during and post-
9 GME. Cohorts of trainees in nearly all fields have trained solely under the 80-hour weekly
10 limit, which should provide fertile ground for research on the adjustment period between
11 training under weekly limits and entering practice as a new physician without such limits.
- 12 • Ethical and professionalism concerns are ongoing, in two different aspects: For residents
13 who exceed duty hour limits and then submit false reports on hours worked (under
14 unspoken pressure by program directors and/or colleagues), and for residents (or
15 “Generation Me,” as one speaker put it) who are all too happy to clock out when their shift
16 ends place individual needs above those of the patient.
- 17 • Testimony was nearly unanimous that professional self-regulation in GME accreditation
18 should not be infringed upon by outside involvement from the federal government or the
19 Joint Commission.
- 20 • In the “court of public opinion,” medicine continues to be misunderstood, as does GME
21 and the justified educational need for what seem to the public to be excessive work hours.
- 22 • Concerns with resident/fellow fatigue must be balanced with the potential
23 miscommunications that occur during handoffs, which can have patient safety
24 implications.
- 25 • The question of costs to replace/augment the resident/fellow workforce if the IOM
26 recommendations are fully implemented.
- 27 • Increasing the length of training is not a good option, and might lead to increased
28 moonlighting, to supplement the trainee’s salary and pay off medical school debt. In
29 addition, longer training would make certain fields (e.g., thoracic surgery) less attractive to
30 students.
- 31 • Further compression of the work week may decrease the amount of time for self-reflection
32 and a deeper understanding of/communication with patients. In addition, the mentor-
33 trainee relationship would suffer.
- 34 • Unless additional health workforce are allocated accordingly, the “Nap Gap” (the IOM’s
35 recommendation for a 5-hour protected nap period after 16 hours on duty) would result in
36 decreased coverage in the emergency department by inpatient services that need to see
37 patients in the ED prior to admission; this, in turn, would lead to increased delays in
38 admissions, increased ED crowding, and decreased patient safety.
- 39 • Reaction to sleep deprivation varies from one individual to the next (and can change over
40 one’s life); it can also be dependent on the activity (reading vs. surgery, for example). A
41 recent study, for example, found a genetic mutation in people who need far less sleep than
42 average.³
- 43

44 At its June board meeting, the ACGME discussed the just-concluded congress as well as the status
45 of its Committee on Innovation, which reported that several of its pilot projects related to the
46 learning environment were on hold due to the congress. It was noted that one of the key themes of
47 the congress was a call for more research on duty hours (and funding for such research). In this
48 regard, ACGME staff have met with the Agency for Healthcare Research and Quality (AHRQ) to
49 discuss funding, by foundations and governmental bodies, of a multi-institutional survey on duty

1 hours. Although it would be inappropriate for the ACGME to use accreditation fees to fund
2 research, the ACGME agreed to help coordinate such research.

3
4 Currently the ACGME is conducting three comprehensive reviews of the literature on duty hours
5 and related topics, which will help inform its response to the IOM. In addition, it is planning a
6 consultation with leading ethicists of the issues of professionalism surrounding duty hours. Finally,
7 “the ACGME will initiate a separate, annual ‘Patient Safety and the Learning Environment’
8 evaluation of each ACGME-accredited sponsor coincident with the implementation of new duty
9 hour standards.”⁴

10 RECENT LITERATURE ON AND MEDIA COVERAGE OF DUTY HOURS

11
12
13 *Note: This section covers the period of March 2008 (when the last CME report on duty hours was*
14 *drafted) through August 2009.*

15
16 Because the IOM report was issued in December 2008, not enough time has elapsed for
17 consideration of its recommendations in peer-reviewed publications. The one significant exception
18 is a study in the May 21, 2009 *New England Journal of Medicine* that estimated a cost of \$1.6
19 billion per year to implement the IOM’s recommendations.⁵ “Implementing the four IOM
20 recommendations would be costly, and their effectiveness is unknown,” the study concluded. “If
21 highly effective, they could prevent patient harm at reduced or no cost from the societal
22 perspective. However, net costs to teaching hospitals would remain high.” In light of this
23 assessment, particularly in today’s tenuous funding paradigm, the authors of a related *NEJM*
24 editorial stated:

25
26 The IOM committee urged rapid implementation of their recommendations. We strongly
27 disagree. In this era of evidence-based medicine and comparative effectiveness, such a major
28 policy change should be based not only on the recommendations of an expert committee but
29 also on careful studies and evidence that improvements in both patient and educational
30 outcomes will result. To date, the necessary research has not been done and the evidence of
31 benefit is lacking.⁶

32
33 Other recent literature of note includes:

- 34
- 35 • A study of 220 pediatrics residents at three hospitals found no changes in total work and
36 sleep hours 1 year after the ACGME duty hour regulations were implemented. Rates of
37 accidental needle-sticks and auto accidents remained the same, although rates of burnout
38 fell from 75 percent to 57 percent.⁷
 - 39
40 • Among neurological surgeons, board certification test scores and levels of participation in
41 national conferences declined after implementation of duty hour limits in 2003. The study
42 also found that 96 percent of chief residents and residency programs directors believed that
43 the 80-hour limit had compromised resident training, and 98 percent believed that it had
44 led to a decrease in surgical experience.⁸
 - 45
46 • A study of 56 internal medicine interns found that cutting shift lengths only compresses
47 more work into less time and results in negative consequences; “increased on-call
48 workload was associated with more sleep loss, longer shift duration, and a lower likelihood
49 of participation in educational activities.”⁹

- 1 • Complication rates for gallbladder surgery at a major public teaching hospital went down
2 significantly after duty hour limits were implemented; the authors speculate that the
3 increased participation of attendings in procedures may in part account for the
4 improvement.¹⁰
5
- 6 • A survey of 314 attending physicians at a major academic medical center found that
7 satisfaction with teaching declined after duty hour limits were implemented in 2003.¹¹
8

9 Through both peer-reviewed and media outlets, numerous physicians have reflected on the impact
10 of duty hours, often comparing their own training experience prior to duty hour limits to the current
11 educational paradigm. A noted commentator in this regard is Pauline Chen, MD, who writes in
12 *The New York Times*. In her December 4, 2008 column, she writes that the exhaustion caused by
13 100-plus hour shifts was not beneficial, but the ability to devote oneself to the patient, without
14 having to look at the clock constantly, meant that graduates could move into real-world practice
15 with confidence.¹² Also writing in the *Times*, Barron Lerner, MD, reflects on the changes in GME
16 after the death of Libby Zion 25 years ago (which many attribute more to lack of supervision than
17 resident fatigue), contrasting the “insanity” of 36-hour shifts to today’s “well-rested, pleasant and
18 enthusiastic residents.”¹³ At the same time, Sandeep Jauhar, MD, cautions that “The Nightmare of
19 Night Float” and botched hand-offs “may well weaken medicine more than exhausted residents
20 ever did.”¹⁴ Stephen Bergman, MD, who authored the novel *The House of God* 30 years ago,
21 contends that, even in surgery, “superhuman” stamina can’t supersede human limits: “In terms of
22 the best care of the patient, the real valor is to turn it over to the fresh surgeon just coming in after a
23 good night’s rest.”¹⁵
24

25 Other physicians are more contentious in their views: One otolaryngology resident lashes back at
26 “doctors who criticize the IOM’s report as nothing more than the coddling of a bunch of soft,
27 whining residents.”¹⁶ Another essay describes “cockamamie resident physician work schedules
28 that look more like Bingo cards than a comprehensive system for providing coordinated medical
29 care or educating future medical specialists.”¹⁷ A third commentator offers a Swiftian modest
30 proposal: Zero duty hours, zero patient errors:
31

32 I predict that if studies based on 60- and 70-hour work weeks fail to eliminate clinical errors or
33 markedly decrease patient mortality rates (a likely result), the next recommended studies will
34 involve decreasing the work week to 50 and then 40 hours. Someday, we may reach the apex
35 of care, reducing clinical errors and patient mortality rates to zero by restricting trainees from
36 providing any medical care and instead giving them complete freedom to learn from books and
37 the Internet, at home, on their own timetables.¹⁸
38

39 These are just a sampling of the views on duty hours in circulation. Readers of the *New England*
40 *Journal of Medicine*, for example, submitted 223 comments on an article detailing the IOM
41 report.¹⁹ In short, physicians have strong opinions on this topic, and the intense debate on the
42 IOM’s recommendations (and the ACGME’s response) will continue.
43

44 Editorial reports in the general media are equally vocal and, in regard to the IOM report, almost
45 universally in favor of its recommendations or even stronger measures. For example, a *New York*
46 *Times* editorial published after the report calls for an outright ban on shifts longer than 16 hours
47 (rather than supporting the IOM’s controversial call for a five-hour nap after 16 hours) and asserts
48 the need for direct federal (and Joint Commission) oversight if violations continue to occur.²⁰
49 Similarly, a *USA Today* editorial applauds the report and directs blame towards the ACGME for
50 weak monitoring of its regulations and ineffective whistle-blower protection.²¹ (In the same issue,
51 Dr. Nasca of the ACGME argues that duty hours is “one element within a complex matrix of

1 educational and health care factors” and notes that quality of care is higher in teaching hospitals
 2 than in non-teaching hospitals.²²) A third editorial, in the *Los Angeles Times*, questions the
 3 authority of physicians to counsel patients about the importance of sleep when sleep deprivation is
 4 an unavoidable component of medical education and practice.²³

5
 6 Among both the media and the general public, the lack of a nuanced understanding of the many
 7 issues surrounding duty hours points to the need for the medical education community, and
 8 medicine as a whole, to better communicate that quality patient care is impossible without quality
 9 education and training. Further, the public must understand that medical education, and the
 10 inculcation of professional values, must perforce involve trainees’ stretching their limits (under
 11 proper supervision), similar to the training, say, of world-class athletes, so that real-life (or, to
 12 continue the metaphor, “game”) situations can be met. Patients have legitimate concerns about
 13 both physician fatigue and discontinuity of care; ensuring true patient-centered care demands that
 14 patient perspectives be taken into account when redesigning resident schedules.²⁴

15 16 DISCUSSION AND FUTURE DIRECTION

17
 18 In measuring the quality of the graduate medical education learning environment and its delivery of
 19 patient care, duty hours is only one metric (albeit the most easily measured, and perhaps the most
 20 hotly debated). In some sense, this issue has become the “whipping boy” for a variety of systemic
 21 ills and inefficiencies in health care, not just GME, and any solution that only “tinker[s] around the
 22 edges with artificial and impractical time restrictions” is necessarily incomplete.²⁵ Looking beyond
 23 the number of hours worked, other more fundamental and perhaps more vexing issues emerge:
 24

- 25 • *Patient quality/safety*—The link between duty hours and quality of patient care is weak or
 26 tenuous, with the few published studies showing weak correlation or conflicting results.
 27 From the patient’s perspective, having one physician dedicated to one’s care is optimal;
 28 patients, however, also want well-rested physicians, so a balance between continuity and
 29 appropriate rest must be maintained. It is also important to realize that susceptibility to
 30 fatigue varies from one individual to the next; rather than a universal measure of number of
 31 hours worked, a more fluid “fitness for duty” tool could be employed, to allow for a
 32 tailored approach that serves both service and educational needs. Such practices should be
 33 part of a larger institutional culture of quality and safety.
 34
- 35 • *Preparedness for practice*—Are physicians training under current duty hour limits as well-
 36 prepared for the real-world rigors of practice as their predecessors? One measure of
 37 practice readiness is board certification test scores; a recent study of neurological surgeons,
 38 referenced above, showed a decline in scores after implementation of duty hour limits in
 39 2003. As residents proceed through their training, they may begin to have misgivings that
 40 their training has fully prepared them for independent practice: A recent survey of resident
 41 and associate members of the American College of Surgeons found that 41 percent
 42 believed that duty hour limits are an “important barrier to their education” and that those
 43 closer to graduation felt more strongly that duty hour limits interfered with their education
 44 as compared with residents in their first and second years (32 percent versus seven
 45 percent).²⁶
 46
- 47 • *Supervision*—Attending physicians and program directors play a key role in ensuring not
 48 only that the letter of the law is obeyed vis-à-vis duty hours but also that training takes
 49 place in a supportive environment that values teamwork, interdisciplinary communication,
 50 and collaborative learning. Further, supervision must be tailored as much as possible to the
 51 trainee, in light of the individual’s level of training, skills, and learning style. In addition,

1 supervision should be proactive, with attendings checking in on a routine basis with
2 residents (particularly first-year residents) rather than waiting to be contacted.
3

- 4 • *Workload*—Closely related to patient safety and appropriate supervision is the
5 compression of the workload for residents/fellows (and throughout health care). The limits
6 for the number of hours worked may be set, but the number of patients is not so easily
7 controlled. With increased use of night-float and at-home call, fewer residents may be
8 responsible for more patients; without adequate supervision, this can be a recipe for
9 disaster. Duties of little or no educational value should be reassigned to other personnel or
10 reengineered (e.g., eliminate the need for carrying charts from one department to the next
11 by developing electronic information systems). The RRCs should set specialty-specific
12 guidelines for the number of patients residents can treat during a shift, taking into
13 consideration the level of training and the characteristics of the patients.
14
- 15 • *Handoffs*—Teamwork, interdisciplinary communication, and appropriate electronic
16 systems are essential to ensuring safe, informative handoffs, which have become even
17 more critical as the lengths of shifts have decreased. Resolution 329 (A-09) calls for the
18 ACGME to require “that GME training institutions ensure that trainees in all specialties are
19 provided with an effective, systematic approach for handoffs of clinical information and
20 transfer of care between trainees within their institution,” as well as to “identify best
21 practices including the presence, quality, and utilization of computerized systems, for
22 transfer of care in training programs in all specialties.” Interest in handoffs extends beyond
23 the GME community to patient safety advocates, both here and abroad; the World Health
24 Organization has listed “Communication during Patient Care Handovers” as one of its
25 High 5 patient safety initiatives,²⁷ and the August 2009 issue of *Quality and Safety in*
26 *Health Care*, based in London, features a wide-ranging collection of papers on this issue.
27 In their commentary on these studies, Drs. Julie K. Johnson and Vineet M. Arora²⁸ offer
28 four recommendations to lead to better processes: 1) Focus on improving the content and
29 the process of handovers, include physician trainees in the redesign process, and work
30 towards “well-designed, ergonomic solutions and consistent policies”; 2) Be cognizant of
31 and responsive to the local context, or culture, of the care-giving team rather than dropping
32 in a best practice wholesale; 3) Move from implicit, on-the-job training for handovers to a
33 more defined, standardized, competency-based training program with a didactic
34 component; and 4) Incorporate new methods for improving handover quality, such as
35 positive deviance, collaborative learning, and systems redesign.
36
- 37 • *The “nap gap”*—The IOM’s recommendation for a five-hour protected sleep period after
38 16 hours on duty has been criticized as difficult to enforce and a potential scheduling
39 nightmare. Although a 2006 study found evidence that naps can increase sleep and
40 decrease fatigue among residents, adherence to the nap schedule was low (19 percent), due
41 in part to residents’ concerns about gaps in patient care.²⁹ Further, the financial costs are
42 significant: Annual costs for substitute providers if this recommendation were adopted
43 would be \$559 million annually, or from \$168 million to \$480 million if additional
44 residents assumed the excess work.³⁰
45
- 46 • *Flexibility for different specialties*—The various specialties/subspecialties have different
47 schedules related to their workflow and different requirements. In surgery, for example,
48 certain procedures require lengthy involvement that could exceed certain shift lengths.
49 Some level of flexibility in duty hour standards is probably needed, but too much variance
50 could be as problematic as too little.

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- *Professionalism and personal responsibility*—The unintended consequence of the shift-work mentality must be addressed; the requirements of patient care and devotion to one’s education must supersede the resident’s personal needs. At the same time, professionalism also extends to the resident’s honest, accurate reporting of actual hours worked. Systems in medical education (including duty hour limits) can enable ethical behavior; a reduction in fatigue can help increase physicians’ empathy and increase the likelihood that physicians make decisions that strengthen the doctor-patient relationship.³¹ Some argue, in fact, that stricter duty hour limits are needed to ensure that medicine remains a “moral enterprise.”³² Others contend that less scheduled time (for example, 75 hours per week with a five-hour cushion, at the resident’s discretion) could help restore a sense of the individual control and self-regulation that characterizes a professional.³³
 - *Moonlighting*—At the ACGME duty hours congress, the majority of testimony was in favor of including all moonlighting, both internal and external, in the 80-hour weekly limit, as proposed by the IOM. Nonetheless, concern was expressed that this could be hard to define accurately and to monitor, and that other activities outside of training (e.g., child care responsibilities) are as demanding, if not more, of one’s time and energy. Recognizing that increasing levels of medical school debt are contributing to the need for residents/fellows to moonlight, more financial assistance (such as subsidized child care, loan deferment, debt forgiveness, and tax credits) may help treat the root causes and make moonlighting a moot point.
 - *At-home call*—The IOM report does not address this issue, although some have expressed concern that at-home call is being used by programs in some specialties to circumvent the intent of duty hour limits. With continuing advances in communications technologies in medicine, the lines between “work” and “home” continue to blur. Just as the practice of telemedicine continues to grow, a “virtual presence” in one’s residency/fellowship program may become more common, particularly in certain disciplines that lend themselves to technological interventions. At the same time, because of the intense demands of training, protected time for rest and relaxation is required, free from e-mails, phone calls, and electronic paging. The growing body of research on sleep deprivation and burnout attest to the importance of “down time.” CME Report 5 (I-08) called for more research into this issue, which is ongoing, and encouraged the ACGME to collect and disseminate data on at-home call by specialty from both program directors and from residents and fellows. It also asked that the ACGME change its program requirements to account for all duty hours, regardless of setting, in calculating the 80-hour work week, while at the same time allowing for flexible solutions from one specialty to the next. Finally, it asked the AMA to encourage the ACGME and the GME community to examine the effects of the increased use of at-home call on resident education and supervision and develop appropriate standards to ensure that appropriate education and supervision is maintained, regardless of the setting.
 - *Costs*—As health care reform advocates urge “bending the growth of the cost curve,” what are the financial consequences of further limiting duty hours, and which entity (or entities) would be responsible for bearing these costs? The study referenced above estimated a cost of \$1.6 billion per year to implement the IOM’s recommendations. If these costs were to fall solely or even largely on teaching hospitals, the effect could be to further endanger these institutions, which play a significant role in many locations as a safety net for the poor and uninsured. This could also jeopardize their ability to continue their educational and research missions.

1 Many have commented on the need for more research and study into duty hours and its effect on
2 the learning and patient care environment. Future study could examine some of these questions:

- 3
- 4 • What has been the impact on the workload and learning of students?
- 5 • What has been the impact on attendings?
- 6 • Are the lengths of training in certain specialties still adequate under duty hour limits—
7 especially in procedural specialties? And, if some specialties are considering extending the
8 length of training, what effect does this have on workforce and other concerns?
- 9 • Is the transition into real-world practice (in which duty hour limits do not apply) becoming
10 more difficult for young physicians?
- 11 • Do residents learn to function in a sleep-deprived environment and to recognize and
12 compensate for their limits?
- 13 • Has professionalism deteriorated?
- 14

15 RECOMMENDATIONS

16
17 The Council on Medical Education, therefore, recommends that the following be adopted in lieu of
18 Resolves 3-6 of Resolution 327 (A-09) and Resolution 330 (A-09) and that the remainder of this
19 report be filed.

- 20
- 21 1. That our American Medical Association continue to monitor the enforcement and impact
22 of the Accreditation Council for Graduate Medical Education duty hour standards, as they
23 relate to the larger issue of the optimal learning environment for residents, and monitor
24 relevant research on duty hours, sleep, and resident and patient safety, with a report back
25 no later than the 2011 Annual Meeting of the AMA House of Delegates. (Directive to
26 Take Action)
- 27
- 28 2. That our AMA, as part of its Initiative to Transform Medical Education strategic focus,
29 utilize relevant evidence on patient safety and sleep to develop a learning environment
30 model that optimizes supervision, professionalism, communication, and teamwork as well
31 as finding a balance between resident education, patient care, quality and safety, and a
32 wholesome personal life for physician learners and teachers—with a report back no later
33 than the 2012 Annual Meeting. (Directive to Take Action)
- 34
- 35 3. That our AMA (through the AMA *GME e-Letter* and other communications) encourage
36 publication of studies (in peer-reviewed publications, including the ACGME's newly
37 developed *Journal of Graduate Medical Education*) and promote educational sessions
38 about a) the potential effects of the Institute of Medicine recommendations and b) the
39 effects of duty hour standards, extended work shifts, handoffs and continuity of care
40 procedures, and sleep deprivation and fatigue on patient safety, medical error, resident
41 well-being, and resident learning outcomes, and disseminate study results to GME
42 designated institutional officials (DIOs), program directors, resident/fellow physicians,
43 attending faculty, and others. (Directive to Take Action)
- 44
- 45 4. That our AMA call for pilot programs and further research into protected sleep periods
46 during prolonged in-house call and, until such research shows improved patient care and
47 safety, encourage the ACGME to not adopt the IOM report's call for a protected sleep
48 period, which could have significant unintended consequences for continuity of patient
49 care and safety, as well as being difficult and expensive to implement and monitor.
50 (Directive to Take Action)

- 1 5. That our AMA encourage the ACGME to allow appropriate flexibility for different
2 disciplines and different training levels within the current ACGME maximum duty hour
3 standards to best train residents for professional practice within their specialties while
4 optimizing patient safety during their training. (Directive to Take Action)
5
- 6 6. That our AMA communicate to all Graduate Medical Education Designated Institution
7 Officials, program directors, resident/fellow physicians, and attending faculty the
8 importance of accurate, honest, and complete reporting of resident duty hours as an
9 essential element of medical professionalism and ethics. (Directive to Take Action)
10
- 11 7. That our AMA ensure that medicine maintain the right and responsibility for self-
12 regulation, one of the key tenets of professionalism, and categorically reject outside
13 involvement by the Centers for Medicare and Medicaid Services or the Joint Commission
14 in the monitoring and enforcement of duty hour regulations. (Directive to Take Action)
15
- 16 8. That our AMA urge the ACGME to include external moonlighting hours in the calculation
17 of duty hours, as defined in the IOM report, and also to ensure increased financial
18 assistance for residents/fellows, such as subsidized child care, loan deferment, debt
19 forgiveness, and tax credits, which may help mitigate the need for moonlighting.
20 (Directive to Take Action)
21
- 22 9. That our AMA collaborate with other key stakeholders to educate the general public about
23 the many contributions of resident/fellow physicians to high-quality patient care; further
24 the public should be made aware that residency/fellowship education offers trainees the
25 opportunity to realize their limits (under proper supervision) so that they can competently
26 and independently practice under real-world medical situations. (Directive to Take Action)
27
- 28 10. That our AMA urge that any costs of further duty hour limits be borne by all health care
29 payers, and that any proposed changes to the ACGME standards have adequate funding
30 allocated prior to implementation. (Directive to Take Action)
31
- 32 11. That our AMA encourage the American Osteopathic Association to monitor duty hours
33 and related issues in collaboration with the ACGME. (Directive to Take Action)

Fiscal Note: \$2500 for staff time.

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REPORT OF THE COUNCIL ON MEDICAL EDUCATION

CME Report 4-I-09

Subject: Factors Affecting the Availability of Clinical Training Sites for Medical Student Education

Presented by: Susan Rudd Bailey, MD, Chair

Referred to: Reference Committee K
(Peter C. Amadio, MD, Chair)

1 Recommendation 1 of Council on Medical Education Report 2 (I-08), asked

2
3 that our American Medical Association work with organizations such as the Association
4 of American Medical Colleges and the American Association of Colleges of Osteopathic
5 Medicine to study and report the current and projected availability of and need for
6 clinical clerkship placements for US medical students. (D-295.931 [1], AMA Policy
7 Database)

8
9 This report will: 1) summarize the challenges facing medical schools in gaining access to
10 sufficient clinical teaching capacity and the possible strategies to address these challenges;
11 2) illustrate the recent expansion in medical education programs and in programs training other
12 health professionals that also require clinical training sites; and 3) provide data on the factors
13 reported to be affecting the availability of clinical training sites.

14 BACKGROUND - CHALLENGES AND STRATEGIES

15
16 Council on Medical Education Report 2 (I-08), "Competition for Clinical Training Sites,"
17 summarized the factors affecting the adequacy of clinical training sites for medical students, both
18 in the inpatient and community-based outpatient settings. It concluded that the availability of
19 sites for clinical training of US medical students was being and, in the future, could increasingly
20 be, affected by:

- 21
22
- 23 • increases in enrollment at existing US medical schools;
 - 24 • creation of new MD- and DO-granting medical schools in the US; and
 - 25 • competition for training sites from offshore medical schools.
- 26

27 The report also described potential strategies to consider in order to maintain a quality clinical
28 education program.

29 *Expand Teaching Capacity at Existing Teaching Sites*

30
31
32 Additional learners could be added to existing clinical teaching sites. This likely would require
33 adding teaching faculty and/or freeing the time of existing teachers to allow additional
34 participation in the educational program. Since participation in teaching reduces the time
35 available for patient care, sources of funding to offset lost revenue may be needed.

1 *Identify New Sites for Training*

2
3 New clinical teaching sites could be identified in the region of the medical school and/or at a
4 distance (for example, through the formation of a branch campus). Such expansion has the same
5 requirements as expansion in the region of the medical school, including identifying and
6 preparing teaching faculty and providing release time for them to participate in teaching. This
7 challenge is exacerbated by the current caps on the creation of new residency positions. It is
8 much more difficult to develop a quality teaching site for medical students where there will be no
9 residents present.

10
11 *Regulations Limiting Access to Clinical Teaching Sites*

12
13 The standards of the Liaison Committee on Medical Education (LCME), which accredits the
14 educational programs leading to the MD degree, require that “institutional resources to
15 accommodate the requirements of any visiting...students must not significantly diminish the
16 resources available to existing enrolled students” (standard MS-12, *Functions and Structure of a*
17 *Medical School*, June 2008 edition). In general, this standard is interpreted to mean that there
18 must be adequate resources (faculty, patients, and teaching space) for the medical school’s own
19 students.

20
21 Council on Medical Education Report 2 (I-08) also noted that state regulations might limit the
22 access of students from offshore medical schools to US clinical teaching sites. The report
23 recommended various strategies that would require that visiting students from offshore medical
24 schools only come from medical schools whose educational programs have met standards for
25 quality.

26
27 **CURRENT STATUS OF EDUCATIONAL PROGRAM EXPANSION**

28
29 There has been significant expansion in medical education programs, as well as in programs to
30 train other health professionals that would utilize inpatient and outpatient clinical sites for
31 training.

32
33 *MD-Granting Educational Programs*

34
35 The number of first-year students enrolled in US MD-granting medical schools grew from 16,856
36 in 2000 to 18,508 in 2008, a 9.8% increase.¹ According to the Association of American Medical
37 Colleges (AAMC) Center for Health Workforce Studies, first-year enrollment is anticipated to
38 continue to increase to about 21,000 by about 2015.² The enrollment increases are a result of the
39 formation of new medical schools and the expansion of existing schools, through the creation of
40 distributed campuses and/or enrollment increases at the “home” campus.

41
42 The number of US MD-granting medical schools accredited by the LCME increased from 125 in
43 2000 to 131 in 2009. Of the newly-accredited medical schools, 4 admitted their first class in
44 2009 and 1 will admit its charter class in 2010. Therefore, the impact of these schools on the
45 number of enrolled students has yet to be felt. There are an additional 5 medical schools that
46 have formally applied for accreditation but have not yet undergone a review by the LCME.

47
48 In addition to creating new medical schools, enrollment increases are being facilitated by the
49 formation of distributed campuses. A distributed campus is defined as a site at a distance from
50 the medical school that offers at least one full year of instruction (basic science and/or clinical) to
51 medical students. In the 2008-2009 academic year, 17 medical schools with enrolled students

1 (13% of the total) reported that they were planning to create a new distributed campus and 9
2 schools (7%) reported that they were planning to expand an existing distributed campus to offer
3 more years in the curriculum within the next 2-3 years.³

4 *DO-Granting Medical Schools*

6 Between 2005 and 2007, the number of accredited DO-granting schools increased from 20 to 25,
7 and the current 25 colleges offer instruction in 31 locations.⁴ Data from the American
8 Association of Colleges of Osteopathic Medicine indicates that first-year enrollment in DO-
9 granting medical schools increased from 2,927 in 1999-2000 to 4,528 in 2007-2008 and is
10 projected to increase to 5,227 in 2012-2013.^{4,5}

12 *International Medical Schools*

14 US citizens who study medicine outside the US, especially in the Caribbean region in medical
15 schools whose language of instruction is English, are likely to pursue their clerkship training in
16 the US. As of 2008, there were a total of 35 international medical schools located throughout the
17 Caribbean that offered the MD degree and delivered the instructional program in English.⁶ There
18 are no summary data available on enrollment of US citizens in international medical schools.
19 However, an estimate can be made based on the number of US citizens pursuing certification by
20 the Educational Commission for Foreign Medical Graduates (ECFMG). US citizens accounted
21 for about 23% of the medical students/graduates seeking ECFMG certification in 2008. The
22 largest number of students/graduates registering for certification were from medical schools
23 located in the Caribbean (Dominica, Netherlands Antilles, Grenada, and the Cayman Islands).⁷
24 These totaled 4,560 individuals.⁷

26 *Other Health Professions Programs*

28 Physician assistant (PA) programs will be used for purposes of this analysis, since it is likely that
29 PA clinical training most closely overlaps with medical student training, especially in terms of
30 training sites. The number of PA programs has been increasing (from 126 in 2000 to 145 in
31 2009).⁸ In 2008, about 12,000 students were enrolled in PA programs, which are about 2-2½
32 years in length.⁹ There are, in addition, many other types of learners who require access to the
33 clinical setting, including those from nurse practitioner/doctor of nursing practice programs and
34 various allied health programs. Educational programs for other health professions are, in general,
35 increasing both in enrollment and in number.

37
38 In summary, the number of learners who require access to clinical education sites is significant
39 and increasing.

41 **FACTORS AFFECTING THE AVAILABILITY OF CLINICAL TRAINING SITES**

42
43 Of the 126 MD-granting medical schools that responded to the 2008-2009 LCME Annual
44 Medical School Questionnaire³, 80 (63%) reported that it had become more difficult to recruit
45 and retain a sufficient number of community-based (volunteer) faculty to meet the school's needs.
46 In addition, 59 schools (47%) reported that it had become more difficult to find inpatient clinical
47 placements for students in the core clerkships. Schools also were asked to identify the reasons
48 causing the increased difficulty.

1 *Difficulty in Recruiting and Retaining Volunteer Clinical Faculty*

2
3 The schools with difficulty in recruiting and retaining volunteer faculty reported experiencing this
4 problem for a number of reasons.

- 5
6 • The inability to compensate/sufficiently compensate volunteer faculty
7 (65 schools/81% of those with difficulty).
8
9 • Increased enrollment at the medical school (37 schools/46%).
10
11 • Increased competition for volunteer faculty due to expansion in other medical
12 education programs, including MD, DO, international (37 schools/46%).
13
14 • Creation of new medical education programs (MD or DO) in the region (19
15 schools/24%).
16

17 It was often the case that medical schools were having problems based on several of these
18 circumstances.

19
20 In summary, while inability to provide payment was the most-frequently cited reason, it was often
21 coupled with expansion in enrollment at the medical school or the presence of additional learners
22 from other educational programs in the region.
23

24 *Difficulty in Finding Inpatient Clinical Placements*

25
26 Many of the same factors affecting access to volunteer faculty also are important reasons for
27 increased difficulty in finding inpatient placements for clinical clerkships:
28

- 29 • Increased medical school class size (43 schools/73% of schools experiencing
30 increased difficulty).
31
32 • Competition for placement sites from other US medical schools (31 schools/53%).
33
34 • New or increased requirements to provide financial compensation to clinical sites
35 and/or their physicians (28 schools/47%).
36
37 • Competition for placement sites from off-shore medical schools (14 schools/24%).
38 [This difficulty is localized in 8 states: California (2 schools), Georgia (1 school),
39 Illinois (3 schools), Michigan (1 school), New Jersey (1 school), New York (4
40 schools), Ohio (1 school), and Pennsylvania (1 school).]
41

42 In summary, the expansion in medical education in the US, and, in some cases internationally,
43 and the inability to provide financial compensation to clinical teaching sites are seriously
44 affecting access to resources for clinical education.

1 DISCUSSION

2
3 Our AMA supports increasing the number of medical students, provided that such expansion does
4 not jeopardize the quality of medical education (Policy D-295.938). In order to assure that lack
5 of access to clinical placements does not have a negative effect on educational program quality,
6 two major changes will be needed.

7
8 *Expand Capacity for Clinical Teaching*

9
10 As the number of learners from all sources increases, medical schools will need to identify
11 additional sites for clinical training and additional faculty to teach. AMA policy supports such
12 planning.

13
14 That each medical school and residency program identify the specific resources needed to
15 support the clinical education of trainees and develop an explicit plan to obtain and
16 maintain these resources. This planning should include identification of the types of
17 clinical facilities and the number and specialty distribution of full-time and volunteer
18 clinical faculty members needed. (Policy H-305.942, [1])

19
20 New clinical sites and their physicians will need to be prepared to assume a teaching role. For
21 hospitals and other clinical facilities, this may include infrastructure upgrades, such as the
22 addition of conference rooms and study space, a library, and information resources, as well as
23 formal changes to their missions and associated medical staff policies and procedures. Physicians
24 assuming the role of faculty for the first time will require faculty development and orientation to
25 the teaching role. Our AMA is working with appropriate collaborators to study how to build
26 additional institutional and faculty capacity in the US for delivering clinical education
27 (Policy D-295.931, [2])

28
29 *Identify Financing Mechanisms to Support Expansion*

30
31 The changes needed to expand both educational infrastructure and the number of full-time and
32 volunteer (community) faculty have financial implications. It is unlikely that most medical
33 schools have the current financial resources to meet the increased costs required to, for example,
34 compensate volunteer clinical faculty. There is a long history of providing other benefits to
35 volunteer clinical faculty. For example, in the 2005-2006 LCME Annual Medical School
36 Questionnaire, the 125 medical schools provided information on how volunteer clinical faculty
37 were being rewarded:

- 38
39
- 40 • Access to the library (118 schools)
 - 41 • Recognition dinners/certificates (111 schools)
 - 42 • Access to faculty development programs (106 schools)
 - 43 • Access to free/discounted continuing medical education (80 schools)
 - 44 • Computers/software supplied or discounted (41 schools)
 - 45 • Access to athletic facilities/sports events (36 schools)
 - 46 • Ability to participate in the medical school practice organization (20 schools)

47 The data from the current survey cast doubt that these benefits, without added compensation, will
48 remain sufficient in all cases.

1 Even if individual medical schools can financially support their own expansion, care must be
2 taken that the sum total of resources in a region are adequate. Competition among medical
3 schools for resources is counterproductive to a quality system of medical education in a city,
4 state, or region. For example, while the creation of a distributed campus may solve the resource
5 problem for a given medical school, the new campus may compete for clinical teaching sites
6 and/or faculty with an existing medical school in the area. Therefore, both new funding and
7 regional planning related to resources are necessary.

8
9 **RECOMMENDATIONS**

10
11 As medical schools continue to expand, there will be increasing pressures on resources for
12 clinical education. Unless these resources are increased, it is likely that the quality of medical
13 education will suffer. Therefore, the Council on Medical Education recommends that the
14 following be adopted and that the remainder of this report be filed:

- 15
16 1. That our American Medical Association work with the Association of American Medical
17 Colleges and the American Association of Colleges of Osteopathic Medical Education to
18 encourage local and state governments and the federal government, as well as private
19 sector philanthropies, to provide additional funding to support infrastructure and faculty
20 development for medical school expansion. (Directive to Take Action)
21
22 2. That our AMA encourage medical schools and the rest of the medical community within
23 states or geographic regions to engage in collaborative planning to create additional
24 clinical education resources for their students. (Directive to Take Action)
25
26 3. That our AMA support the expansion of medical education programs only when
27 educational program quality, including access to appropriate clinical teaching resources,
28 can be assured. (New HOD policy)
29
30 4. That our AMA rescind D-295.931 [1], because the work called for in the directive has
31 been completed. (Rescind HOD Policy D-295.931 [1])

Fiscal Note: \$2000 for advocacy activities

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REPORT 1 OF THE COUNCIL ON MEDICAL SERVICE (I-09)
Emergency Room Contracts and Hospital Privileges
(Resolution 806, I-08)
(Reference Committee J)

EXECUTIVE SUMMARY

At the 2008 Interim Meeting, the House of Delegates referred Resolution 806, introduced by the Florida Delegation, which calls for the AMA to “develop guidelines for contractual arrangements between physicians and hospitals regarding emergency room call and reaffirm the rights of physicians not to sign such contracts and not take call if they choose; ...monitor and oppose any legislation that mandates emergency room coverage as a requirement for medical staff privileges and state licensure; ...and adopt as policy the position that hospital medical staff bylaws not contain any provision that mandates emergency room call as a condition of medical staff privileges.” The Board of Trustees referred this item to the Council on Medical Service for a report back to the House at the 2009 Interim Meeting.

This report provides background on the challenges of mandated on-call coverage for physicians, summarizes relevant AMA policy and guidance on contractual arrangements between physicians and hospitals, reviews options for providing on-call coverage, discusses concerns related to Resolution 806 (I-08), and presents recommendations to encourage physicians and hospitals to work collaboratively to meet the emergency care needs of their communities.

The Council believes that previously established AMA principles for physician on-call coverage for emergency departments continue to be relevant. Council on Medical Service Report 3-I-99, “On-Call Physicians,” and Board of Trustees Report 29-A-00, “On-Call Physicians Task Force,” shared the conclusion that it is highly unlikely that one solution to the on-call coverage problem will universally apply to every situation and every market.

The goal of referred Resolution 806 (I-08) is to protect physicians from unreasonable demands to provide emergency services, which is a goal that should be balanced with the societal need for adequate coverage for emergency services. Onerous on-call schedules are not consistent with providing efficient and high quality care, and the AMA urges physicians or physician groups that believe they are being coerced into specific employment arrangements to contact the AMA/State Medical Society Litigation Center, their state medical association, and/or legal counsel. At the same time, the Council strongly believes that every health care facility and the medical staff should jointly share the responsibility to provide needed emergency and transfer services. Among its recommendations, the Council encourages physicians and hospitals to work collaboratively to develop solutions based on adequate compensation or other appropriate incentives as the preferred method of ensuring mandatory on-call requirements.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 1-I-09

Subject: Emergency Room Contracts and Hospital Privileges
(Resolution 806, I-08)

Presented by: Barbara L. McAneny, MD, Chair

Referred to: Reference Committee J
(William J. Holt, MD, Chair)

1 At the 2008 Interim Meeting, the House of Delegates referred Resolution 806, introduced by the
2 Florida Delegation, which calls for the AMA to “develop guidelines for contractual arrangements
3 between physicians and hospitals regarding emergency room call and reaffirm the rights of
4 physicians not to sign such contracts and not take call if they choose; ...monitor and oppose any
5 legislation that mandates emergency room coverage as a requirement for medical staff privileges
6 and state licensure; ...and adopt as policy the position that hospital medical staff bylaws not
7 contain any provision that mandates emergency room call as a condition of medical staff
8 privileges.” The Board of Trustees referred this item to the Council on Medical Service for a
9 report back to the House at the 2009 Interim Meeting.

10
11 This report provides background on the challenges of mandated on-call coverage for physicians,
12 summarizes relevant AMA policy and guidance on contractual arrangements between physicians
13 and hospitals, reviews options for providing on-call coverage, discusses concerns related to
14 Resolution 806 (I-08), and presents recommendations to encourage physicians and hospitals to
15 work collaboratively to meet the emergency care needs of their communities.

16 17 BACKGROUND

18
19 Access to specialists across national emergency departments (EDs) has deteriorated. In 2005, 73%
20 of EDs reported inadequate on-call coverage by specialist physicians, as compared to 66% in 2004
21 (American College of Emergency Physicians [ACEP], 2006). In the past 10 years, the number of
22 patients accessing EDs has increased 30% (PriceWaterhouseCoopers [PwC] Consumer Access
23 Survey, 2009).

24
25 Several factors have contributed to insufficient ED call coverage, including inadequate payment, a
26 shortage of specialists, increasing demand for ED services, changing physician practice and
27 lifestyle interests, legal concerns, and changes in regulatory rules. Hospitals once were the
28 foundation for developing a private practice and provided physicians an incentive to provide on-
29 call service. More recently, the increase in office-based procedures has led to a decreased
30 dependence on hospital admitting privileges. Physicians sometimes receive little or no payment for
31 being on-call, although the ED is a high-risk liability environment because of the seriousness of
32 cases presenting and the lack of a pre-existing patient-physician relationships. In addition, many
33 physicians desire more flexible work schedules so they can devote more time to their families.
34 Finally, the Centers for Medicare and Medicaid Services (CMS) interpretation of the Emergency
35 Medical Treatment and Labor Act (EMTALA) changed in 2003, resulting in many hospitals either

1 dropping call coverage requirements or adopting partial-call coverage requirements for many
2 specialties.

3
4 AMA POLICY AND GUIDANCE

5
6 Council on Medical Service Report 3-I-99, "On-Call Physicians," addressed mandatory call
7 coverage. In its report, the Council noted that bylaws mandating call coverage appear to work best
8 when there is an adequate number of physicians to share the mandated call, the mandate is
9 reasonable, managed care plans are diligently paying for services provided, and there are not large
10 numbers of uninsured patients. The Council also noted that a mandated approach can fail if
11 physicians simply leave the medical staff or give up their active staff privileges in favor of courtesy
12 privileges, which do not require being on-call. In lieu of opposing mandatory call coverage, the
13 Council developed the following guidance on emergency room contracts and hospital privileging:

14
15 Our AMA: (1) advocates that physician on-call coverage for emergency departments be
16 guided by the following principles: (a) The hospital and physicians should jointly share the
17 responsibility for the provision of care of emergency department patients. (b) Every hospital
18 that provides emergency services should maintain policies to ensure appropriate on-call
19 coverage of the emergency department by medical staff specialists that are available for
20 consultation and treatment of patients. (c) The organization and function of on-call services
21 should be determined through hospital policy and medical staff by-laws, and include methods
22 for monitoring and assuring appropriate on-call performance. (d) Hospital medical staff by-
23 laws and emergency department policies regarding on-call physicians' responsibilities must be
24 consistent with Emergency Medical Treatment and Active Labor Act (EMTALA)
25 requirements. (e) Medical staffs should determine and adopt protocols for appropriate, fair, and
26 responsible medical staff on-call coverage. (f) Hospitals with specialized emergency care
27 capabilities need to have a means to ensure medical staff responsibility for patient transfer
28 acceptance and care. (g) Hospitals that lack the staff to provide on-call coverage for a particular
29 specialty should have a plan that specifies how such care will be obtained. (h) The decision to
30 operate or close an emergency department should be made jointly by the hospital and medical
31 staff; (2) supports the enforcement of existing laws and regulations that require physicians
32 under contract with health plans to be adequately compensated for emergency services
33 provided to the health plans' enrollees; and (3) supports the enactment of legislation that
34 would require health plans to adequately compensate out-of-plan physicians for emergency
35 services provided to the health plans' enrollees or be subject to significant fines similar to the
36 civil monetary penalties that can be imposed on hospitals and physicians for violation of
37 EMTALA. (Policy H-130.948, AMA Policy Database)

38
39 Board of Trustees Report 29-A-00, "On-Call Physicians Task Force," examined several potential
40 coverage options for medical staff on-call requirements including mandatory on-call coverage
41 through medical staff bylaws, mandatory on-call coverage through managed care contracts,
42 voluntary on-call coverage, and regional on-call coverage. The report shared the conclusion of
43 CMS Council Report 3-I-99 that it is highly unlikely that one solution to the on-call coverage
44 problem will universally apply to every situation and every market. The Council and the Board
45 expressed the concern that advocating for specific national policies or solutions may be detrimental
46 to local communities and regions of the country that have developed workable on-call physician
47 coverage arrangements.

48
49 Council on Medical Service Report 8-A-05 addressed methods for offsetting the costs of providing
50 uncompensated emergency care and advocated redirecting funds currently spent to offset the cost
51 of providing coverage for the otherwise uninsured toward the purchase of health insurance

1 coverage (AMA Policy H-160.923). In addition to these reports, the AMA has established a
2 number of policies related to on-call emergency services and physicians (H-130.970, H-225.957,
3 H-225.997, and H-130.978). In particular, Policy H-130.978[3] supports the fair distribution of
4 call-responsibilities and the adequate compensation for physicians providing on-call services.
5 Policies H-310.999[F], H-160.927, and H-383.997[2] provide extensive guidance for physicians
6 regarding hospital contracting. The Council notes in particular that Policy H-310.999[F]
7 acknowledges that onerous on-call schedules are not consistent with efficient delivery of care, and
8 advocates that the hospital should commit itself to fair scheduling of duty time for all members of
9 the house staff, including the provision of adequate off-duty hours. Policies H-160.927 and
10 H-383.997[2] urge physicians who believe hospitals are negotiating contracts without appropriate
11 input, and who feel coerced into signing contracts, to contact the AMA/State Medical Society
12 Litigation Center, their state medical association, and/or legal counsel.

13
14 Policy D-130.971 supports expanding the dialogue among relevant specialty societies to gather
15 data and identify best practices for the staffing, delivery, and financing of emergency/trauma
16 services, including mechanisms for the effective regionalization of care and use of information
17 technology, teleradiology and other advanced technologies to improve the efficiency of care.
18

19 Policy H-130.970[2] supports the principle that all physicians and health care facilities have an
20 ethical and moral responsibility to provide needed emergency services to all patients, regardless of
21 their ability to pay, and an AMA ethical opinion states that physicians may not refuse to care for
22 patients when operating under a contractual arrangement that requires them to treat (Opinion
23 10.015).

24
25 Finally, the AMA “EMTALA Quick Reference Guide for On-Call Physicians” provides a summary
26 of what is expected of on-call physicians. The guide is available on the AMA Web site,
27 www.ama-assn.org/ama1/pub/upload/mm/21/emtalarefguide.doc.

28 29 MANDATED EMERGENCY ROOM CALL

30
31 EMTALA is the federal law enacted by Congress in 1986 to assure that patients who come to
32 hospitals for treatment of an emergency condition are not turned away or transferred to another
33 facility based on their inability to pay. In 2003, the CMS published new rules for the interpretation
34 of EMTALA (Federal Register, 2003), which clarified that it would be up to each hospital to adopt
35 its own reasonable coverage standards, and that there would be no minimum requirement for
36 frequency of on-call coverage based on the number of specialists a hospital had on staff. In
37 addition, physicians under EMTALA are permitted to be on-call at more than one hospital at the
38 same time and may limit the amounts of call time they are willing to take. The more recent
39 interpretation acknowledged the need to balance hospital and physician legal duties with the
40 realities of crowded EDs, but does not address the serious EMTALA-created burden for hospitals
41 to secure specialist care.

42 43 OPTIONS FOR PROVIDING ON-CALL COVERAGE

44
45 In 2005, the American College of Emergency Physicians (ACEP) published a paper entitled
46 “Availability of On-Call Specialists,” which identified best practices to successfully implement
47 mandatory on-call policies and regulations for hospital staff credentialing. The ACEP best
48 practices include:

- 1 • On-call requirements must be included in hospital bylaws and procedures;
- 2 • Hospital administration must be responsive to physician concerns regarding on-call policies
- 3 and bylaws;
- 4 • Physicians must be allowed to participate in strategic and operational decisions regarding on-
- 5 call requirements;
- 6 • Requirements for physician on-call policies and bylaws must be consistently implemented;
- 7 • Regular communication of hospital performance should be reported to physicians; and
- 8 • An on-call physician quality assurance program should be implemented to assess compliance
- 9 with mandatory on-call coverage.

10
11 As noted in Council Report 3-I-99, hospitals are pursuing a variety of strategies to secure specialist
12 emergency on-call coverage, including employing hospitalists or specialists, contracting for on-call
13 services, paying stipends to physicians, and taking legislative or regulatory actions. Other
14 solutions include improving the physician work environment, providing payment for each
15 uninsured patient a physician treated while on-call, providing payment for physician liability
16 insurance premiums, promoting regionalization, and expanding the use of technology (e.g.
17 telemedicine).

18 *Employing Hospitalists or Specialists and Contracting for On-Call Services*

19
20
21 Some hospitals secure ED on-call coverage via contracts with physician groups that take
22 responsibility for ensuring emergency coverage. Alternatively, hospitals may use a direct
23 employment model with specialist physicians or hospitalists hired to treat patients full-time,
24 thereby replacing local physicians. This model may not alleviate on-call problems with certain
25 subspecialties. Smaller hospitals may have difficulty financing the specialist or contract model.

26 *Physician Stipends*

27
28
29 Some hospitals pay stipends or provide other compensation, which recognizes the opportunity costs
30 of serving on an on-call basis and compensates physicians for being available and ready for
31 service. In 2002, the California Medical Association (CMA) adopted the position that hospitals
32 should pay on-call physicians regardless of whether they are called to the ED. The trend to
33 compensate physicians for call service appears to be gaining momentum, with 36% of ED directors
34 reporting that their hospitals paid stipends to specialists for taking coverage in 2005, compared
35 with only 8% in 2004 (ACEP, 2006).

36
37 Although specialists demand higher payments to take call, hospitals are wary of overpayments,
38 which might trigger allegations of violations of the federal anti-kickback statute if the arrangement
39 is used to generate referrals for services that are reimbursed by a federal health care program.

40 *Legislative or Regulatory Actions*

41
42
43 In 2004, a coalition including the California Healthcare Association, the CMA, and the American
44 College of Emergency Physicians of California, sponsored a ballot initiative that would have raised
45 approximately \$500 million a year for emergency services by boosting the state surcharge on long-
46 distance phone calls. Although the initiative was unsuccessful, the proposed legislation provides
47 an example of how physician organizations can promote legislative solutions to adequately staff
48 and equitably compensate all physicians covering the ED.

1 Under the Federal Tort Claims Act (FTCA), liability insurance is provided to protect volunteers of
 2 free health clinics. An ACEP On-Call Task Force report suggests potentially advocating for
 3 national or state legislation that could include protections to emergency and on-call specialty
 4 physicians similar to those found in the FTCA (ACEP, 2008).

5
 6 *Improving the Physician Work Environment*

7
 8 Some hospitals studied offer practice management support by working with orthopaedic surgeons
 9 to develop more “surgeon-friendly” operating room schedules in return for ED call. Another
 10 hospital puts payments for physicians’ time spent providing coverage into a tax-deferred life
 11 insurance investment account that is vested after five years (Center for Studying Health System
 12 Change [HSC], 2007).

13
 14 *Providing Payment to Physicians for Each Uninsured Patient*

15
 16 Increasingly, in addition to stipends, some hospitals pay for each uninsured patient physicians treat
 17 while on-call. Some of the hospitals studied reported paying physicians at least at Medicare rates
 18 for patients with no coverage. One hospital guarantees at least Medicare rates plus 20% for
 19 treating uninsured patients (HSC, 2007).

20
 21 The primary challenge of paying for each uninsured patient is the expense. With particularly large
 22 numbers of uninsured individuals in certain regions of the country, the costs of paying for each
 23 uninsured patient could easily become unmanageable for some hospitals.

24
 25 *Paying Physician Liability Insurance Premiums*

26
 27 Physicians may be reluctant to take call because of the rising cost of liability insurance, and
 28 because the ED is a high-risk environment with respect to liability. To mitigate these concerns, the
 29 on-call physicians could receive affordable liability insurance from the hospital in return for
 30 serving on-call. Also, shielding physicians from frivolous lawsuits may encourage more
 31 physicians to remain on-call.

32
 33 *Promoting Regionalization*

34
 35 Improving regional cooperative coverage and creating a state-based transfer call center are two
 36 policy options that are often offered as solutions to ED staffing problems. A recent article
 37 discussed potential options for regionalization, in which individual hospitals would not need to
 38 maintain on-call coverage for all specialties. Instead, a group of physicians or hospitals would be
 39 designated to provide coverage for the entire region. Such arrangements aim to provide a more
 40 efficient allocation of resources and reduce the burden of taking call for physicians and hospitals
 41 (*Annals of Emergency Medicine*, 2008).

42
 43 Regulations promulgated as a result of the 2003 EMTALA changes clarify that physicians can be
 44 on-call at more than one hospital, if all hospitals are aware of the call schedules and are able to
 45 screen and stabilize emergency patients. Yet there are several challenges to regionalizing call
 46 schedules. As described in a 2008 *South Florida Sun-Sentinel* report, physicians and hospital
 47 executives created a plan for Palm Beach County’s 13 hospitals to voluntarily join a regional
 48 system. An online call schedule was envisioned where hospitals would pay to maintain a full
 49 complement of surgeons. Nevertheless, the plan subsequently failed to obtain sufficient specialist
 50 care.

1 *Expanding the Use of Technology*

2
3 A recent PriceWaterhouseCooper's study found that nearly half of respondents surveyed said they
4 went to the ED for a reason other than an emergency in the past year. The study also found that
5 consumers are willing to participate in a variety of alternative ways to access care
6 (PriceWaterhouseCooper, 2009). Consultative telemedicine services may provide an innovative
7 solution to problems with ED on-call coverage.

8
9 RESOLUTION 806 (I-08)

10
11 Resolution 806 (I-08) seeks AMA support for the physician's right to autonomous decision-making
12 regarding mandatory on-call coverage. The Council recognizes the frustrations caused by an on-
13 call system that fails to adequately compensate physicians for the services they provide while on-
14 call, the time they spend away from their practices and families, and for the related legal costs they
15 encounter. However, the Council notes that long-standing AMA policy and ethical guidance state
16 that physicians have the fundamental responsibility to treat patients in need of care.

17
18 The Council continues to strongly support Policy H-130.948, which established principles for
19 physician and hospital contractual arrangements, regarding on-call coverage. In particular, the
20 Council believes Policy H-130.948 addresses the concerns of the first resolve of Resolution 806
21 (I-08), which asks the AMA to develop guidelines for contractual arrangements between physicians
22 and hospitals regarding emergency room call. Furthermore, the availability of on-call physicians
23 continues to be highly influenced by market forces, with different specialties encountering different
24 obstacles in different regions of the country. The Council recognizes that there are a variety of
25 possible solutions, and believes that no single overall approach is best for all regions and hospitals.

26
27 The first resolve of Resolution 806 (I-08) also asks the AMA to reaffirm the rights of physicians
28 "not to sign such contracts and not take call if they choose," which may conflict with existing
29 AMA policies emphasizing that physicians and health care facilities have an ethical obligation and
30 moral responsibility to provide needed emergency services to all patients and advocating that
31 hospitals and physicians jointly share the responsibility for the provision of care of emergency
32 departments (H-130.970[2]). Regardless, the Council believes that coercive contracts should not
33 be used in lieu of appropriate communication between hospital staff and physicians, and that
34 physicians who believe they are being coerced into specific employment arrangements should
35 contact the AMA/State Medical Society Litigation Center, their state medical association, and/or
36 legal counsel, consistent with Policy H-160.927.

37
38 The second resolve of Resolution 806 (I-08) asks that our AMA monitor and oppose any legislation
39 that mandates emergency room coverage as a requirement for medical staff privileges and state
40 licensure. Because hospitals are governed by state laws externally and hospital bylaws internally,
41 the Council believes this activity has merit, but only if the state medical association also opposes
42 the legislation. The Council does not see the merit in universally opposing mandated call coverage,
43 which may work for the medical staffs in some communities and is supported by some state
44 medical associations.

45
46 The third resolve of Resolution 806 (I-08) asks that our AMA adopt as policy the position that
47 hospital medical staff bylaws not contain any provision that mandates ED call as a condition of
48 medical staff privileges. The goal of Resolution 806 (I-08) is to protect physicians from
49 unreasonable demands to provide emergency services, which is a goal that should be balanced with
50 the societal need for adequate coverage for emergency services. To the extent that a medical staff

1 supports a provision mandating call coverage as the best solution for its community, an AMA
2 policy opposing such a provision could be considered insensitive and intrusive.

3 DISCUSSION

4
5 Emergency services are vital to all communities and a lack of adequate on-call physicians is an
6 increasingly serious concern in some regions of the country, exacerbated by EMTALA
7 requirements. Onerous on-call schedules are inconsistent with providing high quality and efficient
8 care. It is unlikely that one solution to the on-call coverage problem will apply to every situation in
9 every market.

10
11 For that reason, the Council strongly believes that every health care facility and the medical staff
12 should work together in their communities to develop solutions to adequately staff and equitably
13 compensate all physicians providing on-call coverage in the ED. In particular, the Council
14 supports innovative approaches to providing emergency care coverage. Regardless of the method
15 (e.g., physician stipends, contracting for on-call services, improving the physician work
16 environment), the Council believes that solutions based on adequate compensation and appropriate
17 incentives are preferable to mandatory requirements.

18
19 Resolution 806 (I-08) recommended that the AMA adopt policy that hospital medical staff bylaws
20 not contain any provision that mandates emergency room call as a condition of medical staff
21 privileges. The Council concurs with the intent of this recommendation, but only if the state
22 medical association also opposes the legislation. State medical associations are in a much better
23 position to understand local needs and resources.

24
25 The Council supports reaffirmation of Policy H-130.948, which established principles to assist
26 physicians and hospitals in addressing emergency call. In particular, the policy states that the
27 organization and function of on-call services should be determined through hospital policy and
28 medical staff bylaws, and include methods for monitoring and assuring appropriate on-call
29 performance and that medical staffs should determine and adopt protocols for appropriate, fair, and
30 responsible medical staff on-call coverage.

31
32 The Council also supports reaffirmation of Policy H-160.927, which recognizes that individual
33 physicians may feel coerced by hospitals to sign contracts. The policy urges those physicians and
34 urges those who believe hospitals are negotiating contracts inappropriately, and who feel coerced
35 into signing contracts, to contact the AMA/State Medical Society Litigation Center, their state
36 medical association, and/or legal counsel.

37
38 RECOMMENDATIONS

39
40 The Council on Medical Service recommends that the following be adopted in lieu of Resolution
41 806 (I-08), and that the remainder of this report be filed:

- 42
43 1. That our American Medical Association strongly encourage physicians and hospitals to work
44 collaboratively to develop solutions based on adequate compensation or other appropriate
45 incentives as the preferred method of ensuring on-call coverage. (New HOD Policy)
46
47 2. That our AMA monitor and oppose any state legislative or regulatory efforts mandating
48 emergency room on-call coverage as a requirement for medical staff privileges and state
49 licensure that are not supported by the state medical association. (Directive to Take Action)

- 1 3. That our AMA reaffirm Policy H-130.948, which contains a series of principles to assist
2 physicians and hospitals in addressing emergency room call coverage requirements. (Reaffirm
3 HOD Policy)
4
- 5 4. That our AMA reaffirm Policy H-160.927, which urges individual physicians or physician
6 groups that believe they are being coerced into specific employment arrangements to contact
7 the AMA/State Medical Society Litigation Center, their state medical association, and/or legal
8 counsel. (Reaffirm HOD Policy)

Fiscal Note: Staff cost estimated to be less than \$2,000 to implement.

References for this report are available from the AMA Division of Socioeconomic Policy Development.

REPORT 2 OF THE COUNCIL ON MEDICAL SERVICE (I-09)
Geographic Variation in Health Care Cost and Utilization
(Reference Committee J)

EXECUTIVE SUMMARY

The phenomenon of “geographic variation” has been attracting increasing attention among analysts and policymakers struggling to address rising health care costs, and for some has become a rallying cry for the need to decrease waste and increase efficiency in the health care system. This report provides an overview of research into geographic variation; describes the work of the Dartmouth Atlas Project; and discusses the limitations of the Dartmouth Atlas Project’s research to date on explaining geographic variation. The report concludes with a discussion of the importance of pursuing additional research into the causes of geographic variation, and recent efforts by the American Medical Association (AMA) to address efficiency concerns.

While it is widely acknowledged that health care spending patterns vary across the country, the causes and implications of these variations are less clear. A compelling public policy question is whether health care costs in the United States could be reduced by identifying efficiencies in low-spending areas that could be replicated in higher-spending areas, without jeopardizing health care quality and patient access. The answer to this question depends in large part on the ability of researchers to effectively study and document variables that affect health care utilization and cost, and the extent to which these variables can be influenced or manipulated by public policy.

According to a 2008 Congressional Budget Office report, recent research on causes of geographic variation suggests that less than half of the amount of variation is attributable to factors that have already been measured related to local health care prices, health status, and cultural and demographic factors. With as much as half of geographic variation remaining “unexplained” after controlling for basic variables related to prices, health status and demographics, there is a need for further study to effectively identify and describe the remaining causes of health care spending variation.

Work by the Dartmouth Atlas Project provides valuable descriptive information about health care spending and utilization patterns across the United States. However, data are insufficient at this point to make reliable assumptions about why these variations exist, and what policies should be applied to improve health care delivery overall. Although variation research has controlled for many factors, it does a disservice to health system reform efforts to conclude that all remaining variation is unjustified, and that health care delivery patterns in low-spending areas are preferable to delivery patterns in high-spending areas.

Additional research is necessary to determine what other factors affect local health care delivery, and whether these factors lead to desirable variations. From a policy perspective, identifying these factors can help determine if and where there may be opportunities to reduce variation and increase efficiencies throughout the health care system. The Council cautions that policies based on narrowly defined research or simplified data analysis could jeopardize efforts to bend the cost curve and improve patient care. The AMA must continue to emphasize the importance of gathering and disseminating evidence-based clinical information that can be used by physicians to provide the right care at the right time.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 2-I-09

Subject: Geographic Variation in Health Care Cost and Utilization

Presented by: Barbara L. McAneny, MD, Chair

Referred to: Reference Committee J
(William J. Holt, MD, Chair)

1 The phenomenon of “geographic variation” has been attracting increasing attention among
2 analysts and policymakers struggling to address rising health care costs, and for some has become a
3 rallying cry for the need to decrease waste and increase efficiency in the health care system. The
4 June 1, 2009 issue of the *New Yorker* included an article by surgeon Atul Gawande, MD, that
5 examined health care costs in McAllen, Texas, a small border town with – by some measures – the
6 highest health care costs in the nation. The article, which attracted the attention of the
7 Administration, Congress, and the press, describes Dr. Gawande’s attempts to uncover the reasons
8 for McAllen’s high costs, and his discomfort upon “diagnosing” that “the primary cause of
9 McAllen’s extreme costs was, very simply, the across-the-board overuse of medicine.”

10
11 The Council on Medical Service is aware that nothing about health care costs or utilization can be
12 explained “very simply.” This report provides an overview of research into geographic variation;
13 describes the work of the Dartmouth Atlas Project, which has emerged as a leading resource in
14 geographic variation studies; and discusses the limitations of the Dartmouth Atlas Project’s
15 research to date on explaining geographic variation. The report concludes with a discussion of the
16 importance of pursuing additional research into the causes of geographic variation, and recent
17 efforts by the American Medical Association (AMA) to address efficiency concerns.

18 19 RESEARCH ON GEOGRAPHIC VARIATION

20
21 Variations in health care spending across the United States are well documented. The most recent
22 National Health Expenditure data show unadjusted per capita health care spending ranging from
23 \$4,000 in Utah to \$6,700 in Massachusetts (Centers for Medicare and Medicaid Services, 2007).
24 Prior years’ data show similar spending variations across states. Variations have also been
25 documented among smaller geographic units. Using Medicare data, researchers with the
26 Dartmouth Atlas Project have studied variations across hospital referral regions (HRRs), which are
27 defined based on referral patterns to hospitals that provide major cardiovascular surgical
28 procedures and neurosurgery. Dartmouth data show that among 306 HRRs, Medicare spending per
29 patient ranges from nearly \$14,500 in some areas, to as little as \$5,200 in others (Dartmouth,
30 2008). Similarly, county by county analyses by the National Center for Policy Analysis show
31 Medicare per capita spending varies from just over \$5,000 in Nobles County, Minnesota, to \$8,500
32 in Rice County, Kansas (NCPA, July 2008).

33
34 While it is widely acknowledged that health care spending patterns vary across the country, the
35 causes and implications of these variations are less clear. A compelling public policy question is
36 whether health care costs in the United States could be reduced by identifying efficiencies in low-
37 spending areas that could be replicated in higher-spending areas, without jeopardizing health care

1 quality and patient access. The answer to this question depends in large part on the ability of
2 researchers to effectively study and document variables that affect health care utilization and cost,
3 and the extent to which these variables can be influenced or manipulated by public policy.
4

5 Research shows that some health care cost variation is the result of unique local characteristics.
6 For example, prices paid for medical services are influenced by local prices associated with
7 providing medical care, such as office rent, professional liability insurance rates, and local salaries
8 for health professionals (Congressional Budget Office [CBO], 2008). Research also suggests that
9 professional liability costs have some effect on the practice of medicine, leading to variations in
10 practice patterns consistent with varying professional liability climates. One study of the
11 relationship between liability costs and Medicare expenditures suggested that states in the top
12 quartile of professional liability costs could be expected to spend 4% more on total Medicare
13 spending than states in the bottom quartile of liability expenditures (Baicker et al., 2007). The
14 strongest relationship was demonstrated between liability costs and increased spending on imaging
15 services, while a weaker increase in services such as physician visits and diagnostic tests was also
16 present.
17

18 Health status of the local population also explains a portion of variation in health care use. Areas
19 with relatively high concentrations of sicker patients generally have higher per capita health care
20 costs than those with healthier populations. It is difficult to accurately assess, however, the extent
21 to which health status affects health care cost because of the difficulty in selecting or obtaining
22 relevant health status data (CBO, 2008). For example, risk adjustment measures used to control for
23 health status may be unreliable (e.g., data is self-reported by patients), or incomplete (e.g., co-
24 morbidities might not be adequately reflected).
25

26 Cultural and demographic factors such as race, income, and educational attainment have also been
27 the subject of research studies of per capita health care costs. To date, several studies focusing on
28 the Medicare population have suggested a limited effect of demographics on spending variation
29 (CBO, 2008). Yet many researchers feel that the importance of demographic variables has been
30 greatly underestimated, and that further research is necessary to assess the magnitude of the
31 relationship between socioeconomic factors and spending patterns. Specifically, some researchers
32 suggest that factors such as income and insurance have a significant effect on spending patterns of
33 the non-Medicare population (e.g., Cooper, 2008). Similarly, researchers at the Urban Institute,
34 including Jack Hadley, PhD, and Robert Berenson, MD, have found that demographic factors,
35 along with health status, are critical variables that affect health care utilization at the individual
36 level, and caution that their significance is masked in population-based analyses of health care
37 spending.
38

39 According to the 2008 CBO report, recent research on causes of geographic variation suggests that
40 less than half of the amount of variation is attributable to factors that have already been measured
41 related to local health care prices, health status, and cultural and demographic factors. A 2003
42 study by the Medicare Payment Advisory Commission (MedPAC) estimates that variation in prices
43 and practice costs accounts for about 29% of total variation in Medicare spending at the state level,
44 and health status accounts for approximately 16% of Medicare spending by state (CBO, 2008).
45 With as much as half of geographic variation remaining “unexplained” after controlling for basic
46 variables related to prices, health status and demographics, there is a need for further study to
47 effectively identify and describe the remaining causes of health care spending variation.

1 DARTMOUTH ATLAS PROJECT

2
3 The Dartmouth Atlas Project has emerged as a leading source of information regarding geographic
4 variation in health care. Begun in the early 1990s by John E. Wennberg, MD, MPH, the
5 Dartmouth Atlas Project was developed to provide information to help structure the health care
6 reforms proposed by the Clinton Administration. Dartmouth received funding from the Robert
7 Wood Johnson Foundation to conduct an extensive analysis of health care spending and resource
8 use across the United States. Dartmouth researchers proceeded with their analysis, while the
9 Clinton health care reform efforts proved unsuccessful. Realizing they had “data without a
10 customer,” Wennberg and his colleagues committed to producing the Dartmouth Atlas of Health as
11 a publicly available, comprehensive resource for policymakers, analysts and others interested in
12 understanding of the efficiency and effectiveness of the United States health care system.

13
14 In 2003, Wennberg and Dartmouth Atlas co-founder Elliott S. Fisher, MD, MPH published two
15 key studies in the *Annals of Internal Medicine* that examined whether regions with higher levels of
16 Medicare spending experienced better outcomes (defined by mortality rates and improvements in
17 functional status) or increased patient satisfaction than lower-spending regions. The studies found
18 that patients in higher spending regions received more care (primarily inpatient and specialty care),
19 but did not experience better outcomes or increased satisfaction. These studies became the
20 foundation of Dartmouth’s subsequent work and serve as the basis for the Dartmouth Atlas
21 Project’s overarching premise that it is possible to address health care spending growth by
22 examining inefficiencies in the health care delivery system.

23
24 Following is a summary of some of Dartmouth’s key conclusions regarding geographic variation in
25 health care utilization. Dartmouth has characterized the majority of geographic variation as
26 “unwarranted [because] it cannot be adequately explained on the basis of differences among
27 regions in illness rates, patient preferences or the dictates of evidence-based medicine.” Based on
28 its research, the Dartmouth Atlas Project has concluded that “much of the variation relates to
29 provider quality defects,” and that otherwise unexplained differences in utilization are due to an
30 underuse of effective care, misuse of preference-sensitive care, and overuse of supply-sensitive
31 care. Dartmouth researchers have suggested that by addressing these three areas, “the nation could
32 reduce health care spending by as much as 30 percent” without compromising the quality of care.

33
34 It should be noted that Dartmouth’s conclusions about the role of “provider quality defects” in
35 geographic variation are not based on documented causal relationships between physician behavior
36 and utilization patterns. Rather, they are based on the lack of evidence about additional variables
37 that also affect health care utilization, or that may affect both physician supply and utilization.
38 This lack of evidence does not necessarily mean that other variables do not exist. Dartmouth’s
39 research has focused primarily on health care delivery and payment systems, but further research
40 into other variables (e.g., environmental, socioeconomic, or cultural) could lead to further
41 reductions in the amount of unexplained variation.

42
43 *Effective Care*

44
45 “Effective care” refers to services or treatments that are widely accepted as offering value to
46 patients without significant tradeoffs, often in the context of treating chronic conditions. These
47 services are often defined in practice guidelines, with sound clinical evidence supporting their use.
48 Examples include scheduling regular eye exams and blood screening tests for diabetic patients, or
49 using beta-blockers for heart attack patients. Because clinical evidence supports the use of these
50 services as effective ways of reducing morbidity and mortality, it is reasonable to expect that

1 virtually all patients would receive the services when clinically appropriate, and that their use rates
2 would be relatively stable across regions.

3
4 Research by Dartmouth and others shows that patients do not always receive treatments
5 recommended by practice guidelines. A Dartmouth study of diabetic Medicare patients showed
6 that, depending on hospital referral region, the percentage of patients receiving annual blood
7 screening ranged from 10 to 70 percent of patients. Dartmouth research further suggests no
8 correlation between spending levels in a region and the incidence of effective care. Paradoxically,
9 some Dartmouth studies have shown an inverse relationship between health care spending and the
10 likelihood that patients will receive recommended care. Researchers speculate that patients in
11 higher spending regions may have more physicians involved in their care, which increases the need
12 for effective care coordination efforts. In the absence of other explanatory evidence, Dartmouth
13 researchers conclude that the inverse relationship between health care spending and effective care
14 delivery can be partially explained by a lack of effective care coordination systems, resulting in
15 gaps in patient care (Fisher, February 27, 2009).

16 17 *Preference-Sensitive Care*

18
19 Unlike effective care, which is supported by clinical evidence as being the best course of action for
20 a particular illness or condition, “preference-sensitive care” generally refers to situations in which
21 there may be more than one accepted treatment option, and where there are “significant tradeoffs
22 among the available options.” Treatment options may represent varying degrees of intervention
23 (e.g., lumpectomy vs. mastectomy for early stage breast cancer), or choosing between medical and
24 surgical options (e.g., watchful waiting with routine testing for an enlarged prostate vs.
25 prostatectomy).

26
27 The appropriateness of preference-sensitive care should be based on the weight ascribed by the
28 patient to the costs and benefits of one procedure relative to another. Dartmouth’s studies of
29 preference sensitive care show large variations in preference-sensitive procedures across regions,
30 but relative uniformity within a given region. According to Dartmouth researchers, the consistency
31 with which a certain procedure is performed in a single region “suggest[s] that local medical
32 opinion has a strong influence on the choice of treatment.” Dartmouth researchers conclude that, in
33 the case of preference-sensitive care, physician practice style appears to play a much larger role in
34 utilization and costs levels than either patient preference or clinical appropriateness (Dartmouth
35 Topic Brief, 2007).

36 37 *Supply-Sensitive Care*

38
39 Although questions have been raised recently about the relative significance of physician supply to
40 health care utilization, Dartmouth’s conclusions about “supply-sensitive” care have attracted the
41 attention of a wide range of policymakers and analysts. Dartmouth defines supply-sensitive care as
42 “care whose frequency of use is not determined by well-articulated medical theory, much less by
43 scientific evidence. Supply sensitive services include physician visits, diagnostic tests,
44 hospitalizations and admissions to intensive care among patients with chronic diseases...Where
45 there is greater capacity, more care is delivered – whether or not it is warranted.”

46
47 In the 2003 *Annals* articles, the Dartmouth researchers examined the costs and outcomes associated
48 with end-of-life care with the objective of determining if regions with higher Medicare spending
49 delivered better care. The authors determined that patients in higher spending regions received
50 60% more care than patients in the lowest-spending regions, in the form of increased use of
51 evaluation and management services and testing, imaging and minor procedures, and use of a

1 hospital as the site of care. Patients in higher spending areas were also likely to see more
 2 specialists (including general internists) and to be treated by greater numbers of physicians than
 3 those in lower-spending areas. Despite the increased intensity of utilization, the study found that
 4 higher spending regions did not demonstrate higher quality of care on measures such as appropriate
 5 follow-up care or preventive care (Fisher, 2003, Part 1). The study also determined that higher
 6 levels of spending on end-of-life care did not lead to lower mortality rates, better functional status,
 7 or higher patient satisfaction (Fisher, 2003, Part 2). Subsequent research by Dartmouth researchers
 8 suggests that patients in higher spending areas might receive lower quality care, possibly due to the
 9 increased risks associated with receiving care in a hospital setting (e.g., infection or medical
 10 errors), and the lack of care coordination that can be associated with treatment by multiple
 11 physicians (Fisher, February 27, 2009).

12
 13 **LIMITATIONS OF DARTMOUTH ATLAS OF HEALTH CARE DATA**

14
 15 Due to its strong reputation and comprehensive collection of data and analyses, the Dartmouth
 16 Atlas of Health Care has emerged as a respected and influential voice in the health system reform
 17 dialogue. Dartmouth research reveals aspects of health care delivery that could benefit from closer
 18 examination and more deliberate attention in order to achieve maximum efficiencies for patients
 19 and the health care system as a whole. Unfortunately, the Dartmouth research is frequently used to
 20 attack physicians, alleging provision of unnecessary and costly care, and often provides the basis
 21 for sensational and flawed theories about the drivers of health care costs and practice differences
 22 across the country.

23
 24 *Individual vs. Aggregate Data*

25
 26 As noted, Dartmouth’s research, while extensive, is not exhaustive, and some analysts have
 27 expressed caution about conclusions drawn from Dartmouth’s findings. Robert Brook with the
 28 RAND foundation generally praises the work of the Dartmouth Atlas Project, but is concerned that
 29 the conclusions to reduce supply and services in high-spending areas is overshadowing the need to
 30 evaluate clinical appropriateness in the context of level of service use (Newberg, 2006). Similarly,
 31 Jack Hadley of the Urban Institute warns that levels of individual variation could be “distorting”
 32 cost averages, meaning that within a given region individual high-spenders and low-spenders could
 33 already be receiving appropriate levels of care, even if the “average” regional spending appears
 34 high (Newberg, 2006).

35
 36 A recent critique of the 2008 edition of the *Dartmouth Atlas* notes that Dartmouth methodology for
 37 studying the relationship between utilization and outcomes for end-of-life care underestimates
 38 potential treatment benefits by failing to account for variations in the severity and treatability of
 39 illnesses in individual patients “at the time of patient evaluation.” Dartmouth researchers
 40 attempted to control for disease severity by retrospectively studying groups of people at fixed
 41 intervals prior to death. According to the Dartmouth literature, the focus on patients who died
 42 allowed the researchers to “be sure that patients were similarly ill,” because the prognosis for all
 43 the patients was death (Dartmouth Hospital-Specific Data FAQ). Gerald Neuberg, MD, of the
 44 Columbia University College of Physicians and Surgeons, notes that retrospectively looking at
 45 treatments patients received prior to death obscures important information about what benefits the
 46 patients might have gained from the treatments in terms of quality of life in the final weeks.
 47 According to Neuberg, “from the look-back perspective, care is viewed not as a means to improve
 48 health, but as an accumulation of expenses that failed to prevent an inevitable death” (Neuberg,
 49 2009).

1 *Unexplainable is Not Necessarily Unwarranted*

2
3 In March 2009, the Council met with Richard Cooper, MD, and Christopher Hogan, PhD, to
4 discuss their work to expand the available evidence on geographic variation. Dr. Cooper, of the
5 University of Pennsylvania, has been an outspoken critic of Dartmouth's research, particularly of
6 the conclusion that unexplained variation is synonymous with unwarranted variation. Cooper is
7 particularly interested in the "web of economic, demographic, and health spending patterns [that]
8 independently and collectively unite quality, health care spending, and social structure" (Cooper,
9 2008). Specifically, Cooper has emphasized the relationship between health care utilization and
10 poverty, which itself correlates with a wide range of variables such as education levels, community
11 resources, and employment status. According to Cooper, areas with a "higher social burden"
12 experience more doctor visits, more hospital admissions and readmissions, and longer hospital
13 stays in part because patients do not have access to the vast array of services and supports that help
14 individuals achieve and maintain optimal health.

15
16 There seems to be support among those in the research community that more studies should be
17 undertaken to assess the impact of demographic and socioeconomic factors on health care spending
18 and utilization. This is an area that is being targeted by policymakers interested in identifying
19 explanations for some of the as yet "unexplained" variation in health care costs and utilization.
20 The Council notes that smaller case studies of geographic variation uncover additional variables
21 that are unlikely to be controlled in larger studies, but prove to have a significant explanatory effect
22 on service use. For example, Hogan examined the six-to-one variation in Medicare oxygen
23 spending per capita among the 10 states with the highest and lowest spending rates. He identified
24 only a weak correlation ($R=0.16$) between state prevalence of chronic obstructive pulmonary
25 disease (COPD), but a large correlation between a state's altitude and oxygen use ($R=0.89$). States
26 with the highest levels of oxygen spending were those with high mean elevation above sea level
27 (specifically, Nevada, New Mexico, Utah, Colorado and Wyoming), while those with low oxygen
28 spending were closer to sea level (Hawaii, Washington, DC, Minnesota, Rhode Island and North
29 Dakota). Based on Hogan's case study, the variation in state-level Medicare oxygen spending per
30 capita can be almost entirely explained by health status (i.e., COPD prevalence) and elevation
31 above sea level. If Hogan's analysis had been based on a more limited set of variables, some may
32 have concluded that the variation in oxygen usage was "unwarranted," because an explanatory
33 variable was not identified.

34
35 *Medicare is Not Entirely Representative of Total Health Care Spending*

36
37 Medicare is often used as a proxy for information about broader health care spending patterns,
38 because data from the Medicare fee-for-service program provides detailed information about
39 beneficiaries and the use and cost of services covered by Medicare. Comparable information is
40 difficult to obtain for individuals with private insurance coverage. Yet, Medicare spending data is
41 not necessarily representative of total health care spending. A paper by Andrew Rettenmaier and
42 Thomas Saving explores the "multi-dimensional" nature of geographic variation, and demonstrates
43 that the use of Medicare spending data as a proxy for health care utilization overall leads to an
44 incomplete analysis of regional spending variations (Rettenmaier and Saving, 2009). Rettenmaier
45 and Saving compare state-level rankings of health care spending using multiple metrics, and find
46 the relative ranking of high- and low-spending states changes based on the metric used. For
47 example, 2004 data show Louisiana and Maryland ranking highest in Medicare per enrollee
48 spending, but 36th and 17th in overall per capita health care spending. They document similar
49 "resorting" of state rankings when examining elements of Medicaid spending, and spending by the
50 non-Medicare/Medicaid population.

1 Rettenmaier and Saving’s analysis of Medicaid spending vs. percentage of Medicaid enrollees
 2 sheds light on broader policy decisions that may affect health care spending. As shown in Figure 1,
 3 Alaska and New Jersey rank highest for Medicaid per enrollee spending, but 30th and 48th in the
 4 percent of the population enrolled in Medicaid. Conversely, California ranks last in Medicaid
 5 spending per enrollee, but 3rd in percent of population enrolled in its Medicaid program.

Figure 1 Medicaid Rankings

State	Rank of Medicaid spending per enrollee, capita spending	Rank of percent of population enrolled in Medicaid
Alaska	1	30
New Jersey	2	48
California	50	3

Source: Rettenmaier and Saving, 2009

6 The extreme variation in these rankings “indicates the interplay and tradeoffs states make in
 7 determining eligibility criteria and Medicaid benefit generosity.” It should be noted that
 8 Rettenmaier and Saving identify a positive relationship between the number of uninsured in a state
 9 and the level of Medicare spending, indicating that “Medicare cross-subsidizes the uninsured
 10 population.”

11
 12 Rettenmaier and Saving’s observations do not necessarily contradict the findings of Dartmouth
 13 researchers, but shed light on the complexity of geographic variation analysis, and point to the
 14 importance of using data beyond the Medicare program to help enhance knowledge and inform
 15 policy development. Although Dartmouth researchers have suggested that health care spending
 16 could be reduced by as much as 30 percent if utilization in high spending areas of the country
 17 mirrored utilization in lower spending areas, Rettenmaier and Saving suggest that adjusted
 18 potential savings across all populations is only about 5%. This lower estimate, compared with
 19 Dartmouth’s 30% estimate, incorporates spending patterns by non-Medicare populations, which are
 20 generally excluded from the Dartmouth analyses.

21
 22 *The Interplay of Supply and Demand*

23
 24 Finally, Dartmouth’s conclusions about the relationship between capacity and utilization (i.e., the
 25 overuse of supply-sensitive care) may be premature, and the research is insufficient to establish a
 26 causal relationship between levels of capacity and levels of utilization. Further study is needed
 27 about whether the supply of medical resources might itself be influenced by the demand for health
 28 care. For example, physicians might be drawn to areas with higher levels of illness, income, or
 29 preferences for treatments. When supply is affected in this manner, it is empirically difficult to
 30 determine whether utilization is higher because of supply or demand factors. Although the
 31 Dartmouth project controls for many demand factors, some may remain unmeasured, and the
 32 estimates of the extent to which capacity explains variation in use may be somewhat overstated.
 33 Dartmouth’s focus on supply factors diminishes the importance of potentially meaningful variables
 34 that may warrant further study.

1 DISCUSSION

2
3 The Dartmouth Atlas Project characterizes high-spending regions as producing “excess levels of
4 intervention,” and its literature claims that up to 30% of spending on health care is wasted. The
5 Council believes that these conclusions significantly overstate a legitimate concern that the health
6 care delivery system is not maximizing its opportunities for efficiency. Research into geographic
7 variation is a valuable tool to help physicians, policymakers, politicians, and other key stakeholders
8 improve their understanding of issues related to health care cost and quality in the United States,
9 and to identify appropriately targeted policy solutions that will help enhance health care delivery.

10
11 The Dartmouth Atlas and other research into geographic variation provide valuable descriptive
12 information about health care spending and utilization patterns across the United States. However,
13 data are insufficient to make reliable assumptions about why these variations exist, and what
14 policies should be applied to improve health care delivery overall. Although variation research has
15 controlled for many factors, it does a disservice to health system reform efforts to conclude that all
16 remaining variation is unjustified, and to assume that health care delivery patterns in low-spending
17 areas are preferable to delivery patterns in high-spending areas.

18
19 Additional research is necessary to determine what other factors affect local health care delivery,
20 and whether these factors lead to desirable variations. From a policy perspective, identifying these
21 factors can help determine if and where there may be opportunities to reduce variation and increase
22 efficiencies throughout the health care system. The reliance on Medicare data also limits the
23 generalizability of many conclusions based on current geographic variation research. The Council
24 believes that the creation of a national claims database that would include data from all public and
25 private health insurers could facilitate more comprehensive research into health care utilization
26 patterns across all segments of the population.

27
28 The preponderance of the evidence that variation is much less evident for “universally accepted”
29 treatment options suggests an opportunity to improve medicine’s knowledge about best practices
30 with regard to treatments and health care processes. The AMA continues to play a leadership role
31 in developing quality measures through the Physician Consortium for Performance Improvement,
32 and has strong policy supporting well designed clinical comparative effectiveness research efforts
33 (Policy H-460.909, AMA Policy Database), and enhancing efforts to generate and disseminate
34 information about comparative practice patterns among physicians (Policy D-390.961). As part of
35 its commitment to controlling health care costs and advancing health system reform efforts, the
36 AMA joined six other health care organizations in May 2009, in committing to help the
37 Administration reach its goal of reducing the annual health care spending growth rate. In June
38 2009, the AMA agreed to specifically focus on care utilization by leading efforts to improve care
39 transitions to avoid hospital readmissions and reduce unnecessary utilization of certain services or
40 procedures that showed high variation and high cost.

41
42 The AMA is committed to action to help achieve greater value from our nation’s health care
43 spending, and the Council recognizes that work by the Dartmouth Atlas Project and others studying
44 geographic variation has the potential to help bend the spending curve and inform important policy
45 decisions to advance health system reform efforts. However, the Council cautions that policies
46 based on narrowly defined research or simplified data analysis could jeopardize these same efforts.
47 The AMA must continue to emphasize the importance of gathering and disseminating evidence-
48 based clinical information that can be used by physicians to provide the right care at the right time.

1 RECOMMENDATIONS

2

3 The Council on Medical Service recommends that the following be adopted and that the remainder
4 of the report be filed:

5

6 1. That our American Medical Association encourage further study into the possible causes of
7 geographic variation in health care delivery and spending, with particular attention to risk
8 adjustment methodologies and demographic factors that affect demand for health care
9 services. (New HOD Policy)

10

11 2. That our AMA encourage the development of a national claims database in order to
12 facilitate research into health care utilization patterns across all segments of the health care
13 delivery system. (New HOD Policy)

14

15 3. That our AMA support efforts to reduce variation in health care utilization that are based
16 on ensuring appropriate levels of care are provided within the context of specific clinical
17 parameters, rather than on aggregated benchmarks. (New HOD Policy)

Fiscal Note: Staff cost estimated to be less than \$500 to implement.

References available from the AMA Division of Socioeconomic Policy Development.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 3-I-09

Subject: Health Insurance Exchange Authority and Operation

Presented by: Barbara L. McAneny, MD, Chair

Referred to: Reference Committee J
(William J. Holt, MD, Chair)

1 Leading health system reform proposals have called for the establishment of a health insurance
2 exchange to serve as a managed marketplace on the state, regional and/or national level for the
3 purchase of health insurance. Support for creating a health insurance exchange has been based
4 partly on the success of the Massachusetts health reform effort, which resulted in a 2.6%
5 uninsurance rate as of summer 2008. As the American Medical Association (AMA) continues to
6 advocate for mechanisms to cover the uninsured, it has been essential to monitor the development
7 and implementation of the authority and responsibilities delegated to proposed health insurance
8 exchanges to ensure optimal patient choice in health plans and the protection of the physician-
9 patient relationship.

10
11 The entity or entities operating a health insurance exchange could have several potential roles.
12 Many possible functions that have been proposed are based on what the Commonwealth Health
13 Insurance Connector Authority carries out in Massachusetts, as well as the current responsibilities
14 of the Federal Employee Health Benefits Plan (FEHBP). The roles of the entity operating an
15 exchange could also be greater in the context of implementing an individual mandate.

16
17 In particular, there are key issues associated with health insurance exchanges that merit further
18 consideration, especially given long-standing AMA policy conceptually supportive of exchanges.
19 This report describes potential regulatory authority to be delegated to the executive branch related
20 to health insurance exchange organization, potential federal benefit standards, and the possible
21 participation of a public or non-profit plan option within any exchange. The report also outlines
22 other issues associated with health insurance exchange implementation, summarizes relevant AMA
23 policy and advocacy, and presents policy recommendations.

24 25 THE IMPACT OF HEALTH INSURANCE EXCHANGE ORGANIZATION

26
27 Stakeholders involved in the debate surrounding the creation of a health insurance exchange have
28 proposed different models of organization. The two leading approaches have been to create a
29 national exchange or to create exchanges in every state. Proposals have also included options to
30 create regional exchanges or subsidiary exchanges within a state.

31
32 The responsibilities delegated to the executive branch with respect to exchange operation differ
33 between the national exchange and state exchange approaches. In the context of a national
34 exchange, it would be likely that the executive branch would be granted the authority to establish
35 and operate the health insurance exchange, including issuing and accepting bids and negotiating
36 contracts for plans, certifying plans, implementing a risk-pooling mechanism, facilitating outreach
37 and enrollment, determining the size of employers that can participate in the exchange, and

1 specifying benefits to be made available under plans. If regional, state and subsidiary exchanges
2 are created instead of a national exchange, legislation and regulations would likely outline criteria
3 for exchanges, and states then would submit proposals for state and regional exchanges to be
4 certified by the federal government. The federal government could also supply start-up financial
5 assistance, provide technical assistance and develop a module for plan information to be used by all
6 states.

7
8 A requirement that individuals have health insurance coverage would also impact the authority
9 granted to entities administering federal and state health insurance exchanges. For example, an
10 individual mandate would likely require individuals to have coverage that meets a standard for
11 health insurance coverage that would be deemed acceptable to meet the individual mandate and not
12 be assessed any financial penalty. If financial assistance is provided to eligible individuals and
13 families to purchase health insurance coverage through the exchange in order to meet the mandate,
14 the locus of control for administering this assistance would likely be federal for a national
15 exchange and state-based for state exchanges.

16 17 THE IMPACT OF FEDERAL BENEFITS STANDARDS

18
19 In anticipation of health system reform legislation that creates a minimum benefits package
20 individuals would be required to have, the Council on Medical Service presented Report 7-A-07,
21 which established principles to evaluate the adequacy of health insurance coverage options (Policy
22 H-165.846, AMA Policy Database). Proposals for a federally-mandated basic benefits package
23 would likely serve as a foundation to set minimum benefits standards for qualified plans operating
24 in federal, regional or state exchanges; develop criteria related to the minimum benefit standards of
25 plans that individuals and families eligible for financial assistance (i.e., premium and cost-sharing
26 credits) could access; and determine minimum creditable coverage related to the individual
27 mandate. A benefits requirement could also be extended to plans operating outside of the exchange
28 environment. Such proposals have envisioned the Secretary of HHS having the authority to adopt
29 and update benefits standards for qualified plans in the exchange, including covered treatments,
30 items and services, and cost-sharing levels.

31
32 These minimum benefit standards would also likely lead to regulations addressing the coverage of
33 physician services within the exchange. Once the essential benefits package is determined,
34 regulations would likely be promulgated that address the type, scope, frequency and duration of
35 physician services that must be covered by qualified health plans. Regulations would likely also be
36 issued that address which providers are eligible to be paid for providing certain services, which has
37 the ability to emerge as a scope of practice issue. Finally, regulations would likely guide the
38 determination of patient eligibility for certain services.

39 40 THE IMPACT OF A PUBLIC OR NON-PROFIT OPTION

41
42 One of the most controversial aspects surrounding the creation and operation of a health insurance
43 exchange is the establishment of a public or non-profit health insurance option that some proposals
44 have suggested be offered through the exchange to compete against the participating private plans.
45 While some proposals have called for the public plan to offer only a basic benefits package, others
46 have called for the public plan to offer various tiers of benefit levels. Most proposals would
47 require the public health insurance option to meet the same requirements as private plans regarding
48 consumer protections, provider networks, benefit levels and cost-sharing. Proposals have also
49 differed as to whether the public plan would be required to be self-sustaining, not dependent on the
50 federal treasury and meet a federal solvency standard.

1 Some proposals would require physicians who participate in Medicare to also participate in the
2 public health insurance option. Additional proposals would require physicians participating in
3 Medicare to opt out of participating in the public health insurance option if they do not wish to
4 participate, while others would not require physicians to proactively opt out of participating in the
5 public plan option. Another key issue for physicians has been physician payment under the public
6 health insurance option. Whereas some proposals have called for physician payment to somehow
7 be linked to Medicare, other prominent proposals have included provisions to make physician
8 payment within the public plan option negotiated like private plans.

9
10 Establishing “co-op” plans emerged as a leading alternative to creating a truly public health
11 insurance option to participate in the exchange. The notion of consumer cooperatives, initially
12 proposed by Senator Kent Conrad (D-ND), would create a non-profit, non-government, consumer-
13 driven insurance option in every state. These cooperatives would be offered as an option through
14 the exchange and would be subject to all exchange rules. A consumer cooperative would function
15 very much like a traditional cooperative, in that it would be democratically controlled by its
16 members and governed by an elected board. Any surpluses from its operation would be returned to
17 its members or reinvested, potentially in the form of lower premiums, lower cost-sharing or
18 expanded benefits. Consumer cooperatives would receive start-up funds and would be expected to
19 be self-sustaining after the start-up period. Cooperatives could also operate on a regional or
20 national level.

21
22 The authority granted to the Executive Branch would differ based on whether a public or non-profit
23 plan option would participate in an exchange. Should a public plan be established to compete with
24 private plans within an exchange, the Secretary of HHS would likely have a role in the
25 administration of the public health insurance option. These responsibilities could include
26 negotiating premiums and reimbursement rates and developing conditions of participation. As
27 standards for premiums and reimbursement rates will likely be updated for each plan year, this
28 could affect both patient enrollment and physician participation in the program.

29 30 OTHER HEALTH INSURANCE EXCHANGE IMPLEMENTATION ISSUES

31
32 The Council would be concerned with any authority granted to the Executive Branch that could
33 usurp the role of state insurance commissioners in the arenas of oversight and enforcement of the
34 operation of health insurance exchanges and the health plans participating therein. Specifically, the
35 Council believes that state insurance commissioners have a vital regulatory role ensuring consumer
36 protections such as grievance procedures, external review, oversight of agent practices and training,
37 and market conduct. Of concern and importance to physicians is the regulatory role of state
38 insurance commissioners in physician protections including state prompt pay laws, protections
39 against health plan insolvency, and fair marketing practices.

40
41 The Council notes that additional responsibilities may be delegated to the Executive Branch, such
42 as establishing standards to ensure health benefit plan transparency with regard to health care
43 provider reimbursement arrangements. The Executive Branch could also have the responsibility to
44 establish criteria for qualified health plans addressing claims payment policies and practices;
45 periodic financial disclosure; data on enrollment, disenrollment, number of claims denials, and
46 rating practices; and information on cost-sharing and payment regarding out-of-network coverage.

47
48 For qualified health plans sold in state or national exchanges, it is also likely that the Secretary of
49 HHS would have the responsibility to promulgate regulations that address marketing and network
50 adequacy. These regulations will be vital in ensuring that patients have a wide choice of physicians
51 and health plans, regardless of their health status.

1 LEGISLATIVE ACTIVITY

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The Council conceived this self-initiated report at its January 2009 meeting, and preparing the report during the rapid and fluid legislative activity of summer 2009 has been a challenge. At the time this report was written, three pieces of comprehensive health system reform legislation had been proposed. All three of these proposals contained provisions for the establishment of exchanges, but differed in their approaches.

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H.R. 3200, the America’s Affordable Health Choices Act of 2009, developed jointly by the three committees with jurisdiction in the House of Representatives (House Energy and Commerce Committee, House Ways and Means Committee, House Education and Labor Committee), has been the prominent piece of legislation in the House of Representatives. At the time this report was written, a vote on the House of Representatives’ legislation was expected in the fall of 2009. The Senate Health, Education, Labor and Pensions (HELP) Committee approved its bill, the “Affordable Health Choices Act,” in July of 2009. At the time this report was finalized in September 2009, Senate Finance Committee Chairman Max Baucus had released his mark “America’s Healthy Future Act of 2009.” The final Senate product will be an amalgamation of the bills of the Senate HELP and Finance Committees. A vote on the Senate floor of this amalgamated legislation was also expected in the fall of 2009.

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RELEVANT AMA POLICY AND ADVOCACY

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AMA policy is supportive of the general concept of creating a health insurance exchange. Policy H-165.846 (AMA Policy Database) advocates principles to guide the evaluation of adequacy of health insurance options, including the principles that any health insurance exchange must include a wide variety of coverage options from which to choose, and that existing federal guidelines regarding types of insurance coverage should be used as benchmarks of meaningful coverage. Numerous AMA policies support the FEHBP as a model for health system reform based on competition among health plans and choice for patients (Policies H-165.855[1], H-165.856, H-165.995[3], H-165.845[2], and H-330.898[6]). The AMA also advocates the formation of small employer and other voluntary choice cooperatives (Policy H-165.882). Policy H-165.862 endorses the concept and use of Internet-based health insurance marts and health benefits systems as mechanisms for employers and individuals to select and purchase health insurance. AMA policy opposes an expansion of the Medicare program and instead advocates for reforms to strengthen the program in the short-term and its eventual replacement with a self-funded, private-sector approach to financing health care for the elderly, with equitable means testing provisions (H-165.985, H-330.898, H-330.896). The AMA House of Delegates discussed the public plan option at the 2009 Annual Meeting and adopted Policy H-165.888[4], which supports health system reform alternatives that are consistent with AMA principles of pluralism, freedom of choice, freedom of practice, and universal access for patients.

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AMA policy underscores that coverage expansions and the creation of an exchange must be consistent with the broad goals of market regulation. Policy H-165.856 contains a set of principles to guide health insurance market regulation, including greater national uniformity of market regulation across health insurance markets, regardless of type of sub-market (e.g., large group, small group, individual), geographic location, or type of health plan; replacing strict community rating with modified community rating; replacing guaranteed issue regulations with guaranteed renewability; and removing legislative and regulatory barriers to the formation and operation of group purchasing alliances, and to the development of multi-year insurance contracts. Policies H-165.920[11] and H-165.995 support the use of state high-risk pools. AMA policy also supports minimizing benefit mandates unrelated to patient protections in order to expand individual choice

1 and allow market experimentation to find the most attractive combinations of plan benefits and
2 cost-sharing features (Policies H-165.856[9b], H-180.978, H-165.997, and H-165.882[2]).

3
4 The AMA has been an active participant in health reform discussions with the Obama
5 Administration and key authorizing committees in the House and Senate. The AMA submitted its
6 comments in response to the Senate Finance Committee's policy options document addressing
7 coverage (which included alternatives for the inclusion of a public plan option), the House Tri-
8 Committee draft health care reform proposal, and the Senate HELP Committee's "Affordable
9 Health Choices Act" draft health care reform proposal. The AMA also submitted a statement for
10 the record to the House Ways and Means Committee regarding insurance market reforms as part of
11 overall health system reform.

12 13 DISCUSSION

14
15 The Council believes the AMA has an adequate policy foundation from which to participate in
16 discussions and negotiations regarding the establishment of an exchange and the inclusion of a
17 public or non-profit plan option. However, the Council notes that many aspects and specifics of
18 health insurance exchange operation and implementation, including the standards for private and
19 public/non-profit entities operating therein, will be determined in the regulatory process.

20
21 Ultimately, the Council believes that the success of health insurance exchanges not only depends
22 on the number of individuals and families becoming insured through these mechanisms, but the
23 degree of choice of health plans afforded to individuals and families within them. The Council
24 believes that during the regulatory process, the health plan choices to be offered through any
25 exchange should not be further limited so patients have the ability to purchase the coverage that
26 best suits their needs, in accordance with Policy H-373.998[2]. This would entail not only a
27 diversity in the benefits packages available, but also health plans with varying levels of cost-
28 sharing.

29
30 Within any exchange, the Council believes it will be essential for patients to be provided with
31 standardized and easy-to-understand information to be able to compare the health insurance options
32 in the exchange based on cost, level of coverage and other factors. Accordingly, health plans need
33 to provide necessary information to patients and the entity operating an exchange, including clear
34 and accurate explanations of covered services, cost-sharing obligations, out-of-pocket limits and
35 lifetime benefit caps, and excluded services. Existing AMA policy on health insurer conduct
36 applies to all plans, whether or not they participate in an exchange. In an exchange environment,
37 the Council finds it especially critical that AMA policy be followed addressing health plan
38 transparency in interactions with both physicians and patients, and supporting physician freedom of
39 practice (Policies H-185.975, H-165.846[4], H-385.926).

40
41 It will be imperative that any entity or entities tasked with operating an exchange implement
42 transparent processes. The regulatory authority granted to these entities could include
43 implementing standards for benefits and physician payment arrangements of plans offered through
44 an exchange. Accordingly, it will be critical that these processes are open to relevant stakeholders,
45 to ensure that any exchange works in the best interests of patients, that physician choice of practice
46 is upheld, and that the physician-patient relationship is protected.

1 RECOMMENDATIONS

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The Council on Medical Service recommends that the following be adopted and the remainder of the report be filed:

1. That our American Medical Association (AMA) adopt the following principles for the operation of health insurance exchanges:
 - a) Health insurance exchanges should maximize health plan choice for individuals and families purchasing coverage. Health plans participating in the exchange should provide an array of choices, in terms of benefits covered, cost-sharing levels, and other features.
 - b) Any benefits standards implemented for plans participating in the exchange and/or to determine minimum creditable coverage for an individual mandate should be designed with input from patients and actively practicing physicians.
 - c) Physician and patient decisions should drive the treatment of individual patients.
 - d) Actively practicing physicians should be significantly involved in the development of any regulations addressing physician payment and practice in the exchange environment, which would include any regulations addressing physician payment by participating public, private or non-profit health insurance options.
 - e) Regulations addressing physician participation in public, private or non-profit health insurance options in the exchange that impact physician practice should ensure reasonable implementation timeframes, with adequate support available to assist physicians with the implementation process. (New HOD Policy)
2. That our AMA reaffirm Policy H-373.998[2], which supports patient choice and empowering patients with incentives and understandable information about fees and prices. (Reaffirm HOD Policy)
3. That our AMA reaffirm Policy H-165.846[4], which supports transparency among all health plans regarding covered services, cost-sharing obligations, out-of-pocket limits and lifetime benefit caps, and excluded services. (Reaffirm HOD Policy)
4. That our AMA reaffirm Policy H-185.975 addressing health plan transparency and publication of their payment policies, rules, and fee schedules for physicians. (Reaffirm HOD Policy)
5. That our AMA reaffirm Policy H-385.926, which supports physician freedom of practice. (Reaffirm HOD Policy)

Fiscal Note: Staff cost estimated to be less than \$500 to implement.

References are available from the AMA Division of Socioeconomic Policy Development.

REPORT 4 OF THE COUNCIL ON MEDICAL SERVICE (I-09)
Comparability of the Cost Estimates of Health Care Systems

EXECUTIVE SUMMARY

At the 2009 Annual Meeting, the House of Delegates adopted as amended Resolution 124, which calls for the American Medical Association (AMA) to undertake a careful examination of the reported cost estimates of the health care systems of comparable developed countries, clarify the services and attendant expenses which are included in such estimates, publicize any estimates which ignore costs shifted to other parts of national budgets, and use this information in our efforts to ensure that the true cost of all of the services provided by the United States health care system are appropriately figured into any system redesign. The House amended the resolution to request a report back at the 2009 Interim Meeting.

This report focuses on comparisons between the United States and the United Kingdom, Canada, Germany and Switzerland. The UK and Canada are classic examples of “single payer” health care systems. Germany and Switzerland have more market-based health care systems, although the government is still responsible for a large portion of health care expenditures.

As noted in the whereas clauses of Resolution 124 (A-09), there is a wide variation in the type and scope of data collected with respect to health system expenditures. In recognition of the need for consistent and comparable health care cost data, the Organization for Economic Cooperation and Development (OECD) proposed a standardized health system accounting framework that could be used by countries to facilitate data reporting and comparisons. The *System of Health Accounts* (SHA) is based on an International Classification for Health Accounts (ICHA), which highlights three specific dimensions of health care measurement: health care functions, health care service providers, and sources of funding of health care. Tracking and stratifying data along each of these dimensions allows policymakers to more closely examine the interrelationships between different components of health care systems, and to answer more detailed questions about how resources are distributed across services and functions.

OECD’s most recent expenditure data shows the US outpacing similar countries in health care expenditures, even after the reporting data is harmonized using the SHA methodology. It is important to note, however, that there is limited value in highlighting cost comparisons between countries without also considering the socioeconomic and cultural context in which a health care system operates. The Council believes that international comparisons of health system expenditures offer only limited value in terms of helping countries identify strengths, weaknesses, or potential efficiency improvements. Individual countries face unique realities shaped by history and culture that make it unlikely that large scale “successes” in one country could translate into similar successes in another. However, the Council is optimistic that improving the nature of health system accounting will improve the ability of health policy experts to carefully analyze health care systems and identify improvements that are appropriate in the overall context of health care system redesign.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 4-I-09

Subject: Comparability of the Cost Estimates of Health Care Systems

Presented by: Barbara L. McAneny, MD, Chair

1 At the 2009 Annual Meeting, the House of Delegates adopted as amended Resolution 124 (Policy
2 D-155.991, AMA Policy Database), which calls for the American Medical Association (AMA) to
3 undertake a careful examination of the reported cost estimates of the health care systems of
4 comparable developed countries, clarify the services and attendant expenses which are included in
5 such estimates, publicize any estimates which ignore costs shifted to other parts of national
6 budgets, and use this information in our efforts to ensure that the true cost of all of the services
7 provided by the United States health care system are appropriately figured into any system
8 redesign. The House amended the resolution to request a report back at the 2009 Interim Meeting.
9

10 BACKGROUND

11
12 Even before federal health system reform became a top priority for the nation, reports of rising
13 health care costs in the United States and the number of uninsured Americans were frequent
14 features in the news. Reports that US health care expenditures far exceed those of comparable
15 countries, combined with some studies suggesting that the US gets relatively less for its health care
16 dollar, have led some policymakers to speculate that the US health care system is less efficient than
17 that of other countries. This has resulted in increased scrutiny of the decentralized, market based
18 health care system in the US, with some arguing that centralized health care systems are more cost-
19 effective and equitable.
20

21 At the 2006 Annual Meeting, the Council presented Council on Medical Service Report 5,
22 “Comparison of Selected International Health Care Systems.” This informational report was
23 intended to provide a snapshot of how some countries organize their health care infrastructures, and
24 the challenges that arise from different funding structures and delivery systems. The report
25 highlighted the health care systems of the United Kingdom (UK), Canada, Germany, and
26 Switzerland, all of which have nearly universal health insurance coverage. The Council selected
27 these countries because in addition to some fundamental similarities between their governmental
28 structures and economies and those of the US, their health care systems represent a variety of
29 frameworks that offer unique opportunities and challenges for meeting the needs of their
30 populations.
31

32 *Summary of Selected International Health Care Systems*

33
34 The Council again focused on the UK, Canada, Germany and Switzerland in the development of
35 this report. The UK and Canada are classic examples of “single payer” health care systems, and
36 health insurance coverage is available to all residents free of charge. Health care expenditures are
37 financed primarily through general tax revenues, and the private insurance market plays a relatively
38 insignificant role in both systems. In the UK, health care financing and budgeting are controlled at
39 the national level, although local service delivery is coordinated by more than 300 Primary Care
40 Trusts, which together control approximately 80% of the National Health Service (NHS) budget.

1 The Canadian health care system was modeled after the NHS, but is more decentralized because of
 2 the strong, independent nature of the Canadian provinces. Funding responsibility is shared
 3 between the federal and provincial governments, and the provinces assume significant
 4 responsibility for directing and funding the health insurance plan in their regions.

5
 6 Germany and Switzerland have more market-based health care systems, although the government
 7 is still responsible for a large portion of health care expenditures. Most health insurance in
 8 Germany is funded through taxes paid by employers and employees, who choose from a wide
 9 range of independently-operated health insurance plans. In Switzerland, individuals are
 10 responsible for obtaining private insurance from one of several private insurers who offer benefits
 11 mandated by the Swiss government. Individuals who cannot afford health insurance are eligible
 12 for means-tested subsidies provided by the government.

13
 14 It is beyond the scope of this report to evaluate the merits of various health care systems, although
 15 Council on Medical Service Report 5-A-06 included a discussion of the tradeoffs associated with
 16 the various organizational structures represented by the US and the other countries. Council
 17 Report 5-A-06 concluded that, “it will be critical to maintain a pluralistic health care system that
 18 emphasizes patient choice...The Council believes it will continue to be in the best interests of
 19 patients and physicians to advocate for long-term health system reforms that are primarily based on
 20 consumer-driven and market-based principles.”

21
 22 **COMPARABILITY OF HEALTH CARE COST ESTIMATES**

23
 24 As noted in the Whereases of Resolution 124 (A-09), there is a wide variation in the type and scope
 25 of data collected with respect to health system expenditures. National health accounts maintained
 26 by some individual countries allow domestic policymakers to track funding sources and health
 27 expenditures, and provide a snapshot of the resources used to support the health care system.
 28 Depending on the level of detail of the accounts and the data sources available, countries can use
 29 information from their national health accounts to analyze spending or resource-use trends that
 30 reflect specific policy concerns, which are often influenced by the structure of the particular health
 31 care system. For example, the fragmented financing structure of the US health care system has
 32 resulted in a national health account structure that emphasizes the role of financing agents. In
 33 contrast, most European health care systems rely primarily on public financing, so the dominant
 34 policy issue for European nations has been how health care resources are used, rather than how
 35 they are funded (Orosz, 2005).

36
 37 The content and structure of national health accounts is often dictated by the availability of relevant
 38 health accounting data. Countries rely on available administrative information (e.g., claims data
 39 from public and private insurers) and on surveys that may target specific information not otherwise
 40 available from administrative records (*A System of Health Accounts* [SHA], 2000). Examples of
 41 data that may need to be supplemented by surveys include private out-of-pocket health care
 42 spending or health care spending by charities. The extent to which countries collect and maintain
 43 accurate records of certain health expenditure data depends on the resources available and on the
 44 perceived relevance of the data for analytical purposes.

45
 46 Even if all countries were collecting the same basic set of health care expenditure information,
 47 estimates of total health expenditures are dependent on what each country includes in its definition
 48 of “health expenditure.” Identifying the “boundaries” of health care expenditures is critical to
 49 establishing a degree of comparability among international health care cost data. From country to
 50 country, health care expenditure data may or may not include such categories as medical education

1 costs, research and development on health-related issues, environmental health, home health
 2 services, long-term care, or administrative costs (Orosz and Morgan, 2004).

3
 4 A particular source of variability among countries is the overlap between services that could be
 5 classified as either social welfare or health care costs. For example, services for people with
 6 physical or mental disabilities, or substance abuse problems often include medical and social
 7 service components, and there is a lack of consistency about how these services are categorized.
 8 The classification of long-term care expenditures is especially problematic and has a significant
 9 effect on the comparability of health care expenditure data. In the US, a large portion of long-term
 10 care costs are reported as health care expenditures (primarily through the Medicaid program),
 11 whereas many other countries classify long-term care as a social welfare expenditure (i.e., it is not
 12 included in health care cost estimates) (Orosz and Morgan, 2004). The distinctions between
 13 medical support services and social support services in long-term care delivery are easily blurred,
 14 and in the absence of a standardized reporting format, countries vary in how long-term care costs
 15 are classified. It has been estimated that the lack of comparability in long-term care reporting may
 16 affect total expenditure reporting by as much as 10% (Orosz and Morgan, 2004).

17
 18 A SYSTEM OF HEALTH ACCOUNTS

19
 20 Along with the US, the UK, Canada, Germany and Switzerland are among the 30 member
 21 countries of the Organization for Economic Cooperation and Development (OECD) that “share a
 22 commitment to democratic government and the market economy.” In 2007, OECD countries spent
 23 an average of 8.9% of gross domestic product on health care expenditures, up from around 7% in
 24 1990. Rising health care costs and the need to define and ensure adequate levels of health care
 25 resources are pressing problems for most of the OECD member countries. Accordingly, OECD
 26 has devoted significant resources to providing meaningful data on health system expenditures that
 27 analysts can use to help identify appropriate and effective health policy solutions.

28
 29 In recognition of the need for consistent and comparable health care cost data, the OECD proposed
 30 a standardized health system accounting framework that could be used by countries to facilitate
 31 data reporting and comparisons. In 2000, the OECD published *A System of Health Accounts*,
 32 “designed to meet the needs of analysts of health care systems and policymakers. [The proposed
 33 accounts] provide a common framework for enhancing the comparability of data over time and
 34 across countries. They are intended for use in international comparisons that include a broad range
 35 of countries with different ways of organizing health care and its financing” (SHA, 2000).

36
 37 The SHA is based on an International Classification for Health Accounts (ICHA), which highlights
 38 three specific dimensions of health care measurement: health care functions, health care service
 39 providers, and sources of funding of health care. Tracking and stratifying data along each of these
 40 dimensions allows policymakers to more closely examine the interrelationships between different
 41 components of health care systems and to answer more detailed questions about how resources are
 42 distributed across services and functions.

43
 44 The concept of health care function is generally not captured in national health accounts, and
 45 provides a basis for identifying clear, uniform boundaries for health care expenditure classifications
 46 and sub-classifications. Standard boundaries are especially important for harmonizing international
 47 cost reporting data, and also add an important informational dimension for domestic policy
 48 analysis.

1 Under the ICHA framework, health care is divided into specific functional categories that are
 2 defined according to the goals and purposes of health care. Examples of functional categories
 3 include curative care, rehabilitative care, and services of prevention and public health. ICHA also
 4 defines a set of health care-related functions, which includes education and training of health
 5 personnel, and research and development. A complete list of the ICHA categories is available on
 6 the OECD Web site (OECD.org).

7
 8 Under the SHA, total health expenditures – a figure commonly quoted in health policy literature –
 9 is defined by the sum of expenses related to core health care functions. SHA distinguishes between
 10 core health care functions that are provided directly to individuals (or collectively as in the case of
 11 public health), and health care-related functions. Although health care-related functions are
 12 “closely linked” to core health care functions, SHA recommends tracking them separately, since
 13 many of them (e.g., medical education, environmental health) represent separate “parameters under
 14 health policy” (SHA, 2000).

15
 16 The SHA proposes the use of distinct ICHA classifications for providers (e.g., hospitals, providers
 17 of ambulatory care, nursing care facilities) and financing sources, as well as function. The ICHA
 18 classification system includes sub-categories to further refine health care system reporting.
 19 According to OECD, because implementation is ongoing, data comparability is likely to be more
 20 reliable for broader categories, rather than the sub-categories. However, the ultimate goal of SHA
 21 implementation is that the level described will enable “a multifaceted analysis of how financial
 22 resources in health care systems are raised..., and allocated among functions and service
 23 providers” (Orosz and Morgan, 2005).

24
 25 **OECD HEALTH DATA 2009**

26
 27 The most recent *OECD Health Data* edition was released in July 2009. The full database is
 28 available for purchase, but a limited amount of data and detailed information about the sources and
 29 methods of data collection are publicly available. According to OECD, “the overriding aim of the
 30 OECD Secretariat is to ensure that data presented in *OECD Health Data 2009* is as comparable as
 31 possible, both across countries and over time...The structure and definition of the variables in
 32 *OECD Health Data 2009* are consistent with the concepts presented in the SHA manual.” OECD
 33 notes that because countries are at “varying stages” of implementing the SHA, the comparability of
 34 the data is not exact. OECD data include individual notes on each member country that provide
 35 specific information about the consistency between the country data and SHA definition and
 36 boundaries.

37
 38 The Council contacted the OECD for clarification regarding the comparability of cost data reported
 39 in the latest OECD publication. The US, Canada, Germany and Switzerland currently use SHA
 40 methodology to compile the data they submit to OECD for inclusion in the database, so that the
 41 format and content of the information in the OECD database for these countries is generally
 42 consistent. However, in some cases, lack of available data at the national level, or structural
 43 differences in reporting boundaries or sub-classifications, compromise the degree of comparability.
 44 These issues are noted in the *OECD Health Data 2009*’s explanatory notes for each country.

45
 46 The UK has not yet adopted the SHA methodology and reports health expenditures based primarily
 47 on their national account structure. The implications of this departure from SHA methodology are
 48 noted in the OECD’s explanatory notes for the UK.

49
 50 Data from *OECD Health Data 2009* is publicly available for the following macro-level statistics
 51 (for survey year 2007): total health expenditures as a percentage of gross domestic product (GDP),

1 percentage of total health expenditure from public sources (defined as state, regional and local
 2 government bodies and social security schemes), and per capita health expenditures in US dollars
 3 adjusted for purchasing power parities (which helps standardize exchange rates and the relative
 4 costs of goods or services). Based on the OECD explanatory notes, the overall comparability of
 5 these macro-level statistics appears to be high.

6
 7 *United States*

8
 9 In 2007, health expenditures accounted for 16% of GDP; 45.4% of total health expenditure was
 10 from public funds, and per capita spending was \$7,260. Expenditures as a percent of GDP and per
 11 capita spending were significantly higher than those of the other four countries. Percent of public
 12 spending on health care was significantly lower.

13
 14 The main data source for US data is the National Health Expenditure data, which are compiled by
 15 the Centers for Medicare and Medicaid Services. OECD notes regarding data comparability
 16 identify several differences in national data reporting that affect the comparability of some of the
 17 sub-categories reported in the OECD database. For example, data estimates for some
 18 classifications were not available (e.g., curative and rehabilitative care, separate state and local
 19 spending figures), and hospital estimates include some nursing home and home health spending.
 20 This results in an over-reporting of hospital spending, and an under-reporting of home health
 21 spending according to the SHA framework.

22
 23 *United Kingdom*

24
 25 In 2007, health expenditures accounted for 8.4% of GDP; 81.7% of total health expenditure was
 26 from public funds, and per capita spending was \$2,992. Expenditures as a percent of GDP and per
 27 capita spending were lower than those of the other four countries. Percent of public spending on
 28 health care was higher.

29
 30 As noted, the UK does not use SHA methodology to report its data. However, OECD indicates
 31 that “total health expenditure data for the UK includes funds spent by health administrations,
 32 prisons, the armed forces, households, and not-for-profit institutions and investment in medical
 33 facilities by all sections of the economy. These figures are considered fit for the purposes of
 34 analyzing health expenditure in the UK and for making international comparisons.” Of note,
 35 however, is the fact that health expenditure data do not include non-National Health Service
 36 spending on nursing care in nursing homes, occupational health care, and household production of
 37 health care (i.e., home care delivered by lay people as a substitute for formal nursing care). These
 38 spending categories are included in health care expenditures as defined by the SHA, therefore the
 39 UK’s health expenditure figures may be underreported relative to the other countries whose
 40 statistics include these costs.

41
 42 *Canada*

43
 44 In 2007, health expenditures accounted for 10.1% of GDP; 70.6% of total health expenditure was
 45 from public funds, and per capita spending was \$3,895.

46
 47 Factors that may influence the comparability of Canadian health care expenditure reporting include
 48 the inclusion of expenditures not included in SHA boundaries (e.g., care for non-Canadians in
 49 Canadian hospitals; expenditure on in-patient facilities for drug/alcohol addiction [SHA notes that
 50 residential drug/alcohol treatment facilities include a large social service component]; and
 51 expenditures on personal health care items, such as toothbrushes, medicated shampoos and

1 deodorant), and the exclusion of expenditures that fall within SHA boundaries (e.g., spending on
2 school health, private sector expenditure on occupational health, expenditures of voluntary health
3 associations).

4
5 *Germany*

6
7 In 2007, health expenditures accounted for 10.4% of GDP; 76.9% of total health expenditure was
8 from public funds, and per capita spending was \$3,588.

9
10 The OECD notes on data comparability note that the German Health Accounts were revised in
11 2006 in order to better harmonize with SHA. Although some differences remain, OECD finds the
12 definition of health expenditures consistent with the SHA definition.

13
14 *Switzerland*

15
16 In 2007, health expenditures accounted for 10.8% of GDP; 59.3% of total health expenditure was
17 from public funds, and per capita spending was \$4,417.

18
19 OECD notes on data comparability indicate that Switzerland's expenditure on investment is likely
20 to be under-estimated, and that data is unavailable for several categories, including health
21 administration and health insurance, nursing and residential care, and health care-related goods and
22 services.

23
24 **US HEALTH CARE EXPENDITURES IN CONTEXT**

25
26 OECD's most recent expenditure data shows the US outpacing similar countries in health care
27 expenditures. Although it is possible that the magnitude of the difference could be inflated as a
28 result of persistent data comparability issues, it appears likely that US health care expenditures are
29 generally higher than those of comparable countries. However, this observation in itself is
30 insufficient to conclude that the US is spending an inappropriate amount on health care. There is
31 limited value in highlighting cost comparisons between countries without also considering the
32 socioeconomic and cultural context in which a health care system operates. The demand for health
33 care in the US is uniquely affected by national assets such as a high gross domestic product per
34 capita that indicates an overall "ability to pay" for health care services, and national liabilities such
35 as high rates of homicide, suicide, and domestic violence. Economists note that labor-market
36 dynamics also contribute to health care costs in the US. Health care professionals are paid
37 relatively more in the US than in other countries, in part because the US health care sector is
38 competing with other fields such as law, finance and engineering to attract the highest levels of
39 talent (Reinhardt, 2004).

40
41 A March 2009 paper released by the National Center for Policy Analysis notes that comparisons
42 based on tangible resources rather than monetary accounts offer a different perspective on
43 comparative health care resource use. The US uses fewer physicians, nurses, hospital beds,
44 physician visits and hospital stays than the median OECD country (Goodman, 2009). Similarly, an
45 analysis of global health care spending by McKinsey & Company notes that the US has relatively
46 higher levels of spending on outpatient care than similar countries, in part because the US health
47 care system delivers a higher percentage of care on an outpatient basis (Farrell, 2008).

48
49 A final consideration often obscured by comparisons based exclusively on health system
50 expenditures is the extent to which health care supply is limited by policies or practices in a
51 particular country. Wait times for certain health care services are generally much higher in the UK

1 and Canada than they are in the US, in part because the resources are not available to meet the
2 demand generated by the national insurance schemes operated in those two countries. Britain has
3 far fewer computed tomography scanners and magnetic resonance imaging scanners as the US, and
4 lower rates of heart surgery, hip replacements, and treatments for kidney failure (Goodman, 2009).
5 It is difficult to quantify these restrictions on supply in monetary terms, but it is appropriate to note
6 that expenditure levels will correlate with the level of services accessible to a country's residents.
7

8 DISCUSSION

9
10 The US often compares unfavorably with other countries in terms of per capita expenditures and
11 total health care spending. Addressing methodological issues associated with the comparability of
12 health care data is important to ensure that expenditures in the US are not over-reported relative to
13 other countries. Although OECD efforts to promote the use of the SHA have resulted in significant
14 improvements in the comparability of international health care cost data, more work is necessary to
15 ensure maximum comparability. Importantly, OECD's efforts have increased the transparency of
16 health care cost reporting data and methods and have raised awareness about the variability among
17 national health accounting systems.
18

19 The Council believes that international comparisons of health system expenditures offer only
20 limited value in terms of helping countries identify strengths, weaknesses, or potential efficiency
21 improvements. Individual countries face unique realities shaped by history and culture that make it
22 unlikely that large scale "successes" in one country could translate into similar successes in
23 another. However, the Council is optimistic that improving the nature of health system accounting
24 will improve the ability of health policy experts to carefully analyze health care systems and
25 identify improvements that are appropriate in the overall context of health care system redesign.
26

27 Council on Medical Service Report 1-A-06 studied health expenditures within the US and, in its
28 comparison of public and private health care expenditures, concluded that use of consistent,
29 detailed and relevant health care cost accounting methodologies across all payers and sectors of the
30 health care system is critical to efforts to meaningfully analyze US health care spending. After
31 studying the SHA framework, the Council believes that a key benefit of improving the
32 comparability of health care data is that it will enable analysts to examine multiple dimensions of
33 resource use and to identify patterns and relationships between the different elements of a health
34 care system. Regardless of the level of spending across countries, important policy decisions can
35 be guided by an increased knowledge of how countries use the resources they have.

REPORT 5 OF THE COUNCIL ON MEDICAL SERVICE (I-09)
Radiology Benefits Managers
(Reference Committee J)

EXECUTIVE SUMMARY

At the 2009 Annual Meeting, the House of Delegates adopted as amended Resolution 231, which asked that the American Medical Association (AMA) address the intrusion of radiology benefits managers (RBMs) into the doctor-patient interaction (e.g., denying one diagnostic test in favor of another) by (a) studying the prevalence of forced test substitution and denial of requested imaging services by RBMs contracted by third party payers; (b) advocating against such practices; (c) supporting the use of appropriate use criteria (AUC) developed by medical societies and physicians with expertise in the specialty relevant to the condition of the patient as an alternative to RBMs; and (d) reporting back progress on this issue at the 2009 Interim Meeting.

There has been a growing concern with increasing utilization and costs of imaging services in recent years and a common strategy used by private health insurance companies to control imaging growth is the use of radiology benefits managers (RBMs). Some of the nation's largest insurers contract with RBMs in the provision of imaging services to patients. The three largest RBMs are CareCore National; American Imaging Management, a WellPoint subsidiary; and National Imaging Associates, a unit of Magellan Health Services. While Medicare has historically used retrospective payment safeguards, such as identifying medical claims that do not meet certain billing criteria, there has been recent focus on having Medicare follow the private health insurers' trend of controlling utilization and costs using RBMs and other prospective strategies. Although RBMs are commonly used to control imaging use, there are better alternative mechanisms for private payers and Medicare to monitor and control imaging utilization.

The main concerns physicians report with the use of RBMs are denial or delays of payment for medically warranted imaging studies; lack of proper administrative cost assessments; inconsistent rules and practices; lack of clinical guideline transparency; interference in the patient-physician relationship; acceptance of tests or studies contingent upon referral to other physicians or practice groups; and forced test substitution.

This report describes the increasing use of RBMs, reviews the prevalence of RBM interference, identifies claims denial management practices, outlines related AMA advocacy and policy, and discusses alternatives to RBMs. The report recommends that RBMs adhere to uniform physician-developed best practice guidelines by radiology benefits management programs (RBMPs). The report also recommends that the AMA support the use of appropriate use criteria (AUC) developed by physicians with relevant expertise working in a collaborative process involving all national medical specialty societies that provide and/or order the service in question. In addition, the report suggests that an independent study be conducted to assess the burden of imaging utilization strategies on physicians and patients, and that the AMA advocate against the practice of forced test substitution and denial of requested imaging services by RBMs, which should be held accountable for harm caused by substitution or delay of requested studies. In addition, the report recommends that the AMA encourage the Physician Consortium for Performance Improvement[®] to continue to develop patient-centered measures, including those that address the appropriate use of imaging.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 5-I-09

Subject: Radiology Benefits Managers

Presented by: Barbara L. McAneny, MD, Chair

Referred to: Reference Committee J
(William J. Holt, MD, Chair)

1 At the 2009 Annual Meeting, the House of Delegates adopted as amended Resolution 231, which
2 asked that the American Medical Association (AMA) address the intrusion of radiology benefits
3 managers (RBMs) into the doctor-patient interaction (e.g., denying one diagnostic test in favor of
4 another) by (a) studying the prevalence of forced test substitution and denial of requested imaging
5 services by RBMs contracted by third party payers; (b) advocating against such practices; (c)
6 supporting the use of appropriate use criteria (AUC) developed by medical societies and
7 physicians with expertise in the specialty relevant to the condition of the patient as an alternative to
8 RBMs; and (d) reporting back progress on this issue at the 2009 Interim Meeting. The Board of
9 Trustees assigned the requested study to the Council on Medical Service.

10
11 This report describes the increasing use of RBMs; reviews the prevalence of RBM interference;
12 identifies claims denial management practices; outlines related AMA advocacy and policy;
13 discusses alternatives to RBMs; and presents a series of recommendations.

14 15 USE OF RADIOLOGY BENEFITS MANAGERS (RBMs)

16
17 There has been a growing concern with increasing utilization and costs of imaging services in
18 recent years. Although Medicare growth in imaging spending has subsequently declined, the
19 Government Accountability Office (GAO) found in a 2008 report that, from 2000 to 2006,
20 Medicare spending for physician imaging services doubled from \$7 billion to \$14 billion. An
21 increasingly common strategy used by private health insurance companies to control imaging
22 growth is the use of radiology benefits managers (RBMs). While Medicare has historically used
23 retrospective payment safeguards, such as identifying medical claims that do not meet certain
24 billing criteria, there has been recent focus on having Medicare follow the private health insurers'
25 trend of controlling utilization and costs using RBMs and other prospective strategies.

26
27 The June 2008 GAO report recommended that the Centers for Medicare and Medicaid Services
28 (CMS) examine the feasibility of expanding its payment safeguard mechanisms by adding more
29 prospective approaches, such as prior authorization, which is often used by RBMs. President
30 Obama's proposed 2010 budget includes the use of RBMs to control payments for Medicare
31 imaging services, which would result in an estimated ten-year savings of \$260 million.

32
33 Some of the nation's largest insurers contract with RBMs in the provision of imaging services to
34 patients. The three largest RBMs are CareCore National; American Imaging Management, a
35 WellPoint subsidiary; and National Imaging Associates, a unit of Magellan Health Services.
36 According to Robert LaGalia, president of National Imaging Associates, quoted in a November
37 2008 *Wall Street Journal* article, approximately 90 million consumers, or more than half of all

1 Americans with private insurance, are now covered by RBMs. With such numbers, it appears that
2 RBMs have become a central part of the imaging benefits for many health plans. Efforts are
3 needed to address the policies of RBMs that may restrict appropriate access to care for patients and
4 appropriate payment for physicians.

5
6 The main concerns physicians report with the use of RBMs are denial or delays of payment for
7 medically warranted imaging studies; lack of proper administrative cost assessments; inconsistent
8 rules and practices; lack of clinical guideline transparency; interference in the patient-physician
9 relationship; acceptance of tests or studies contingent upon referral to other physicians or practice
10 groups; and forced test substitution, a concern expressed in Resolution 231 (A-09).

11 12 PREVALENCE OF RBM INTERFERENCE

13
14 While RBMs exist to intervene with physician decision-making, detailed rates of denials and test
15 substitutions do not appear to be tracked by any independent source. Anecdotal reports have been
16 published in the press and professional journals. A November 2008 *Wall Street Journal* article
17 reported that the three largest RBMs stated that they approve 70% or more of requests for imaging
18 tests, which is generally consistent with reported denial rates ranging between 15% to 30%. For
19 example, Gregg Allen, MD, the chief medical officer of MedSolutions, an RBM that provides
20 services for CIGNA Corp., Aetna Inc., and several other health plans, stated that the company
21 approves 80% to 85% of imaging requests. Dr. Allen reported that half of the approvals are
22 immediate, and the rest are approved within 24 hours. The remaining 15% to 20% typically are
23 questioned for appropriateness, or are withdrawn or denied.

24
25 The Radiology Business Management Association (RBMA) conducted a January 2009 survey of
26 radiology practices in order to assess the impact of RBMs on radiology practices, specifically
27 looking at revenue, cost, and network inclusion or exclusion. Almost two-thirds of the respondents
28 reported that they have RBMs in their markets. Ten percent of denials were reportedly related to
29 RBM preauthorization. In addition, the survey found that 87% of responding practices stated that
30 the use of RBMs caused their administrative costs to increase. While this survey sheds some light
31 on the details of this issue, the small sample size does not allow for a comprehensive picture, which
32 limits widespread application. The American College of Radiology (ACR) and the RBMA have
33 recommended that an independent study be conducted on the magnitude of the cost burden of
34 imaging utilization strategies on ordering physician offices and imaging providers.

35 36 CLAIMS DENIAL MANAGEMENT

37
38 With the increased use of RBMs, payment for imaging services has become increasingly
39 challenging. Practices need to take proactive measures to prevent internal billing errors and
40 increase the acceptance rate of submitted claims. The following examples highlight two strategies
41 that radiology groups have found helpful.

42
43 The Radiology Group of Abington (RGA) in Abington, Pennsylvania has identified strategies to
44 ensure the highest percentage of accepted Medicare radiology claims, which has increased revenue
45 and assured that patients receive needed tests. Since contracting with an outside billing company
46 to handle claims submissions, RGA has considerably reduced its magnetic resonance imaging
47 (MRI) and computed tomography (CT) denial rates for Medicare claims. RGA's Medicare denial
48 rates decreased for outpatient MRI from 8.9% to 1.3%, for inpatient MRI from 7.3% to 2.5%, for
49 emergency department CT from 4.8% to 1.1%, and for inpatient CT from 7.3% to 2.3%. The key
50 strategies that achieved these reductions in denials were correct coding of claims, accurate
51 documentation, detailed report dictation, and ensuring that diagnostic data were consistent between

1 a hospital's information system and the radiology group's information system. In addition, RGA
2 makes sure to follow payer requirements for claims submissions, such as the preferred format of
3 submission, and when and how to use modifiers.

4
5 St. Paul Radiology is the largest private-practice radiology group in the United States, with 96
6 radiologists providing diagnostic imaging and interventional radiology services at six imaging
7 centers and eleven hospitals in Minnesota, North Dakota and Wisconsin. Using improved
8 strategies for coding and claims submission, St. Paul Radiology has reduced its denial rate for
9 Medicare claims from 35% to below 1%. The practice credits the use of ClaimStaker, a claims
10 editing application, from Alpha II for its improved claims acceptance. This type of software
11 product edits claim files for validity prior to submission and gives the practice's coders additional
12 information on issues like proper modifiers and code pairing, which assists the practice in
13 successful claim submissions.

14 15 AMA ADVOCACY AND POLICY

16
17 Physicians are encouraged to notify the AMA of instances of inappropriate interventions by health
18 insurance plans and RBMs (Policy H-320.947, AMA Policy Database), because the AMA works
19 with specialty societies to correct payer and RBM policies that unfairly exclude qualified
20 physicians from providing imaging services (Policy H-410.995[4]). The AMA opposes attempts to
21 restrict reimbursement for imaging procedures based on physician specialty, and continues to
22 support the reimbursement for imaging procedures being performed and interpreted by physicians
23 based on the proper indications for the procedure and the qualifications and training of the imaging
24 specialists in that specific imaging technique regardless of their medical specialty
25 (Policy D-385.974).

26
27 The AMA has been working with the American Academy of Neurology (AAN) and the American
28 Society of Neuroimaging (ASN) since 2008 to address the wholesale exclusion of neurologists
29 from providing imaging services by one of the largest RBMs, CareCore. Following long-term
30 discussions with the AAN and ASN regarding CareCore's policies, the groups collaborated with
31 the AMA on a March 2009 letter to the RBM. The letter expressed concern that CareCore's policy
32 regarding neurologists has the potential to arbitrarily prevent qualified physicians from providing
33 important imaging services. In addition, the letter requested a dialogue with CareCore to discuss
34 alternative ways to ensure that only trained and qualified physicians provide imaging services. As
35 a result, the AMA facilitated a joint conference call in August 2009 with the AAN, ASN, and
36 CareCore to further discuss CareCore's privileging policies for neurologists. The AMA plans to
37 continue discussions with CareCore, other RBMs, and affected specialty societies in an effort to
38 ensure increased quality, efficiency and fairness in the provision of imaging services.

39
40 The AMA encourages collaborative specialty development and review of any appropriateness
41 criteria, practice guidelines, technical standards, and accreditation programs, particularly as
42 Congress, federal agencies and third party payers consider their use as a condition of payment, and
43 to use the AMA Code of Ethics as the guiding code of ethics in the development of such policy
44 (Policy D-385.974).

45
46 Board of Trustees Report 8-A-09 was the first in a series of annual reports detailing the actions the
47 AMA is taking to oppose efforts by payers, RBMs, and others to deny patients' access to
48 appropriate, high quality imaging services provided by qualified physicians regardless of their
49 medical specialty. Recommendations from Board Report 8-A-09 ensure that the AMA will
50 monitor a two-year Medicare "Appropriate Use of Imaging Services" demonstration project,
51 scheduled to begin in 2010, and work with CMS to develop appropriateness (and exceptions)

1 criteria if it decides to move forward with a permanent program. In addition, the AMA encourages
2 Congress and the Administration to allow the Medicare Improvement for Patients and Providers
3 Act (MIPPA) mandated Medicare accreditation program to be fully implemented and evaluated
4 before further changes to Medicare's imaging standards and payments are made. The AMA will
5 work with CMS to ensure that fair Medicare accreditation standards for advanced imaging services
6 are adopted by the selected accrediting organizations. (Policy D-410.995[1-3])
7

8 The AMA opposes efforts to preauthorize, precertify or otherwise restrict the application of
9 advanced imaging services when such services are provided by qualified physicians in accordance
10 with appropriateness guidelines, practice guidelines and technical standards for the imaging
11 modalities utilized, as developed by specialty societies involved with the diagnosis and treatment
12 of such patients (Policy H-410.956). The AMA also opposes efforts to impose policies designed to
13 control utilization and costs of medical services unless those policies can be proven to achieve cost
14 savings and improve quality while not curtailing appropriate growth and without compromising
15 patient access or quality of care. In addition, the AMA condemns efforts to require patients to
16 receive imaging services at imaging centers that are mandated to require specific medical specialty
17 supervision and supports patients receiving imaging services at facilities where appropriately
18 trained medical specialists can perform and interpret imaging services regardless of medical
19 specialty (Policy D-385.974).
20

21 PERFORMANCE MEASURES

22

23 The AMA-convened Physician Consortium for Performance Improvement[®] (PCPI) is committed to
24 enhancing the quality of care and patient safety by taking the lead in the development, testing, and
25 maintenance of evidence-based clinical performance measures and measurement resources for
26 physicians. The following eight PCPI performance measures have been developed for radiology
27 through collaboration by ACR and the National Committee for Quality Assurance (NCQA):
28

- 29 • Stenosis measurement in carotid imaging reports
- 30 • Mammography assessment category data collection
- 31 • Inappropriate use of "probably benign" assessment category in mammography screening
- 32 • Communication of suspicious findings from the diagnostic mammogram to the practice
33 managing ongoing care
- 34 • Communication of suspicious findings from the diagnostic mammogram to the patient
- 35 • Reminder system for mammograms
- 36 • CT radiation dose reduction
- 37 • Exposure time reported for procedures using fluoroscopy
38

39 These measures have been designed for radiologists and other physicians directing or performing
40 the selected imaging examinations (i.e., carotid imaging studies, screening and diagnostic
41 mammograms, CT examinations, procedures which use fluoroscopy). The intended use is for
42 individual physician quality improvement and for calculating reporting or performance
43 measurement at the individual physician level.
44

45 ALTERNATIVES TO RBMs

46

47 The ACR has developed Appropriateness Criteria[®], which contains evidence-based guidelines
48 intended to assist referring physicians, radiologists and other providers in making initial decisions
49 about diagnostic imaging and therapeutic techniques. Currently, the guidelines include 159 topics
50 with more than 800 variants. The ACR advocates that this systematic process of criteria

1 development will provide credible guidelines for radiology decision-making based on scientific
2 analysis and broad-based consensus techniques.

3
4 A 2008 study by researchers from the University of Florida Health Center and Massachusetts
5 General Hospital found significant benefits in controlling high cost imaging growth rates with the
6 implementation of a computerized radiology order entry and decision support system. Physicians
7 were provided with an appropriateness score ranging from one to nine for their diagnostic
8 recommendation after clinical indications for the patient had been provided. Appropriateness
9 scores were based on the existing ACR Appropriateness Criteria®. Statistical analysis showed
10 significant benefit in controlling high cost imaging growth rates with this implementation. The
11 most noticeable procedural decreases were in annual outpatient CT growth, from 12% to 1%,
12 followed by MRI from 12% to 7%, and ultrasonography (US) from 9% to 4%. This system is now
13 used throughout the Partners HealthCare integrated healthcare system, which along with
14 Massachusetts General Hospital, includes Brigham and Women's Hospital in Boston. Reportedly,
15 all major health insurance companies in Massachusetts accept this system and allow users to
16 bypass the RBM preauthorization process.

17
18 The American College of Cardiology Foundation (ACCF) issues a series of clinical documents that
19 include guidelines, performance measures and appropriate use criteria to ensure that cardiovascular
20 professionals provide evidence-based, high quality care. The ACCF, the American Society of
21 Nuclear Cardiology, and United Healthcare (UHC) collaborated on a pilot study to determine if
22 ACCF appropriateness criteria for single-photon emission computed tomography myocardial
23 perfusion imaging (SPECT-MPI) could be used as an alternative to UHC's Radiology Notification
24 Program. The study focused on SPECT-MPI usage at six sites of varying sizes and locations
25 nationwide. A total of 6,351 patients were involved in the study and a computer-based algorithm
26 determined test appropriateness using ACCF appropriate use criteria. The results, presented in July
27 2009, indicate that 66% of SPECT-MPI tests were performed for appropriate indications, 13.4%
28 for inappropriate indications, and 13.9% were of uncertain appropriateness. The lead investigator
29 stated that once the practices became aware of their utilization pattern, the physicians were quickly
30 able to correct any inappropriate use. As a result, the system is being refined and plans are in place
31 for widespread implementation.

32 33 DISCUSSION

34
35 RBMs frequently interfere with patient care, place an unnecessary burden on physicians, and
36 compromise patient health by substituting tests or denying approval for tests. While RBMs are
37 commonly being used by private health insurance companies, and are being considered for use by
38 Medicare, mechanisms exist that provide better alternatives for private payers and Medicare to
39 monitor and control imaging utilization.

40
41 Best practice guidelines for RBM Programs have been developed through a joint effort of the ACR
42 and the RBMA. The guidelines are intended to provide guidance to payers, managed care
43 organizations, RBMs and radiology providers on best practices to consider when implementing a
44 radiology benefits management program. The guidelines apply to many provider-payer
45 relationships and can serve as a benchmark for RBM performance. Acknowledging the widespread
46 use of RBMs to control imaging, the Council strongly believes that RBMs should adhere to
47 uniform physician-developed best practice guidelines to ensure that that the RBMs do not interfere
48 with physician decisions and infringe on the patient-physician relationship.

49
50 Several specialty societies are taking steps to ensure that only medically necessary imaging
51 procedures are performed and that any inappropriate utilization is eliminated through widespread

1 use of appropriate use criteria. As some health insurance companies seek alternatives to costly and
2 time consuming RBMs, appropriate use criteria is an available option, with successful results and
3 increasing credibility. Supporting the use of appropriate use criteria developed by medical
4 societies and physicians with expertise in the specialty relevant to the condition of the patient as an
5 alternative to RBMs is consistent with AMA policy. Properly designed and non-punitive programs
6 that rely on appropriate use criteria could provide a less intrusive and more patient-centered
7 alternative to RBMs.

8
9 Given the lack of comprehensive data from a neutral source on the impact of RBMs on physician
10 practices, specifically denial and test substitution rates, the Council agrees with the ACR and
11 RBMA that an independent study is needed to determine the burden of imaging utilization
12 strategies on physicians and patients. The organizations recommend that the Center for Health
13 System Change or other comparable independent organization perform this study. In addition, the
14 Council believes that the AMA should advocate against the practice of forced test substitution and
15 denial of requested imaging services by RBMs contracted by third-party payers that meet
16 appropriate use criteria, and that RBMs should be held accountable for harm caused by substitution
17 or delay of requested studies.

18
19 Ensuring appropriate use of imaging requires widely accepted evidence-based performance metrics
20 in order to enable quality improvement and further accountability. The AMA-convened PCPI has
21 worked closely with the ACR to develop and adopt the use of evidence-based performance
22 measures, and the Council encourages their use. In late 2009 and in 2010, the PCPI will continue
23 to expand its portfolio of measures. Specifically, measures targeting appropriateness and overuse
24 of imaging services will be developed on areas including diagnostic imaging, sinusitis (including
25 sinus radiography) and back pain.

26 RECOMMENDATIONS

27
28
29 The Council on Medical Service recommends that the following be adopted and that the remainder
30 of the report be filed:

- 31
32 1. That our American Medical Association strongly encourage radiology benefits managers
33 (RBMs) to adhere to uniform physician-developed best practice guidelines. (New HOD
34 Policy)
- 35
36 2. That our AMA support the use of appropriate use criteria developed by physicians with
37 relevant expertise working in a collaborative process involving all national medical
38 specialty societies that provide and/or order the service in question. (New HOD Policy)
- 39
40 3. That our AMA support an independent study assessing the magnitude of the cost and
41 administrative burden of imaging utilization strategies on ordering physician offices,
42 imaging providers, and patients and the impact these strategies have on patient safety and
43 outcomes. (New HOD Policy)
- 44
45 4. That our AMA oppose the practice of forced test substitution and denial of requested
46 imaging services by RBMs contracted by third-party payers that meet appropriate use
47 criteria, and that RBMs be held accountable for harm caused by substitution or delay of
48 requested studies. (New HOD Policy)

- 1 5. That our AMA encourage the Physician Consortium for Performance Improvement[®] to
- 2 continue to develop patient-centered measures, including those that address the
- 3 appropriate use of imaging. (New HOD Policy)

Fiscal Note: Staff cost estimated to be less than \$500 to implement.

References are available from the AMA Division of Socioeconomic Policy Development.

This report is being submitted for publication in peer-reviewed journals and therefore cannot be posted to this Web site. For further information, please send an email to HOD@ama-assn.org.

REPORT 1 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (I-09)
Health Care Disparities in Same-Sex Households
(Reference Committee K)

EXECUTIVE SUMMARY

Objective. This report: (1) reviews the legal definitions relevant to same-sex unions in the United States; (2) examines health care disparities affecting same-sex households; and (3) evaluates the effect that exclusion from civil marriage to a same-sex partner may have on these dynamics.

Data Sources. English-language reports on studies using human subjects were selected from a PubMed search of the literature from 1990 to August 2009 using the MeSH terms “homosexuality” “(male or female),” “marriage/*legislation & jurisprudence,” *family characteristics,” “parent-child relations,” “healthcare disparities,” and “health policy.” Additional articles were identified by manual review of the references cited in these publications. Web sites of the Human Rights Campaign, the Gay and Lesbian Medical Association, the Institute for Gay and Lesbian Strategic Studies, Lambda Legal, National Center for Lesbian Rights, Williams Institute, National Conference on State Legislatures, Kaiser Family Foundation, and the Employee Benefit Research Institute also were searched for relevant resources. Members of the AMA Advisory Committee on Gay, Lesbian, Bisexual, and Transgender Issues also were consulted for relevant background information.

Results. The federal government defines marriage as “a legal union between one man and one woman as husband and wife” and spouse as “only...a person of the opposite sex who is a husband or a wife.” At least 1138 statutory provisions confer rights to spouses and dependent children based on federal recognition of civil marriage. Forty-one states have statutes defining marriage as between one man and one woman, and thirty have constitutional language defining marriage; six states currently recognize, or will soon recognize same-sex marriages. Based on census and survey data, approximately 1% of the households in the U.S. are same-sex households.

Marriage is a strong predictor of health insurance in the U.S. Women, in particular, in same-sex households are significantly less likely than women in opposite sex relationships to have health insurance coverage. Same-sex households also do not experience the tax benefits for health insurance premiums, and lack the protection afforded married couples under COBRA and FMLA. Several other federal benefits that affect the socioeconomic status of the household are not available to same-sex households including parenting-related federal income tax breaks, spousal benefits under retirement plans, social security survivor benefits, and long term care. Children in same-sex households may be disadvantaged because of barriers to coparent or second parent adoption.

Conclusions. Many of the statutory advantages enjoyed by married partners are financial, including those derived from tax laws, employee benefits, inheritance, insurance and survivorship rights, and entitlement programs. Some benefits, such as access to employer-based health insurance and the authority to make medical decisions on behalf of a spouse, have more direct implications for health care access and delivery of care. Survey data confirm that same-sex households have less access to health insurance. If they have health insurance, they pay more than married heterosexual workers, and also lack other financial protections. Additionally, both provider and patient-based barriers to health care access and culturally competent care for gay and lesbian individuals continue to exist, and children in same-sex households lack the same protections afforded children in heterosexual households.

REPORT 2 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (I-09)
Identifying and Reporting Suspected Child Abuse
(Resolution 426, A-08)
(Reference Committee K)

EXECUTIVE SUMMARY

Objective. This report reviews the incidence of child abuse, current mandatory reporting requirements, physician compliance with reporting, current medical training on recognizing and reporting suspected child abuse, and common barriers to the reporting process. In addition the report notes solutions which have been proposed to address the current disparity between reporting requirements and compliance.

Data Sources. English-language articles were identified by a Medline search using the terms “child abuse,” “child abuse reports,” “mandatory reporting,” “pediatricians,” and “child maltreatment.” Additional articles were identified by manual review of the references cited in these publications. The Web sites of the American Academy of Pediatrics and the American Academy of Child and Adolescent Psychiatry also were reviewed. In addition, pediatricians with expertise in child and adolescent trauma at Rush University Medical Center, La Rabida Hospital, Children’s Memorial Hospital (all located in Chicago), and the Illinois Department of Children and Family Services were consulted. Finally, a Google search was conducted to further identify possible relevant information or articles on child abuse.

Results. Annually, nearly 3 million cases of suspected child abuse are reported to child protective services. Although physicians are required to report suspected cases of child abuse, several retrospective studies indicate physicians do not report all suspected cases of child abuse. Physicians are more likely to report a case if they perceive the injuries to be inconsistent with the medical history and if the patient was referred for suspected abuse. Variables influencing the decision to report include injury type, severity, and apparent family risk factors.

Several explanations have been advanced for physicians not reporting suspected abuse, including lack of training and clinical experience and gaps exist in medical school curricula and residency training. Other barriers to reporting include uncertainty surrounding HIPAA requirements, lack of clinical support services, and poor communication and collaboration among professionals who evaluate, investigate, and adjudicate child maltreatment.

Conclusions. Mandatory reporting laws do not specify what level of suspicion should trigger a report, only that it be reasonable. Nevertheless, many well-trained physicians are underreporting cases of suspected abuse. Rationales for this behavior include lack of trust in child protective services, concern about breaching the doctor/patient relationship, damaging the physician’s relationship with the family, concern that no positive finding may be made, and the possibility of overzealous protective services’ workers removing the child from the home when the physician (implicitly) does not believe this is indicated. An ongoing need exists for evidence-based clinical interventions and closer collaboration among all individuals and agencies involved in this process in order to ensure the ultimate victims receive the protections and services they need and deserve

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 2-I-09

Subject: Identifying and Reporting Suspected Child Abuse
(Resolution 426, A-08)

Presented by: C. Alvin Head, MD, Chair

Referred to: Reference Committee K
(Peter C. Amadio, MD, Chair)

1 Resolution 426, submitted by the Resident and Fellow Section and referred at the 2008 Annual
2 Meeting, asked:

3
4 That our American Medical Association (AMA) support comprehensive reporting and
5 investigation of all cases of reasonably suspected child abuse and neglect using an
6 inclusive and interdisciplinary method in accordance with state and federal laws; and

7
8 That our AMA support the creation of a national standardized pediatric intentional
9 trauma curriculum for medical students and residents.

10
11 Current Policy H-515.965 (AMA Policy Database) strongly supports mandatory reporting of
12 suspected or actual child maltreatment and encourages state societies to ensure that all mandatory
13 reporting laws contain adequate protections for the reporting physician and to educate physicians
14 on the particulars of the laws in their states. Furthermore, physicians should be trained in issues
15 of family and intimate partner violence through undergraduate and graduate medical education as
16 well as continuing professional development. Policy H-515.965 also notes that our AMA,
17 working with state, county and specialty medical societies, as well as academic medical centers
18 and other appropriate groups, should develop and disseminate model curricula on violence for
19 incorporation into undergraduate and graduate medical education, and all parties should work for
20 the rapid distribution and adoption of such curricula when developed.

21
22 Given that a significant percentage of physicians do not report child abuse even when they
23 strongly suspect it, this report briefly reviews the incidence of child abuse, current mandatory
24 reporting requirements, physician compliance with reporting, current medical training on
25 recognizing and reporting suspected child abuse, and common barriers to the reporting process.
26 In addition the report notes solutions which have been proposed to address the current disparity
27 between reporting requirements and compliance, and also offers recommendations on how our
28 AMA can advocate for improvements in identifying and reporting suspected child abuse.
29 Although much of the published literature reviewed in this report is from pediatrics, the findings,
30 implications, and recommendations of this report apply to emergency room physicians, family
31 physicians, and other physicians who also may encounter suspected child abuse.

32
33 **METHODS**

34
35 English-language articles were identified by a Medline search using the terms “child abuse,”
36 “child abuse reports,” “mandatory reporting,” “pediatricians,” and “child maltreatment.”
37 Additional articles were identified by manual review of the references cited in these publications.

1 The Web sites of the American Academy of Pediatrics and the American Academy of Child and
2 Adolescent Psychiatry also were reviewed. In addition, pediatricians with expertise in child and
3 adolescent trauma at Rush University Medical Center, La Rabida Hospital, Children's Memorial
4 Hospital (all located in Chicago), and the Illinois Department of Children and Family Services
5 were consulted. Finally, a Google search was conducted to further identify possible relevant
6 information or articles on child abuse.

7 8 BACKGROUND

9 10 *Scope of the Problem.*

11
12 The National Incidence Study of Child Abuse and Neglect (NIS) gathers information from
13 multiple sources to estimate the number of children who are abused or neglected, providing
14 information about the nature and severity of the maltreatment, and characteristics of the children,
15 perpetrators, and families. Based on the third NIS published more than 15 years ago, only 28% of
16 child abuse or neglect cases were investigated. This study noted that the overall incidence of
17 abuse increased by two-thirds between 1986 and 1993.¹ The fourth NIS is currently underway
18 and will help establish the extent of changes in the incidence or epidemiology of child
19 maltreatment since the third study was completed.

20
21 The Department of Health and Human Services in 2005 noted that more than six million children
22 were reported as maltreated. This includes emotional neglect and abuse, physical abuse, sexual
23 abuse, and medical neglect. In 2005, 2.9 million cases of suspected child abuse were reported to
24 child protective services (CPS), even though a lack of consistent physician reporting exists.^{2,3}
25 Among these reports, there were 825,000 indicated cases of abuse or neglect. It is estimated that
26 approximately 1,500 children die annually as a result of abuse.³

27
28 Minorities are substantially overrepresented among those who have been reported; African
29 American children are most frequently reported as victims of abuse. The degree to which racial
30 bias in reporting and actual racial differences in child abuse explain this trend is not clear.⁴⁻⁷
31 Children who have caregivers with a history of substance use disorders or alcohol misuse are at
32 increased risk, as are children living in a family with domestic violence occurring.⁸

33
34 Attempts have been made to evaluate the impact of child abuse on communities. Wolfe et al.
35 developed a consensus framework involving factors contributing to harm, the role of community
36 institutions such as hospitals, understanding the dimensions of harm, and physicians' concern
37 about (apparent) betrayal of and diminished trust from their patient and the patient's family.⁹ A
38 need for further assessment of policy and prevention initiatives exists in order to develop better
39 safeguards in the community and to recognize vulnerabilities and risk factors related to abuse.⁹

40 41 MANDATORY REPORTING LAWS

42
43 In 1962, Kempe et al. first described the battered child syndrome and focused attention on public
44 policy regarding child maltreatment in the United States.¹⁰ Initially, it was believed that the
45 battered child syndrome likely affected only a few hundred children who were subjected to
46 violent behavior by disturbed parents. However, it was soon recognized that a larger problem
47 existed and to adequately address it would require health professionals to report suspected abuse
48 to public authorities. By 1967, all 50 states had adopted mandatory reporting laws.^{11,12}

49
50 State eligibility for federal grants requires that they provide immunity to mandated reporters.¹³
51 Every state provides immunity from civil and criminal liability for health care professionals who

1 report suspected child abuse or neglect.¹³ Clear statutes exist that must be followed regarding
2 mandatory reporting and immunity, most of which are based on a “reasonable cause to suspect”
3 and “good faith” reporting. These statutes also provide a presumption of “good faith.” That is, a
4 person acting in good faith who makes a report, cooperates in an investigation, or assists in any
5 other requirement for reporting child abuse is immune from civil or criminal liability that might
6 otherwise be incurred by that action. A person making a report or assisting in any other
7 requirement of the reporting requirement is presumed to have acted in good faith. In complying
8 with state laws, the physician needs to report to the appropriate authorities and maintain some
9 level of confidentiality. A few states (e.g., California, Tennessee) grant absolute immunity to
10 mandated reporters. Under absolute immunity, a person cannot be held liable for reporting child
11 abuse and for related testimony and communications with authorities.

12
13 Most experts on child maltreatment believe mandated reporting is extremely important. Bringing
14 abuse cases to public awareness continues to be in a child’s best interest; otherwise these cases
15 remain hidden.¹⁴

16 17 PHYSICIAN COMPLIANCE WITH REPORTING REQUIREMENTS

18
19 Several retrospective studies indicate physicians do not report all suspected cases of child
20 abuse.¹⁵⁻¹⁸ The Child Abuse Recognition Experience Study (CARES) gathered prospective data
21 on how primary care providers decided whether injuries they encountered were caused by abuse,
22 and whether they actually reported suspicious injuries to their state child protective services
23 agency.¹⁹ This study involved 1,683 patients for whom primary care physicians (n = 327) had
24 some level of suspicion that the child’s injury was caused by child abuse. Only 6% of these cases
25 were reported to the CPS. Physicians did not report 76% of the injuries they thought were
26 possibly a result of abuse, and of even greater concern, did not report 27% of injuries considered
27 “likely or very likely” to have been caused by child abuse.

28
29 While physicians are not expected to report every child for whom they have any level of
30 suspicion regarding physical abuse, more than one-quarter of cases in the CARES study were not
31 reported even when the physician had a high degree of suspicion that the injury was caused by
32 abuse. Physicians were more likely to report the case if they perceived the injuries to be
33 inconsistent with the medical history and if the patient was referred to the clinician for suspected
34 abuse. Cases most likely to be reported were those in which the patient: (1) had an injury other
35 than a laceration; (2) had a serious injury; (3) had apparent family risk factors; (4) was black; or
36 (5) was unfamiliar to the clinician.

37
38 Mandatory reporting laws do not specify what level of suspicion should trigger a report, only that
39 it be “reasonable.” In a follow-up qualitative analysis of the physicians in the CARES study who
40 concluded that the injury was suspicious and actually reported the injury to CPS, four major
41 variables were described that influenced their decision to report: (1) familiarity with the family;
42 (2) elements of the case history; (3) their use of available resources; and (4) their perception of
43 expected outcomes after reporting to CPS.²⁰ Reporting is a complex issue, and different
44 rationales exist for not reporting (see below). For many physicians, the decision to report is
45 secondary not only to their clinical judgment, but also to their relationship with the family.

46 47 *Reasons for Not Attributing and Reporting Injuries due to Child Abuse*

48
49 Several explanations have been advanced for physicians not reporting suspected abuse. Many
50 physicians feel inadequately trained to identify and manage child maltreatment. Although some
51 physicians may knowingly not report suspected abuse, others may fail to identify child

1 maltreatment, either because of insufficient knowledge or clinical experience, or because the case
2 history itself is inadequate. Lack of training and clinical experience contributes to indecision
3 about whether the child has been abused, and uncertainty about what actually must be reported.
4 Even when evaluating sentinel events of physical abuse such as traumatic brain injury or femur
5 fracture, physicians at community hospitals are less likely to report the case than physicians at
6 pediatric specialty hospitals.²¹

7
8 Some physicians may not report suspected abuse, in part, because of confusion about the
9 definition of abuse. Physicians have various views on what constitutes medical neglect,
10 emotional neglect, and physical abuse. Research definitions categorizing the severity of abuse
11 include (what may be termed) definitive abuse, likely abuse, questionable abuse vs. questionable
12 unintentional injury, and likely and definitive unintentional injury. Leventhal et al. reviewed
13 specific criteria for clinicians in an attempt to distinguish between abuse and unintentional
14 injuries.²² Interestingly, definitions regarding sexual abuse are consistent, and this type of abuse
15 also has the highest incidence of reporting.

16
17 Physicians' reluctance to report child abuse often reflects a belief that referral to CPS will not
18 result in an effective (or even the "right") intervention.^{19,20,23} Distrust between physicians and
19 CPS workers reflects a shared pattern of poor communication, faulty and biased interactions, lack
20 of ongoing collaboration, and misunderstanding about confidentiality requirements. Reluctance
21 to report also includes the possibility of irreparable harm to the doctor/patient/family relationship
22 and undue disruption of the patient's family. Additionally, a belief may exist that the
23 investigating agency will fail to corroborate the findings or, alternatively, may overreact to
24 positive findings resulting in unnecessary transfer of the child to relatives or placement in a foster
25 home. Previous negative experiences with CPS ultimately lead to fewer cases of suspected abuse
26 and neglect being reported by physicians. Generally speaking, physicians believe that mandated
27 reporting is imperfect, results in increased work loads for child protective services, is a potential
28 waste of resources, and most importantly, may be associated with a poor quality of services
29 provided to the children identified in the assessments.²⁴

30
31 Finally, some physicians may not report suspected child abuse because they are concerned that
32 reporting will lead to involvement in court proceedings. In one study, 16% of physicians
33 considered spending time in court as a negative outcome of reporting.¹⁶ However, in the CARES
34 study, physicians were more likely to report suspected child abuse if they had previous
35 experience in court.²⁰

36 37 *Liability Concerns*

38
39 As noted above, physician reporters are granted civil and criminal immunity when they comply
40 with state statutes and report child abuse cases in good faith based on a reasonable level of
41 suspicion. The key federal legislation addressing child abuse and neglect is the Child Abuse
42 Prevention and Treatment Act (CAPTA), originally enacted in 1974 (Public Law 93-247). This
43 Act has been amended and reauthorized several times, most recently by the Keeping Children and
44 Families Safe Act of 2003 (P.L. 108-36). CAPTA directs state programs to identify and report
45 cases of abuse and provides federal funding to states in support of various activities related to
46 child abuse. CAPTA also established the Office on Child Abuse and Neglect and mandates the
47 National Clearinghouse on Child Abuse and Neglect Information. Although CAPTA does not
48 require states to punish individuals if they fail to report, all 50 states have criminal penalties for
49 failure to report child abuse, and some have civil penalties as well.¹²

1 The most common cause of liability exposure is a failure of physicians and hospitals to recognize
2 abuse and/or fail to report recognized abuse.²⁶ Criminal liability also may be incurred for
3 knowingly, or negligently, making a false report.^{12,26} Other types of situations such as voluntarily
4 informing third parties (e.g., public officials, attorneys in child custody cases), or relying on third
5 party allegations for decision-making may create incriminating circumstances.²⁶

6
7 Thus, ramifications exist for physicians who do appropriately comply with mandatory reporting
8 laws for child abuse. Although physicians may believe that they know what is best for the child
9 and family, failure to report is generally not in the best interests of the child who has been abused.
10 Failure to report child abuse or neglect can deny a child the social and protective interventions he
11 or she may need. At present, it is likely that hundreds of thousands of children who are being
12 abused or neglected are not receiving interventions through departments of protective services, in
13 part, because health care professionals are not complying with legal mandates to report suspected
14 child abuse and neglect.²⁷

15 16 TRAINING ACROSS THE CONTINUUM OF MEDICAL EDUCATION

17 18 *Medical Schools*

19
20 Medical school students should be educated to be vigilant for possible child abuse and neglect.
21 The LCME Accreditation Standards state “the curriculum must prepare students for their role in
22 addressing the medical consequences of common societal problems, for example, providing
23 instruction in the diagnosis, prevention, appropriate reporting and treatment of violence and
24 abuse.”²⁸ Although medical schools are supposed to teach about child maltreatment, many do
25 not. Currently, the educational exposure for medical students on child maltreatment ranges from
26 0 to 16 hours, with a median of 2 hours. Forty-one schools have preclinical instruction and 49
27 have instruction during the pediatric clerkship, but 21% of medical schools have no required
28 instruction.²⁹

29 30 *Residents*

31
32 A 2006 survey of chief residents in pediatric residencies revealed that 25% of accredited pediatric
33 residency programs do not offer rotations in child abuse and neglect and only 41% mandated such
34 clinical experience.^{30,31} Nevertheless, a recent survey of pediatric, emergency medicine, and
35 family medicine residents on their level of knowledge, comfort, and training related to the
36 medical management of child abuse found that exposure to child abuse training and abused
37 patients was highest for pediatric residents and lowest for family medicine residents.³² Overall,
38 findings on residents’ knowledge and clinical decision-making support the need for improved
39 education in this sector.³³

40 41 *Physicians in Practice*

42
43 Approaches to improve the training of practicing physicians as mandated reporters include Web-
44 based continuing medical education (CME) programs on recognizing child maltreatment. Online
45 tutorials can potentially help physicians better identify child abuse and understand the process of
46 being a mandated reporter, including reporting to the appropriate department of protective
47 services or other institutions.³⁴ A specific model program designed to educate physicians,
48 provide office tools, and promote interaction with child protective services is EPIC-SCAN
49 (Educating Physicians in Their Communities on Suspected Child Abuse and Neglect). This is a
50 statewide community-based CME program developed in Pennsylvania under the auspices of the

1 Pennsylvania chapter of the American Academy of Pediatrics (AAP) and the Pennsylvania
2 Department of Public Welfare.³⁵

3
4 SOLUTIONS TO LACK OF REPORTING

5
6 In response to the ongoing recognition that health care professionals are not adequately reporting
7 suspected cases of child abuse to CPS, barriers to effective reporting and potential solutions were
8 addressed by a multidisciplinary conference hosted by the American Academy of Pediatrics (see
9 Appendix).³⁶ This conference, entitled Child Abuse, Recognition, Research, and Education
10 Translation Conference (or CARRET) identified five strategies involving confidentiality
11 regulations, development and support of multidisciplinary centers of excellence, regional
12 solutions for sparsely populated areas, education across the continuum of professional
13 development, and better training/collaboration among medical, law enforcement, and CPS
14 professionals.³⁷ Within the latter domain, changing CPS procedures to require medical
15 consultation for those specific allegations of abuse that include medical assessment, and reducing
16 CPS workload to allow sufficient time for adequate investigation of suspected cases of abuse
17 seem to be a necessary ancillary approach.²³

18
19 Typically, multidisciplinary teams in university-based hospitals are positioned to assess types of
20 suspected abuse and determine the appropriateness of referrals to protective services. For
21 example, in infants who have sustained trauma resulting in bone injuries it is often difficult to
22 determine whether abuse should be suspected. These hospital-based programs can evaluate the
23 complexities of these types of injuries.³⁸

24
25 In general, when a physician or mandated reporter suspects child abuse, he or she is mandated by
26 law to report the case to CPS. If done appropriately, this is not a HIPAA violation. However, as
27 noted in the CARRET conference, “hospitals have varying interpretation of how HIPAA applies
28 to child abuse cases, which limits hospital-based personnel’s ability to discuss cases with CPS.
29 CPS regulations and practices vary according to locality, often preventing them from providing
30 even the most basic feedback to mandated reporters concerning the outcome of their reports.”
31 Thus, it remains important to “clarify and expand confidentiality regulation to improve
32 communication and collaboration between CPS workers and other professionals.”³⁷

33
34 The AAP also has advanced the idea of a Child Abuse Research, Education and Service (CARES)
35 Network which is a proposal for federal investment in a national health care infrastructure to
36 reduce the health harms resulting from child abuse and neglect.³⁹

37
38 Departments of protective services have begun to develop solutions to address lack of reporting.
39 These include the development of centers with areas of expertise on sexual abuse, physical abuse,
40 and medical neglect. Many university-based emergency rooms have access to child abuse teams;
41 physicians who are not certain of maltreatment in particular cases can refer those cases to a child
42 abuse team for evaluation or consult with their local child abuse expert. This approach can foster
43 the doctor/patient relationship and help to bring more objectivity to the process. Most
44 importantly, this approach can provide safe and appropriate interventions for patients.

45
46 Child abuse may be easily overlooked within emergency rooms. Because emergency rooms,
47 particularly in urban areas, can be extremely busy, child abuse cases can be missed. Minimally,
48 there should be an abuse-specific checklist. Benger et al. described a 4-point checklist to include
49 in the medical notes when preschool-aged children present with thermal injuries (a common
50 abuse-related injury). Use of this checklist improved awareness and documentation of intentional

1 injuries, and increased referral rates.⁴⁰ In addition, quality improvement programs in community
2 hospitals may be indicated to promote better identification.²¹

3
4 The American College of Emergency Physicians “encourages emergency personnel to assess
5 patients for family violence in all its forms, including that directed toward children.” Similar to
6 the discussion noted above, ACEP acknowledges the: (1) need for standard education and
7 training; (2) development of best practices for assessment and intervention; (3) use of
8 collaborative interdisciplinary approaches; (4) development of working relationships with
9 agencies that oversee investigation of family violence; and (5) appropriate education of hospital
10 personnel on state legal requirements for reporting suspected cases of abuse and maltreatment.⁴¹

11 CONCLUSIONS

12
13
14 Child abuse is endemic. In the United States, focus on the issue began in the early 1960s and by
15 1967 all 50 states had mandatory reporting requirements. Importantly, physicians must
16 understand that the intent of mandatory reporting is to protect the child. Even though a
17 fellowship with certification in pediatrics for child abuse now exists, some debate continues
18 within the discipline of child welfare on issues related to mandatory reporting, such as the relative
19 role of reporting and investigation, and the overall effects of mandatory reporting on child
20 welfare.⁴²

21
22 Although a common reason that physicians give for not reporting is uncertainty, the law does not
23 require that they be certain, only that they have “reasonable suspicion to report.” Some cases are
24 clearly more straightforward, such as sexual abuse (which physicians report much more
25 consistently). Suspected cases of physical abuse are more complicated based on the age of the
26 patient and the type of trauma observed. Among the more difficult types of cases to assess are
27 medical neglect and certain pathological types of abuse.

28
29 At the present time, training in recognizing and reporting child abuse varies among medical
30 schools and residency programs. Nevertheless, many well-trained physicians are underreporting
31 cases of suspected abuse. Rationales for this behavior include lack of trust in child protective
32 services, concern about breaching the doctor/patient relationship, damaging the physician’s
33 relationship with the family, concern that no positive finding may be made, and the possibility of
34 overzealous protective services’ workers removing the child from the home when the physician
35 (implicitly) does not believe this is indicated.

36
37 Finally, there is a need for ongoing evidence-based clinical interventions and closer collaboration
38 among all individuals and agencies involved in this process in order to ensure the ultimate victims
39 receive the protections and services they need and deserve.

40 RECOMMENDATIONS

41
42
43 The Council on Science and Public Health recommends that the following statements be adopted
44 in lieu of Resolution 426 (A-08) and that the remainder of this report be filed.

- 45
46 1. That our American Medical Association (AMA) recognize that suspected child abuse is
47 being underreported by physicians. (New HOD Policy)
- 48
49 2. That our AMA support development of a comprehensive educational strategy across the
50 continuum of professional development that is designed to improve the detection,
51 reporting, and treatment of child maltreatment. Training should include specific

- 1 knowledge about child protective services policies, services, impact on families, and
2 outcomes of intervention. (New HOD Policy)
3
- 4 3. That our AMA support the concept that physicians, whether emergency room physicians,
5 pediatricians, family practitioners, or child and adolescent psychiatrists, act as advocates
6 for children, and as such, have a responsibility legally and otherwise, to protect children
7 when there is a suspicion of abuse. (New HOD Policy)
8
- 9 4. That our AMA recognize the need for ongoing studies to better understand physicians
10 failure to recognize and report suspected child abuse. (New HOD Policy)
11
- 12 5. That our AMA acknowledge that conflicts often exist between physicians and child
13 protective services, and that physicians and child protective services should work more
14 collaboratively, including the joint development of didactic programs designed to foster
15 increased interaction and to minimize conflicts or distrust. (New HOD Policy)
16
- 17 6. That our AMA support efforts to develop multidisciplinary centers of excellence and
18 adequately trained clinical response teams to foster the appropriate evaluation, reporting,
19 management, and support of child abuse victims. (New HOD Policy)
20
- 21 7. That our AMA encourage all state departments of protective services to have a medical
22 director or other liaison who communicates with physicians and other health care
23 providers. (Directive to Take Action)
24
- 25 8. That our AMA reaffirm Policy H-515.965, which strongly supports mandatory reporting
26 of suspected child maltreatment. (Reaffirm HOD Policy)

Fiscal Note: \$5,000

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APPENDIX

Barriers that Impede Effective Protection of Children Who May Have Been Abused and Strategies for Addressing these Barriers

1. **Barrier:** Hospitals have varying interpretations of how the Health Insurance Portability and Accountability Act (HIPAA) applies in child abuse cases, which limits hospital-based personnel's ability to discuss cases with CPS. CPS regulations and practices vary according to locality, often preventing them from providing even the most basic feedback to mandated reporters concerning the outcome of their reports.

Solution: Clarify and expand confidentiality regulations to improve communication and collaboration between CPS workers and other professionals.

2. **Barrier:** Research has produced much new knowledge about the identification and management of child maltreatment. The expanding knowledge base has resulted in the development of a new subspecialty: child abuse pediatrics. In addition, because this expertise is needed, some hospitals have developed centers of excellence following guidelines published by the National Association of Children's Hospitals and Related Institutions (NACHRI). The American Academy of Pediatrics (AAP) has developed the Child Abuse Research, Education, and Service (CARES) Network proposal, which would provide federal support for centers of excellence.

Solution: Develop and support multidisciplinary centers of excellence that would provide consultation, referrals to other services in the community, research, surveillance, and training to support and provide resources to reporters.

3. **Barrier:** Some areas of the country are sparsely populated and cannot effectively utilize a full-time specialized child abuse team.

Solution: Develop more mobile methods and assemble regional service teams for assessment of possible child abuse and neglect.

4. **Barrier:** No standards specify the quantity or quality of education that medical students, pediatric residents, or other physicians should receive about child maltreatment. Many physicians indicate that they feel inadequately trained to identify and manage child maltreatment.

Solution: Develop a comprehensive educational strategy that builds knowledge and experience from medical school and residency through continuing education once a clinician is in practice, including segments that describe prevention, identification, and interaction with the state CPS system. Training should include specific knowledge about CPS policies, services, and outcomes of intervention.

5. **Barrier:** Poor communication and collaboration between the professionals who evaluate, investigate, and adjudicate child maltreatment can lead to ineffective or inappropriate intervention. Poor communication may result from the lack of understanding of the roles of the other professionals. This misunderstanding often includes unrealistic expectations about the power and scope of the other professional's work.

Solution: Clarify the roles of the different professionals who evaluate, investigate, and adjudicate child maltreatment. Encourage and facilitate collaboration between medical, law enforcement, and CPS by including the other professionals in the training to explain their respective roles. One example of how this strategy could be implemented is Pennsylvania's EPIC program. In the EPIC training, CPS workers participate in physician training about child maltreatment.

This report is being submitted for publication in peer-reviewed journals and therefore cannot be posted to this Web site. For further information, please send an email to HOD@ama-assn.org.

REPORT 3 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (I-09)
Use of Cannabis for Medicinal Purposes
(Resolutions 910, I-08; 921, I-08; and 229, A-09)
(Reference Committee K)

EXECUTIVE SUMMARY

Objective. This report: (1) provides a brief historical perspective on the use of cannabis as medicine; (2) examines the current federal and state-based legal envelope relevant to the medical use of cannabis; (3) provides a brief overview of our current understanding of the pharmacology and physiology of the endocannabinoid system; (4) reviews clinical trials on the relative safety and efficacy of smoked cannabis and botanical-based products; and (5) places this information in perspective with respect to the current drug regulatory framework.

Data Sources. English-language reports on studies using human subjects were selected from a PubMed search of the literature from 2000 to August 2009 using the MeSH terms “marijuana” “cannabis,” and tetrahydrocannabinol,” or “cannabinoids,” in combination with “drug effects,” “therapeutic use,” “administration & dosage,” “smoking,” “metabolism,” “physiology,” “adverse effects,” and “pharmacology.” Additionally the terms “abuse/epidemiology,” and “receptors, cannabinoid” in combination with “agonists,” or “antagonists & inhibitors” as well as “endocannabinoids,” in combination with “pharmacology,” “physiology,” or “metabolism” were used. Additional articles were identified by manual review of the references cited in these publications. Web sites of the Food and Drug Administration, Drug Enforcement Administration, National Institute on Drug Abuse, Marijuana Policy Project, ProCon.org, and the International Association for Cannabis as Medicine also were searched for relevant resources.

Results. The cannabis sativa plant contains more than 60 unique structurally related chemicals (phytocannabinoids). Thirteen states have enacted laws to remove state-level criminal penalties for possessing marijuana for qualifying patients, however the federal government refuses to recognize that the cannabis plant has an accepted medical benefit. Despite the public controversy, less than 20 small randomized controlled trials of short duration involving ~300 patients have been conducted over the last 35 years on smoked cannabis. Many others have been conducted on FDA-approved oral preparations of THC and synthetic analogues, and more recently on botanical extracts of cannabis. Federal court cases have upheld the privileges of doctor-patient discussions on the use of cannabis for medicinal purposes but also preserved the right of the federal government to prosecute patients using cannabis for medicinal purposes. Efforts to reschedule marijuana from Schedule I of the Controlled Substances Act have been unsuccessful to date. Disagreements persist about the long term consequences of marijuana use for medicinal purposes.

Conclusions. Results of short term controlled trials indicate that smoked cannabis reduces neuropathic pain, improves appetite and caloric intake especially in patients with reduced muscle mass, and may relieve spasticity and pain in patients with multiple sclerosis. However, the patchwork of state-based systems that have been established for “medical marijuana” is woefully inadequate in establishing even rudimentary safeguards that normally would be applied to the appropriate clinical use of psychoactive substances. The future of cannabinoid-based medicine lies in the rapidly evolving field of botanical drug substance development, as well as the design of molecules that target various aspects of the endocannabinoid system. To the extent that rescheduling marijuana out of Schedule I will benefit this effort, such a move can be supported.