Statement 1

Position of the Federation of State Medical Boards

Practice Drift

When a physician is granted a license by a state medical board in the United States, the physician is given the privilege of practicing the full breadth of medicine. This general undifferentiated license provides physicians with broad discretion to expand, narrow, or alter their areas of practice as they see fit. While many physicians spend their entire careers practicing in the area in which they completed formal medical training, others decide to expand or shift their practice to additional areas beyond their recognized specialty.

In considering changing or expanding their areas of practice, physicians have a professional and ethical duty to put their patients' best interests before their own and only offer treatments to patients that they are able to provide competently.

In recent times, various economic and lifestyle pressures have led to an increase in the rate at which physicians are seeking to change or expand their areas of practice.[1] This can be seen as a positive development for both physicians and the patients they treat: competently meeting patient health needs is an important way in which physicians fulfill their duty of beneficence to patients. Expanding one's area of practice can provide opportunities for alternate specializations to meet patient demands, as well as options for ensuring or increasing career satisfaction. For patients, flexibility in terms of the areas of practice of physicians can provide greater assurances that they will have access to medical care when needs arise.

However, changes in physicians' areas of practice may also present risks to patients in circumstances where a physician is not appropriately trained to provide the treatments that fall within their newly chosen area of practice. As such, it is incumbent upon physicians to ensure that they are able to demonstrate competence in their selected area of practice and that they only provide treatments to patients for which they have received adequate and appropriate training. This will often involve seeking additional training by attending educational programs. Physicians are encouraged to seek information about the quality of any such programs by researching their accreditation status and the nature of any oversight involved.

Additional training sought need not always be limited to formal medical training offered through academic medical centers or continuing medical education providers, but can also include observation of procedures performed by recognized experts, followed by provision of these same procedures under the supervision of a qualified physician. Once a physician has taken the appropriate steps to be able to demonstrate competence in an area outside of their recognized area of practice, it is recommended that the physician

[1] St. Peter, et al., Changes in the Scope of Care Provided by Primary Care Physicians, *N Engl J Med* 1999; 341:1980-1985

determine whether their medical liability insurance adequately covers them in the performance of any new procedures.

Fundamental to the concept of professional self-regulation is the development of principles of medical ethics and the enforcement of professional expectations and standards by the medical profession itself. Hospital administrators should therefore be diligent in monitoring the areas of practice of physicians at the time of reappointment to ensure that adequate training has been received for procedures listed. Where feasible, state medical boards can also examine physicians' insurance billing patterns in the course of investigations to determine whether practice areas have shifted to include non-traditional procedures for given specialties, or whether harms may have resulted from the performance of procedures in the absence of adequate qualifications or training.

It is also essential that patients only seek medical treatment from physicians who are qualified to provide the medical care that they need. Patients should therefore seek information about prospective physicians, including the level of experience they have with particular procedures, their education (especially graduate medical education), and any board certifications held. Patients are encouraged to ask their physicians about their qualifications for performing particular procedures and also to consult the Federation of State Medical Boards' DocInfo website where they can find information about physicians' education, board certifications, and any disciplinary actions taken against a physician's license.

A related responsibility exists on the part of physicians to clearly inform patients regarding their training and credentials to perform specific procedures or services. Physicians should also be prepared to provide information about their qualifications and any additional training undertaken that has prepared them to provide treatment that falls outside of their original area of practice and should provide this information to patients as part of the informed consent process.

While licenses granted by state medical boards allow licensees to practice the full breadth of medicine and surgery, boards are nonetheless responsible for ensuring that licensees can practice competently within their chosen area of practice. In fulfilling this responsibility, state medical boards are encouraged to collect information about licensees' areas of practice as part of the license renewal process. This may increase their ability to protect patients within their jurisdictions in the event that issues with a licensee's area of practice arises. The FSMB has provided recommendations for categories of information to collect, as well as possible formatting of questions, in its Report on a Recommended Framework for a Minimal Physician Data Set.

Statement 2

Position of the Federation of State Medical Boards

Duty to Report

In order for state medical boards to fulfill their mission to regulate the medical profession in the interests of patients, it is essential that they are equipped with all relevant information that allows them to operate effectively. Some of the information that is pertinent to patient safety and protection is not immediately available to state medical boards in the course of their existing programs and functions. As such, boards rely upon other individuals and entities to submit this information, as necessary.

A sample of relevant categories of information includes patient safety issues and events, observed impairment, incapacity or incompetent performance, and instances of professional misconduct, including but not limited to child abuse, sexual misconduct with patients or surrogates, controlled substance diversion, fraudulent billing, and other disruptive behavior.

All of these categories of information include instances of harm to patients, or circumstances that have a high risk of leading to patient harm. In addition to the oft-cited professional obligation to "do no harm," physicians also have various responsibilities to patients that fall under the ethical principle of beneficence. These involve promoting the best interests of patients by preventing harm from occurring to them and by removing conditions that will lead to their harm. The duty to report is a fundamental way in which physicians and others can fulfill duties of beneficence by removing potentially harmful conditions.

While responsibilities to report this information to state medical boards and other relevant parties are outlined in state medical practice acts and other legislation, the Federation of State Medical Boards (FSMB) wishes to highlight the importance of reporting relevant information to the state medical boards themselves. In a system that protects the public and that is complaint based, it is imperative that state medical boards have access to the information necessary to fulfill their duties of beneficence. Peers, the public, hospitals, and insurers support the fulfillment of these duties by reporting instances of professional misconduct or incompetence to state medical boards.

In its *Essentials of a State Medical and Osteopathic Practice Act*, the FSMB provides sample language that addresses a wide variety of infractions and the related reporting responsibilities. In addition to physicians' duties to report any actions against their own licenses or hospital privileges, the *Essentials* outlines duties that reside with other physicians and organizations to report, or cause a report to be made, to the state medical board anytime there is evidence or information that appears to show that a physician is incompetent, guilty of negligence, guilty of a violation of the medical practice act, engaging in inappropriate relationships with patients, is mentally or physically unable to practice safely, or has an alcohol or drug abuse problem. The *Essentials* further states that these same duties exist on the part of hospital or health organization chief executive officers, medical officers, and medical staff. This is in addition to their duty to report to

the state medical board any adverse action taken by a health care institution or peer review body.

Despite similar language being included in most states' medical practice acts, there is evidence that demonstrates that reporting often does not occur. Campbell and colleagues found in a survey of 3504 physicians that while "96% of respondents agreed that physicians should report impaired or incompetent colleagues to relevant authorities, 45% of respondents who encountered such colleagues had not reported them."[2]

With respect to institutional reporting, the FSMB has heard complaints from its member boards that hospitals and health organizations regularly ignore reporting requirements, find ways to circumvent them, or provide reports that are too brief and general to equip the board with relevant information for carrying out its regulatory functions. Boards have reported having to resort to subpoenaing hospital medical directors, threatening disciplinary action to obtain information, and resorting to civil sanctions. In some instances, failures to report by physicians and hospitals have resulted in additional avoidable adverse events to patients.

An inability to report anonymously in some jurisdictions or health organizations may inhibit physicians and members of the public from making reports. This may also force physicians who choose to make reports to take reputational risks and jeopardize interprofessional relations. While physicians and hospital administrators are encouraged to adhere to the relevant legislation in their jurisdictions and fulfill their professional duty to report, the ability to make anonymous complaints and avoid being identified during hearing processes contributes to a culture that encourages reporting of adverse events and clinical conditions. As such, state medical boards and hospital administrators should work to ensure that appropriate protections are in place to enable physicians and patients to complain anonymously.

[2] Campbell, EG, et al., *Annals of Int Med* 2007;147(11) 795-802

Statement 3

Position of the Federation of State Medical Boards

Sale of Goods by Physicians and Physician Advertising

Sale of Goods by Physicians

Physicians may choose to make health-related and non-health-related goods available to patients from their offices or on their practice websites. This is often in order to meet a legitimate patient need in instances where the goods are medically necessary for patients and not immediately or reliably available to patients by other means.

Physicians who choose to make goods available to patients must be mindful of the inherent power differential that characterizes the physician-patient relationship and therefore the significant potential for exploitation of patients. Physicians must always place the interests of their patients above their own financial interests so that they may avoid conflicts among these interests that could place patient wellbeing at risk. This means only offering treatments or products that can be shown to maintain or enhance their patients' health, in accordance with professional duties of beneficence. Physicians also demonstrate respect for patient autonomy by allowing patients to make their own informed health-related decisions in the absence of any undue influence arising from the substantial degree of trust they have in their physicians.

In order to avoid any perceived or real conflicts of interest, physicians should:

- Make products available at reasonable cost and refrain from excessive mark-ups,
- Ensure that products sold balance benefits to patients with any financial benefit to the physician,
- Provide a disclosure statement with the sale of any goods, informing patients of their financial interests,
- Not engage in exclusive distributorships and/or personal branding, and
- Only offer products that are not otherwise readily available to patients.

An exception exists with respect to non-health-related goods associated with a charitable or service organization (for example, raffle tickets for a local charity or Girls Scout cookies). If physicians choose to make such goods available, they are encouraged to follow the advice of the American Medical Association and ensure that: "(1) the goods in question are low-cost; (2) the physician takes no share in profit from their sale; (3) such sales are not a regular part of the physician's business; (4) sales are conducted in a dignified manner; and (5) sales are conducted in such a way as to assure that patients are not pressured into making purchases."[3]

The principle of non-exploitation of patients also applies to scenarios involving physician-owned pharmacies located in practice offices. In such instances, physicians

[3] Opinion 8.062 of the American Medical Association, "Sale of Non-Health-Related Goods from Physicians' Offices"

should offer patients freedom of choice in filling any prescriptions and must therefore allow prescriptions to be filled elsewhere. The existence of such a pharmacy must not influence the physician's clinical judgment in any way and does not change the acceptable standard of care. Further, if medications are prepared and dispensed by physicians and members of their staff, rather than by licensed pharmacists, patients may not be offered the same safeguards and safety checks that pharmacists are obligated by law to provide.

Physician Advertising

Physicians are permitted to advertise themselves, their practice and services offered, provided that the advertisements do not contain any claims that may be deceptive or are intentionally false or misleading. Further, physicians should be mindful of ways in which patient testimonials, quality ratings, or other evaluative data is presented to prospective patients through advertisements. Such information must be presented in an objective manner and physicians must not deliberately misrepresent the expected outcomes or results of treatments offered. This also applies to advertisements about the benefits or efficacy of medical devices sold or rented by physicians. Physicians should be prepared to support any claims made about benefits of treatments or devices with documented evidence, for example with studies published in peer-reviewed publications.

Physicians must be accurate and not intentionally misleading in providing descriptions of their training, skills, or treatments they are able to competently offer to patients. This includes descriptions of one's specialization and any specialty board certifications. For example, a family physician who chooses to expand his or her area of practice to offer cosmetic procedures cannot describe him or herself as a cosmetic or plastic surgeon in advertisements, unless they have undergone the appropriate postgraduate training to assume the relevant title. As part of the informed consent process, it is essential that patients are fully informed and not misled about any treatment to which they are consenting, as well as the qualifications of the person or people providing it.

Statement 4

Position of the Federation of State Medical Boards

Compounding of Medications by Physicians

Compounding means combining or preparing separate ingredients into a single medication for a specific patient. A common example of a compounded drug is an allergy medication that is typically available in pill form, but may be compounded for patients who wish to take it in eye drop or nasal mist form. However, compounding can involve numerous types of preparations, from simple dilution to the complex creation of a novel substance.

Safety concerns exist with compounded drugs, especially those drugs that require a sterile preparation such as injectable drugs, irrigations, or inhalants. If a pathogenic agent is introduced into a drug during the compounding process, it can result in significant patient harm and even death. Further, medications that are compounded incorrectly have the potential to harm patients. Compounding should therefore occur according to protocols to ensure that ingredients are added in the appropriate proportions.

The decision to compound or prescribe a compounded medication should be in the best interests of the patient. The prescription of a compound and the act of compounding should be triggered by a specific need in an individual patient. Medications should not be compounded in bulk in anticipation of patients who exhibit a particular set of symptoms. This could fall under the definition of medication manufacturing, a practice that presents greater safety risks to patients and is therefore restricted to entities that are registered with the FDA and abide by a more stringent set of safeguards for the preparation of medications.

Physicians must ensure that active ingredients included in a compound are necessary for treating a medical condition in an individual patient. The medical condition and rationale for prescribing a compounded medication should be reflected in the patient's medical record. Physicians must not add or request the addition of unnecessary substances in order to ensure a higher rate of reimbursement, as this would unnecessarily put patients at greater risk. Physicians must also refrain from charging unreasonable or excessively high fees for compounded medications. This would be considered exploitation of the patient.

In instances where patients require sterile medications in forms that are different from those typically available, physicians are encouraged to establish relationships with pharmacies or other entities that have registered as outsourcing facilities with the U.S. Food and Drug Administration (FDA). These facilities are required to compound according to "good manufacturing practices" and are subject to risk-based inspection and additional standards that reduce the risk that contamination might occur during the compounding process.

If physicians choose to compound medications themselves, they are encouraged to limit compounding activity to non-sterile preparations and also to consult Federal and state legislation regarding compounding and dispensing drugs. While state legislation on

compounding varies across the U.S., physicians are encouraged to familiarize themselves with the requirements set out in the United States Pharmacopeia-National Formulary (USP-NF), particularly sections 795, 797, and 800. Sections 795 and 797 provide guidance on the preparation of non-sterile and sterile compounds and describe conditions and practices that can prevent patient harm. Section 800 addresses the compounding and handling of hazardous drugs in healthcare settings. These sections of the USP-NF also describe the responsibilities of supervisors of compounding practices, which may be relevant for physicians who oversee compounding activities of employed staff.

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