

AMA principles and legislative language regarding liability safe harbors for the practice of evidence-based medicine

Overview

In 2009, the AMA adopted principles related to liability safe harbors for physicians when they practice in accord with evidence-based medicine (EBM) guidelines. This is a concept that has garnered increased attention in the health system reform debate. While EBM guidelines hold potential for improving patient care and lowering health care costs, they may also expand physician liability if policymakers do not establish protections for physicians who comply with EBM guidelines. The AMA principles are meant to offer guidance to federal, state or local policymakers investigating this approach.

In the early 1990s, a handful of states attempted to implement programs that offered EBM guideline protections to physicians. States had a twofold purpose in pursuing these programs. First, they hoped to improve patient care by encouraging physicians to practice according to best practices. Second, they hoped to contain health care costs by discouraging physicians from practicing defensive medicine. The program in Maine was the most thorough and lasted for close to a decade. The Maine program was sunset eventually due to a lack of use by physicians, but several of the provisions included in the Maine program are relevant to current efforts and could be used as a starting point by lawmakers.

The following AMA principles and legislative recommendations include several aspects of the Maine statutory and regulatory framework. We encourage policymakers to utilize them as the foundation for state or local pilot projects that attempt to create a liability safe harbor for physicians. The principles are broad enough to provide state or local entities with necessary flexibility as they implement such a program, but they also highlight the key provisions that are needed to ensure that the program offers sufficient liability protections to physicians to make it successful.

AMA principles

The following principles should be included in efforts to grant physicians liability protections for compliance with EBM guidelines:

- Participation in a pilot program relating to evidence-based guidelines would be voluntary for patients and physicians.
- Physicians who elect to participate in the program would utilize evidence-based guidelines that could include a decision support process/application based on the guidelines.
- Participating physicians who follow evidence-based guidelines should receive liability protections for diagnosis and treatment in compliance with the guidelines.
- Such liability protections could include, but are not limited to:

- civil immunity related to the claims;
 - an affirmative defense to the claims; or
 - a higher burden of proof for plaintiffs.
- There would be no presumption of negligence if a participating physician does not adhere to the guidelines.
 - Admissibility of a guideline by a plaintiff(s) should be prohibited unless the physician introduces that guideline first.
 - The evidence-based guidelines should be developed and promulgated by national medical specialty societies or other public or private groups that provide physicians with substantial representation on oversight committees and with central decision-making roles in the development of the guidelines.
 - Implementation of the evidence-based guidelines in the pilot program should be done in accord with AMA policy H-410.980 “Principles for the Implementation of Clinical Practice Guidelines at the Local/State/Regional Level.”

AMA Policy

H-435.947 Liability Reform in Health Care Reform

Our American Medical Association: (1) supports that best clinical practice guidelines represent a medical guideline not a legal one and recognize and encourage that such guidelines do not supplant clinical judgment and that failure to follow each and every clinical guideline should not be used to create a presumption of negligence; and (2) will strongly advocate for clarification in any legislation or regulation relating to risk management, utilization review, and/or cost containment to ensure that any provision does not lead to new theories of liability, such as presumption of negligence in cases of hospital acquired conditions, or inadvertently create new legal causes of action against physicians. (Res. 206, I-09)

H-450.935 Health Care Standards

Our AMA: (1) supports the ability of non-governmental organizations to evaluate appropriate medical diagnosis or therapy or current or new diagnostic or therapeutic tests, procedures, medications or other procedures that improve the quality of patient care; (2) supports the position that any practice guidelines, parameters, best practices models, or similar set of principles or clinical recommendations, whether developed or issued by government or non-government organizations, including those that result from any comparative effectiveness research or evidence-based medicine system, do not, and should expressly state that they do not, establish standard of care or create specific requirements for physicians that restrict the exercise of their clinical judgment; (3) urges any organization, whether governmental or non-governmental, promulgating any practice guidelines, parameters, best practices models, or similar set of principles or clinical recommendations, to include a statement that they are guidelines only; and (4) urges any organization, whether governmental or non-governmental, promulgating any practice guidelines, parameters, best practices models, or similar set of principles or clinical recommendations, to set and make publicly available a regular schedule for review and update and to include the level of evidence supporting the guidelines. (Res. 205, A-10; Reaffirmation I-10)

Discussion of AMA principles

Principle 1: Participation in a pilot program relating to evidence-based guidelines would be voluntary for patients and physicians.

The first principle calls for voluntary participation for physicians and patients. There is a twofold purpose for making a program voluntary. First, it allows patients and physicians who are not interested in taking part in the pilot program to opt out of participating. Second, if there is a constitutional challenge to the pilot program, a system based on voluntary participation should have a better chance of surviving judicial scrutiny.

Principle 2: Physicians who elect to participate in the program would utilize evidence-based guidelines that could include a decision support process/application based on the guidelines.

The use of EBM guidelines could assist a physician in diagnosing and treating his or her patients. Assuming that a physician documents such use, then such documentation would assist with any subsequent legal proceedings. If a physician decides that the EBM guidelines are inapplicable in a case, then there should not be any legal penalty for this conclusion.

Principle 3: Participating physicians who follow evidence-based guidelines should receive liability protections for diagnosis and treatment in compliance with the guidelines.

The third principle calls for liability protections for physicians who follow EBM guidelines. If physicians do not have a liability safe harbor, then they will be hesitant to comply with an EBM guideline that calls for fewer tests or procedures. Such liability fears could undercut efforts to reduce unnecessary diagnoses and treatments, which in turn would limit any of the potential cost savings that could result from a decrease in defensive medicine.

Principle 4: Such liability protections could include, but are not limited to: (1) civil immunity related to the claims; (2) an affirmative defense to the claims; or (3) a higher burden of proof for plaintiffs.

Civil Immunity

The strongest option for states to pursue would be providing physicians with outright immunity in civil actions if they follow an EBM guideline. Earlier this year, Connecticut lawmakers introduced a bill (H.B. 6600) that included such immunity language in an early draft (relevant text in Sample Legislative Language section). The early language would have eliminated monetary liability and causes of actions against physicians who follow an EBM guideline and participate in the state's Sustinet plan. The language was deleted as the bill moved through the legislative process. The bill also called for the implementation of a no-fault system to compensate patients who do suffer an injury despite a physician's compliance with an EBM guideline. The bill carved out exceptions for (1) a mistaken determination that a guideline applies if such mistake is caused by the provider's negligence or intentional misconduct, or (2) a failure to properly follow a particular guideline where such failure is caused by the provider's negligence or intentional misconduct.

Affirmative defense

Another option for states would be to provide physicians with an affirmative defense if a physician followed an EBM guideline. The 1990 Maine law (full text in Sample Legislative Language section) provides an example of this approach. Under the program, the burden fell to the physician or the physician's employer to

prove that the physician was in compliance with the EBM guideline in order to be eligible to plead the affirmative defense. The defense was not used during the nine years that the law was in effect, and it was eventually sunset.

Increased evidentiary burden

A third option would be to require plaintiffs to prove their medical liability claim by clear and convincing evidence rather than just a preponderance of the evidence if a physician can document that he or she was following EBM guidelines. This would add another layer of liability protection for physicians involved in litigation. The AMA has called for the use of this standard for the award of punitive damages, and states have used it for claims related to emergency care. The AMA has also adopted this standard as the recommended standard for state medical board disciplinary proceedings.

Traditional MLR options

Finally, states could also link traditional medical liability reforms, such as caps on non-economic damages, affidavit of merit requirements or pre-trial screening panels for physicians participating in EBM guideline pilot projects. Such a legislative approach was included in HR 3400, “Empowering Patients First Act,” at the federal level. Introduced by Congressman Tom Price (R-GA), HR 3400 includes a provision that would impose limits on non-economic damage and punitive damage awards if a physician follows certain guidelines. HR 3400 would also prohibit a presumption of negligence if a participating physician does not adhere to the guidelines. It would also permit states to revise their medical liability statutes to include an affirmative defense if a physician follows certain EBM guidelines (relevant text in Sample Legislative Language section).

Principle 5: There would be no presumption of negligence if a participating physician does not adhere to the guidelines.

The fifth principle ensures that the court will not allow a presumption of negligence if the physician did not follow an EBM guideline. The plaintiff would still have the burden of proving all the elements of a negligence claim. If a presumption is permitted, then the burden could be shifted to the physician, who would then have to justify why deviating from the EBM guideline was the proper course of treatment.

Principle 6: Admissibility of a guideline by a plaintiff(s) should be prohibited unless the physician introduces that guideline first.

Under the sixth principle, plaintiffs would only be able to introduce an EBM guideline if the physician introduced it first. The 1990 Maine statute included such a provision. The purpose is to protect physicians who used their own discretion and did not follow the EBM guideline. This principle ensures that plaintiffs cannot distort the purpose of EBM guidelines and use them as a tool to expand physician liability.

Principle 7: The evidence-based guidelines should be developed and promulgated by national medical specialty societies or other public or private groups that provide physicians with substantial representation on oversight committees and with central decision-making roles in the development of the guidelines.

The seventh principle addresses the development and promulgation of EBM guidelines. Ideally, the EBM guidelines would be developed by national medical specialty societies or other physician-led organizations, but governmental, quasi-governmental and private organizations are already involved in the process – especially with comparative effectiveness research (CER) initiatives. The drafters of any pilot project should consider making the liability protections broad enough to cover these circumstances.

Principle 8: Implementation of the evidence-based guidelines in the pilot program should be done in accord with AMA policy H-410.980 “Principles for the Implementation of Clinical Practice Guidelines at the Local/State/Regional Level.”

This policy should be followed by those entities implementing the pilot program. The text of the policy follows:

Our AMA has adopted the following principles regarding the implementation of clinical practice guidelines at the local/state/regional level:

(1) Relevant physician organizations and interested physicians shall have an opportunity for input/comment on all issues related to the local/state/regional implementation of clinical practice guidelines, including: issue identification; issue refinement, identification of relevant clinical practice guidelines, evaluation of clinical practice guidelines, selection and modification of clinical practice guidelines, implementation of clinical practice guidelines, evaluation of impact of implementation of clinical practice guidelines, periodic review of clinical practice guideline recommendations, and justifications for departure from clinical practice guidelines.

(2) Effective mechanisms shall be established to ensure opportunity for appropriate input by relevant physician organizations and interested physicians on all issues related to the local/state/regional implementation of clinical practice guidelines, including: effective physician notice prior to implementation, with adequate opportunity for comment; and an adequate phase-in period prior to implementation for educational purposes.

(3) Clinical practice guidelines that are selected for implementation at the local/state/regional level shall be limited to practice parameters that conform to established principles, including relevant AMA policy on practice parameters.

(4) Prioritization of issues for local/state/regional implementation of clinical practice guidelines shall be based on various factors, including: availability of relevant and high quality practice parameter(s), significant variation in practice and/or outcomes, prevalence of disease/illness, quality considerations, resource consumption/cost issues, and professional liability considerations.

(5) Clinical practice guidelines shall be used in a manner that is consistent with AMA policy and with their sponsors' explanations of the appropriate uses of their clinical practice guidelines, including their disclaimers to prevent inappropriate use.

(6) Clinical practice guidelines shall be adapted at the local/state/regional level, as appropriate, to account for local/state/regional factors, including demographic variations, patient case mix, availability of resources, and relevant scientific and clinical information.

(7) Clinical practice guidelines implemented at the local/state/regional level shall acknowledge the ability of physicians to depart from the recommendations in clinical practice guidelines, when appropriate, in the care of individual patients.

(8) The AMA and other relevant physician organizations should develop principles to assist physicians in appropriate documentation of their adherence to, or appropriate departure from, clinical practice guidelines implemented at the local/state/regional level.

(9) Clinical practice guidelines, with adequate explanation of their intended purpose(s) and uses other than patient care, shall be widely disseminated to physicians who will be impacted by the clinical practice guidelines.

(10) Information on the impact of clinical practice guidelines at the local/state/regional level shall be collected and reported by appropriate medical organizations. (CMS Rep. D, A-93; Reaffirmed: CMS Rep. 10, A-03)

State programs

The Maine program was established in 1990. It focused on a handful of practice parameters from four specialties: anesthesiology, emergency medicine, obstetrics/gynecology and radiology. The practice parameters were either developed by the national medical specialty societies or created by state specialty advisory committees. The goal was to eliminate litigation over the standard of care in medical liability claims by providing physicians with an affirmative defense - if they followed the guidelines. The program was established for five years originally, and it was extended once before being sunset. A majority of the physicians in each of the four specialties had to enroll in order to trigger the start of the program, which they did. While the program was successful in enrolling sufficient numbers of physicians, it was unsuccessful in finding a test case that would have measured the effectiveness of the affirmative defense, so it went unutilized while the program was in existence.

While Florida, Maryland, Minnesota, and Vermont also attempted to implement similar programs, they did not proceed as far as Maine on this issue. Minnesota enacted legislation in 1992 that would have created a safe harbor for the use of EBM guidelines. However, like Maine, the provision was not used in a legal proceeding. The Minnesota legislature established an advisory committee to develop statewide practice parameters. The committee met for over two years and developed a few parameters, but they were not helpful in providing liability protection. Minnesota repealed the statute in 1995.

As part of Vermont's efforts to enact universal access in the early 1990s, the state passed a contingent amendment that would have allowed state-sanctioned practice guidelines to be used as the standard of care in medical liability cases. The provision never went into effect. Florida and Maryland also attempted to address EBM guidelines and medical liability, but these programs were not pursued after initial implementation efforts.

Sample legislative language

Connecticut House Bill 6600, Section 7, January 2009 (not enacted)

“Notwithstanding any provision of the general statutes, there shall be no monetary liability on the part of, and no cause of action for damages shall arise against, a participating provider for a Sustinet Plan member's injury caused by such provider's provision of care when such care was consistent with guidelines approved by the board. The board shall establish and implement a process for providing a member with no-fault compensation for injuries sustained by such member notwithstanding the fact that the provider's provision of care was consistent with guidelines approved by the board. Exemption from liability shall not apply to injuries that result from: (1) A mistaken determination by the provider that a particular guideline applied to a particular patient, where such mistaken determination is caused by the provider's negligence or intentional misconduct, or (2) a

failure to properly follow a particular guideline where such failure is caused by the provider's negligence or intentional misconduct.”

Maine Medical Liability Demonstration Project, 24 M.R.S. § 2971 (repealed)

§ 2971. Medical Liability Demonstration Project

The Bureau of Insurance and The Board of Registration in Medicine shall, by January 1, 1992, establish a Medical Liability Demonstration Project as provided in this subchapter.

§ 2972. Medical Specialty Advisory Committees Established

1. Medical specialty areas. The Medical Specialty Advisory Committee on Anesthesiology, in accordance with Title 5, Section 12004-i, Subsection 58-a; the Medical Specialty Advisory Committee on Emergency Medicine, in accordance with Title 5, Section 12004-i, Subsection 58-b; and the Medical Specialty Advisory Committee on Obstetrics and Gynecology, in accordance with Title 5, Section 12004-i, Subsection 58-c are established and shall develop practice parameters and risk management protocols for their respective medical specialty areas.

2. Membership. The Medical Specialty Advisory Committees are made up as follows.

A. The Medical Specialty Advisory Committee on Anesthesiology consists of members with an interest in and knowledge of the specialty area. It consists of 6 members:

(1) one physician who practices in a tertiary hospital, appointed by the Board of Registration in Medicine;

(2) one physician who practices in a medium-sized hospital, appointed by the Board of Registration in Medicine;

(3) one physician who practices primarily in a rural area, appointed by the Board of Registration in Medicine;

(4) one board-certified anesthesiologist, appointed by the Governor in consultation with the Maine Chapter of the American Society of Anesthesiologists; and

(5) two public members:

(a) one representing the interests of payors of medical costs, appointed by the President of the Senate; and

(b) one representing the interests of consumers, appointed by the Speaker of the House of Representatives.

B. The Medical Specialty Advisory Committee on Emergency Medicine consists of members with an interest in and knowledge of the specialty area. it consists of 9 members:

(1) one physician who practices in a tertiary hospital, appointed by the Board of Registration in Medicine from nominations submitted by the Maine Medical Association;

(2) one physician, appointed by the Board of Osteopathic Examination and Registration from nominations submitted by the Maine Osteopathic Association;

(3) one physician who practices primarily in a rural area, appointed by the Board of Registration in Medicine from nominations submitted by the Maine Medical Association;

(4) one family practice physician, appointed by the Board of Registration in Medicine from nominations submitted by the Maine College of Family Physicians;

(5) two physicians, appointed by the Governor, at least one of whom is board certified in emergency medicine, appointed in consultation with the Maine Chapter of the American College of Emergency Medicine Physicians; and

(6) three public members:

(a) one representing the interests of payors of medical costs, appointed by the President of the Senate;

(b) one representing the interests of consumers, appointed by the Speaker of the House of Representatives; and

(c) one representing allied health professionals, appointed by the Governor.

C. The Medical Specialty Advisory Committee on Obstetrics and Gynecology consists of members with an interest in and knowledge of the specialty area. It consists of 9 members:

(1) one physician who practices in a tertiary hospital, appointed by the Board of Registration in Medicine from nominations submitted by the Maine Medical Association;

(2) one physician who practices in a medium-sized hospital appointed by the Board of Osteopathic Examination and Registration from nominations submitted by the Maine Osteopathic Association;

(3) one physician who practices primarily in a rural area, appointed by the Board of Registration in Medicine from nominations submitted by the Maine Medical Association;

(4) one physician who practices primarily in a rural area, appointed by the Board of Osteopathic Examination and Registration from nominations submitted by the Maine Osteopathic Association;

(5) one family practice physician, appointed by the Board of Registration in Medicine from nominations submitted by the Maine Academy of Family Physicians;

(6) one board-certified physician, appointed by the Governor in consultation with the Maine Chapter of the American College of Obstetricians and Gynecologists; and

(7) three public members:

(a) one representing the interests of payors of medical costs, appointed by the President of the Senate;

(b) one representing the interests of consumers, appointed by the Speaker of the House of Representatives; and

(c) one representing allied health professionals, appointed by the Governor.

3. Terms. Each member serves a term of 3 years.

4. Proceedings. The Medical Specialty Advisory Committees shall conduct all proceedings pursuant to the Maine Administrative Procedure Act.

5. Board of Registration in Medicine; Administration and Funding. The Board of Registration in Medicine shall provide funding and administrative support to the Medical Specialty Advisory Committees. The Board of Registration in Medicine may accept funds from outside sources, including the Board of Osteopathic Examination and Registration, to help finance the operation of the Medical Specialty Advisory Committees.

§ 2973. Practice Parameters; Risk Management Protocols

Each medical specialty advisory committee shall develop practice parameters and risk management protocols in the medical specialty area relating to that committee. The practice parameters must define appropriate clinical indications and methods of treatment within that specialty. The risk management protocols must establish standards of practice designed to avoid malpractice claims and increase the defensibility of the malpractice claims that are pursued. The parameters and protocols must be consistent with appropriate standards of care and levels of quality. The Board of Registration in Medicine and the Board of Osteopathic Examination and Registration shall review the parameters and protocols, approve the parameters and protocols appropriate for each medical specialty area and adopt them as rules under the Maine Administrative Procedure Act.

§ 2974. Report to Legislature

By March 1, 1991, each medical specialty advisory committee shall provide a report to the joint standing committee of the legislature having jurisdiction over judiciary matters and the office of the executive director of the legislative council setting forth the parameters and protocols developed by that medical specialty advisory committee and adopted by the Board of Registration in Medicine and the Board of Osteopathic Examination and Registration. The Medical Specialty Advisory Committees also shall report the extent to which the risk management protocols reduce the practice of defensive medicine.

§ 2975. *Application to Professional Negligence Claims*

1. *Introduced by Defendant.* In any claim for professional negligence against a physician or the employer of a physician participating in the project established by this subchapter in which a violation of a standard of care is alleged, only the physician or the physician's employer may introduce into evidence, as an affirmative defense, the existence of the practice parameters and risk management protocols developed and adopted pursuant to Section 2973 for that medical specialty area.

2. *Burden of Proof; Parameters and Protocols.* Any physician or physician's employer who pleads compliance with the practice parameters and risk management protocols as an affirmative defense to a claim for professional negligence has the burden of proving that the physician's conduct was consistent with those parameters and protocols in order to rely upon the affirmative defense as the basis for a determination that the physician's conduct did not constitute professional negligence. If the physician or the physician's employer introduces at trial evidence of compliance with the parameters and protocols, then the plaintiff may introduce evidence on the issue of compliance. This subsection does not affect the plaintiff's burden to prove the plaintiff's cause of action by a preponderance of the evidence as otherwise provided by law.

3. *No Change in Burden of Proof.* Nothing in this subchapter alters the burdens of proof in existence as of December 31, 1991, in professional negligence proceedings.

4. *Application.* This section applies to causes of action accruing between January 1, 1992 and December 31, 1996.

§ 2976. *Physician Participation*

Any physicians practicing in a medical specialty area for which practice parameters and risk management protocols have been developed and adopted pursuant to Section 2973, shall file notice with the Board of Registration in Medicine or the Board of Osteopathic Examination and Registration prior to November 1, 1991, indicating whether they elect to participate in the project. The Medical Liability Demonstration Project authorized by this subchapter does not begin with respect to a medical specialty area unless at least 50% of the physicians licensed in the state and practicing in that specialty area elect to participate. Continuation of a project is not dependent on the level of participation.

§ 2977. *Evidence; Inadmissibility*

Unless independently developed from a source other than the demonstration project, the practice parameters and risk management protocols are not admissible in evidence in a lawsuit against any physician who is not a participant in the demonstration project or against any physician participating in the project who is defending against a cause of action accruing before January 1, 1992 or after December 31, 1996.

§ 2978. *Information and Reports*

1. *Reports by insurers.* Any insurance company providing professional, malpractice or any other form of liability insurance for any physician practicing in a medical specialty area described in Section 2972 or for any hospital in which that practice has taken place shall provide to the Bureau of Insurance in a format established by the superintendent the following:

A. A report of each claim alleging malpractice during the 5-year period ending December 31, 1991, involving any physician practicing in a medical specialty area described in Section 2972. Each report must include the name of the insured, policy number, classification of risk, medical specialty, date of

claim and the results of the claim, including defense costs and indemnity payments as a result of settlement or verdict, as well as any awards paid in excess of policy limits. For any claim still open, the report must include the amount of any funds allocated as reserve or paid out. The insurance company shall annually report on any claims that have remained open;

B. For the 5-year period ending December 31, 1991, an annualized breakdown of the medical liability premiums earned for physicians practicing in the medical specialty areas described in Section 2972. This information must be provided according to a schedule established by the Bureau of Insurance;

C. A report of each claim brought against any physician practicing in a medical specialty area described in Section 2972, alleging malpractice as a result of incidents occurring on or after January 1, 1992 and before January 1, 1997, that includes, but is not limited to, the name of the insured, policy number, classification of risk, medical specialty, date of claim and the results of each claim, including defense costs and indemnity payments as a result of settlement or verdict, any awards or amounts paid in excess of policy limits and any finding, if made, of whether the physician's practice was consistent with the parameters and protocols developed and adopted under Section 2973. These reports must be provided not less than semiannually according to a schedule established by the Bureau of Insurance. At the discretion of the Bureau of Insurance, reports must be provided until all claims are closed; and

D. An annualized breakdown of the medical liability premiums earned, as of January 1, 1992, for physicians practicing in the medical specialty areas described in Section 2972. This information must be provided according to a schedule established by the Bureau of Insurance.

2. Reports by Bureau of Insurance and Board of Registration in Medicine. The Bureau of Insurance and the Board of Registration in Medicine shall report the results of the project to the Governor and to the joint standing committees of the legislature having jurisdiction over insurance and judiciary matters and to the office of the executive director of the legislative council by December 1, 1997. The report must include the following.

A. The Bureau of Insurance shall report:

- (1) the number of claims brought against physicians in the project alleging malpractice as a result of incidents occurring on or after January 1, 1992;*
- (2) the results of any closed claims described in this section, including defense costs and indemnity payments as a result of settlement or verdict;*
- (3) the status of all open claims described in this section, including defense costs, indemnity payments and any amounts held in reserve; and*
- (4) the effect of the project on the medical liability claims experience and premiums of those physicians in the project.*

B. The Board of Registration in Medicine shall quantify and report on any identifiable impact of the project on the cost of the practice of defensive medicine.

- (1) the Board of Registration in Medicine shall establish an economic advisory committee to establish the methodology for evaluating the effect of the project on the cost, utilization and the practice of defensive medicine. The economic advisory committee shall report the methodology developed to the Board of Registration in Medicine by January 1, 1992.*

3. Immunity. All insurers reporting under this section and their agents or employees, the superintendent and the superintendent's representatives, the Board of Osteopathic Examination and

Registration and its agents and employees and the Board of Registration in Medicine and its agents or employees, including members of the Medical Specialty Advisory Committees established under Section 2972, are immune from liability for any action taken by them pursuant to this subchapter.

4. Confidentiality. Reports made to the superintendent and report records kept by the superintendent are not subject to discovery and are not admissible in any trial, civil or criminal, other than proceedings brought before or by the Board of Registration in Medicine or the Board of Osteopathic Examination and Registration. The superintendent shall maintain the reports filed in accordance with this section and all information derived from the reports that identifies or permits identification of the insured or the incident for which a claim was made as strictly confidential records. Information derived from reports filed in accordance with this section that does not identify or permit identification of any insured or incident for which a claim was made may be released by the superintendent or otherwise made available to the public.

5. Rules. The superintendent and the Board of Registration in Medicine may adopt rules necessary to implement this subchapter.

Sec. 6. Medical Demonstration Project Advisory Committee. The Medical Demonstration Project Advisory Committee is established to review the Medical Liability Demonstration Project established by the Maine Revised Statutes, Title 24, Chapter 21, Subchapter ix and make recommendations to the Governor and the legislature regarding the project.

1. The Medical Demonstration Project Advisory Committee consists of the following 14 members:

- a. the chair of the Board of Registration in Medicine or a designee;*
- b. the chair of the Board of Osteopathic Examination and Registration or a designee;*
- c. the president of the Maine Medical Association or a designee;*
- d. the president of the Maine Osteopathic Association or a designee;*
- e. the president of the Maine Academy of Family Practice Physicians or a designee;*
- f. the president of the Maine State Bar Association or a designee;*
- g. the president of the Maine Trial Lawyers Association or a designee;*
- h. a representative of a tertiary hospital, to be appointed by the Governor;*
- i. a representative of an insurer providing medical malpractice insurance in the state, to be appointed by the Governor;*
- j. a representative of a profit or nonprofit health insurer, to be appointed jointly by the President of the Senate and the Speaker of the House of Representatives;*
- k. the superintendent of insurance or a designee; and*
- l. three public members, one to be appointed by the Governor, one to be appointed by the President of the Senate and one to be appointed by the Speaker of the House of Representatives.*

The appointing authorities shall make the appointments no later than August 1, 1990, and shall report the names of the members to the office of the executive director of the legislative council. The chair of the legislative council shall call the first meeting on or before October 1, 1990.

2. The committee shall annually elect a chair from among the members.

3. The committee may review Title 24, Chapter 21, Subchapter ix, consult with interested parties and develop recommendations to be submitted to the legislature, the Governor and the executive director of the legislative council concerning the Medical Liability Demonstration Project, including the levels of participation and other participation requirements.

4. *The committee may submit any implementing legislation it prepares pursuant to this section to the joint standing committee on judiciary and the office of the executive director of the legislative council. The committee members shall serve without legislative staff assistance.*

5. *All members of the committee shall serve without compensation and are not entitled to reimbursement for expenses.*

6. *This section is repealed on December 31, 1996.*

Minnesota Statutes, 1992, 62J.34 Outcome-based Practice Parameters. (repealed)

Subdivision 1. [PRACTICE PARAMETERS.] The health care analysis unit may develop, adopt, revise, and disseminate practice parameters, and disseminate research findings, that are supported by medical literature and appropriately controlled studies to minimize unnecessary, unproven, or ineffective care. Among other appropriate activities relating to the development of practice parameters, the health care analysis unit shall:

(1) determine uniform specifications for the collection, transmission, and maintenance of health outcomes data; and

(2) conduct studies and research on the following subjects:

(i) new and revised practice parameters to be used in connection with state health care programs and other settings;

(ii) the comparative effectiveness of alternative modes of treatment, medical equipment, and drugs;

(iii) the relative satisfaction of participants with their care, determined with reference to both provider and mode of treatment;

(iv) the cost versus the effectiveness of health care treatments; and

(v) the impact on cost and effectiveness of health care of the management techniques and administrative interventions used in the state health care programs and other settings.

Subd. 2. [APPROVAL.] The commissioner of health, after receiving the advice and recommendations of the Minnesota health care commission, may approve practice parameters that are endorsed, developed, or revised by the health care analysis unit. The commissioner is exempt from the rulemaking requirements of chapter 14 when approving practice parameters approved by the federal agency for health care policy and research, practice parameters adopted for use by a national medical society, or national medical specialty society. The commissioner shall use rulemaking to approve practice parameters that are newly developed or substantially revised by the health care analysis unit. Practice parameters adopted without rulemaking must be published in the State Register.

Subd. 3. [MEDICAL MALPRACTICE CASES.]

(a) In an action against a provider for malpractice, error, mistake, or failure to cure, whether based in contract or tort, adherence to a practice parameter approved by the commissioner of health under subdivision 2 is an absolute defense against an allegation that the provider did not comply with accepted standards of practice in the community.

(b) Evidence of a departure from a practice parameter is admissible only on the issue of whether the provider is entitled to an absolute defense under paragraph (a).

(c) Paragraphs (a) and (b) apply to claims arising on or after August 1, 1993, or 90 days after the date the commissioner approves the applicable practice parameter, whichever is later.

(d) Nothing in this section changes the standard or burden of proof in an action alleging a delay in diagnosis, a misdiagnosis, inappropriate application of a practice parameter, failure to obtain informed consent, battery or other intentional tort, breach of contract, or product liability.

H. R. 3400, 111TH CONGRESS, 1ST SESSION (not enacted)

SEC. 515. AFFIRMATIVE DEFENSE BASED ON COMPLIANCE WITH BEST PRACTICE GUIDELINES.

(a) **SELECTION AND ISSUANCE OF BEST PRACTICES GUIDELINES.**—

(1) **IN GENERAL.**—The Secretary of Health and Human Services (in this section referred to as the “Secretary”) shall provide for the selection and issuance of best practice guidelines (each in this subsection referred to as a “guideline”) in accordance with paragraphs (2) and (3).

(2) **DEVELOPMENT PROCESS.**—Not later than 90 days after the date of the enactment of this Act, the Secretary shall enter into a contract with a qualified physician consensus-building organization (such as the Physician Consortium for Performance Improvement), in concert and agreement with physician specialty organizations, to develop guidelines for treatment of medical conditions for application under subsection (b). Under the contract, the organization shall take into consideration any endorsed performance-based quality measures described in section 802. Under the contract and not later than 18 months after the date of the enactment of this Act, the organization shall submit best practice guidelines for issuance as guidelines under paragraph (3).

(3) **ISSUANCE.**—

(A) **IN GENERAL.**—Not later than 2 years after the date of the enactment of this Act, the Secretary shall issue, by regulation, after notice and opportunity for public comment, guidelines that have been recommended under paragraph (2) for application under subsection (b).

(B) **LIMITATION.**—The Secretary may not issue guidelines unless they have been approved or endorsed by qualified physician consensus building organization involved and physician specialty organizations.

(C) **DISSEMINATION.**—The Secretary shall broadly disseminate the guidelines so issued.

(b) **LIMITATION ON DAMAGES.**—

(1) **LIMITATION ON NONECONOMIC DAMAGES.**— In any health care lawsuit, no noneconomic damages may awarded with respect to treatment that is within a guideline issued under subsection (a).

(2) **LIMITATION ON PUNITIVE DAMAGES.**—In any health care lawsuit, no punitive damages may be awarded against a health care practitioner based on a claim that such treatment caused the claimant harm if—

(A) such treatment was subject to the quality review by a qualified physician consensus-building organization;

(B) such treatment was approved in a guideline that underwent full review by such organization, public comment, approval by the Secretary, and dissemination as described in subparagraph (a); and

(C) such medical treatment is generally recognized among qualified experts (including medical providers and relevant physician specialty organizations) as safe, effective, and appropriate.

(c) **USE.**—

(1) INTRODUCTION AS EVIDENCE.—Guidelines under subsection (a) may not be introduced as evidence of negligence or deviation in the standard of care in any civil action unless they have previously been introduced by the defendant.

(2) NO PRESUMPTION OF NEGLIGENCE.—There would be no presumption of negligence if a participating physician does not adhere to such guidelines.

(d) CONSTRUCTION.—Nothing in this section shall be construed as preventing a State from—
(1) replacing their current medical malpractice rules with rules that rely, as a defense, upon a health care provider’s compliance with a guideline issued under subsection (a); or
(2) applying additional guidelines or safe-harbors that are in addition to, but not in lieu of, the guidelines issued under subsection (a).

Conclusion

As health system reform continues and the use of EBM guidelines increases, states may wish to consider a liability safe harbor for physicians. If not, their efforts to improve patient care and contain costs may not be successful. The AMA principles are a good foundation for states to start a program. For more information on this issue, please contact Mike Glasstetter at 312/464-5033 or at michael.glasstetter@ama-assn.org.