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Lecture Series on Patient Rights To Begin in Early February

An ASLM sponsored lecture series on "The Rights of Hospital Patients and the Consumers' Role in Health Care Policy" will begin on February 4, 1976 at 4:00 p.m. in the Ames Courtroom at Harvard Law School. The lecture series will run for six weeks, from February 4 to March 10, and will meet every Wednesday at Harvard Law School from 4:00-6:00 p.m. Topics to be covered include hospital and physician liability, the emergency room, malpractice, informed consent, human experimentation, patients' rights, the right to refuse treatment, the "living will," unionization of hospital personnel, OSHA, certificate of need, the consumer's role under the National Health Planning and Resources Development Act of 1974, and confidentiality and privacy of medical records (including PSRO profiles).

Program Director and principal lecturer will be George J. Annas, J.D., M.P.H., author of *The Rights of Hospital Patients* (Avon, 1975). Other experts will also participate, both as guest lecturers and as commentators on the lectures. The fee for the entire program, including all course materials, is \$75.00 for ASLM members and \$90.00 for nonmembers (single sessions are \$15 for members and \$25 for nonmembers). Full time students, interns and residents can register for \$30 for ASLM members and \$35 for nonmembers. The lecture series will be accredited for continuing education credits by the American Academy of Family Physicians and the Federation of Nursing Home Administrators. Physicians may also elect to receive credit from the American Medical Association, *Physicians Recognition Award* (Category II).

For a descriptive brochure, write the ASLM, 454 Brookline Avenue, Boston, MA 02215.

GUIDE TO PUBLISHED "STANDARDS OF CARE"

by
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Recent court decisions and legislative enactments in the medical and hospital malpractice areas suggest a growing trend toward substantial easing of the traditional plaintiff's burden of proof in defining the standard of professional conduct that he alleges was breached by the defendant physician, hospital or other health-care provider leading thereby to his suffering harm.

In an increasing number of jurisdictions, the pool of expert medical witnesses available to plaintiffs in malpractice actions has been significantly enlarged by court or legislature abolition of the long prevalent evidentiary requirement that an expert witness testifying as to the applicable standard of care be from the *same* community as the defendant (the locality rule) by allowing the expert to be drawn from the *same or similar* community and, in the case of specialists, applying a "national" standard. Also, in many states, the plaintiff can compel the *defendant physician, even though an adverse witness, to take the stand to provide through his own testimony a definition of the standard of care he is alleged to have breached.*

In regard to the admission in evidence of published standards of professional conduct and care, several states have, for some time, permitted the introduction, following due notice of intent, of medical texts and "learned" treatises without requiring that the author or authors be made available for cross-examination. Now, with widespread adoption by state legislative bodies of mandatory arbitration and pretrial screening panel hearings in medical malpractice cases, it can be expected that a wide variety of published definitions of "standards of care" for physicians, nurses, dentists and hospitals will be made available for inspection and consideration by arbitration board or panel members, and even by juries, to be considered as at least one acceptable mode of professional conduct against which the action of the defendant (or defendants) can be measured.

Accordingly, physicians, attorneys and others involved in medical and hospital malpractice actions must be aware of the types and sources of "standards of care" currently available in published form to avoid the obvious problems that will arise should such writings first come to their attention when produced by the adversary party in a courtroom or other legal forum.

To aid in the pretrial or prehearing evaluation of a given instance of alleged medical or hospital negligence or other form of malpractice, the following is a listing of categories of currently available published definitions and guidelines of medical care that might be accepted as a "standard of care" and the major bibliographic tools by which these writings can be located. Although every attempt has been made to make this compilation comprehensive, it is recognized that other potentially useful source data undoubtedly exist. To enhance the reference value of this material in future up-dates, *Medicolegal News* readers are urged to submit additional pertinent information to the attention of the author.

Even if these standards do not clear the evidentiary hurdles of admissibility, they are extremely useful to attorneys and physicians in determining appropriate conduct and procedures relevant to the issues at bar.

"Standards" Produced by Hospitals

Most hospitals publish for internal use a wide variety of material that, in part or in whole, outlines recommended or prescribed professional and administrative conduct in the area of patient-care and, therefore, can be considered as their own definitions of minimal acceptable "standards of care." Included among these are: admission and discharge procedures for out-patients, in-patients, emergency room, intensive care, recovery room and similar units; rules and regulations affecting staff physicians, department heads, interns

Continued on page 7

Guide to Published "Standards of Care"

(continued from page 1)

and residents, medical student participation in patient-care, nurses and other hospital personnel; safety and engineering regulations covering maintenance and inspection of hospital physical equipment; procedures for reporting accidents and untoward incidents; procedures to be followed in preparing patients for x-ray and other diagnostic testings and for surgery; rules and regulations concerning the prescription, dispensing, control, and records of drugs; and many other facets of the care of the hospital patient.

A convenient check-list of hospital publications potentially defining standards of professional care includes:

- The hospital by-laws and constitution
- Medical staff by-laws, constitution, regulations, etc.
- Hospital trustee, medical staff and professional committee rules, regulations and reports
- Departmental rules, regulations, guidelines, bulletins, memoranda, etc.
- Procedure books, instruction sheets, etc.
- Job description outlines
- Patient information sheets, booklets, pamphlets, such as "Patients' Rights," "Introduction to the Hospital," etc.

Publications of Medical Societies and Professional Organizations

State and national medical societies and other professional associations or groups frequently author and publish material for distribution to members and others covering various aspects of professional conduct, codes of professional ethics, statements of "official" policy, guidelines and standards of care in particular areas of medical and surgical treatment or define recommended or required standards of conduct for their membership in general and for admission to various categories of membership.

The number of such societies and professional groups is large and ever-growing. Bibliographic tools to locate a professional organization which may have published material pertinent to a particular "standard of medical care" include:

—JAMA Reference Directories — a bimonthly listing in the *Journal of the American Medical Association* of the names, addresses and officers of each state medical society, the State Boards of Medical Examiners and the U.S. Medical Specialty Boards.

—*Health Organizations of the United States, Canada and International*, published by the McGrath Publishing Company, 821 Fifteenth St., N.W., Washington, DC 20005

—*American Hospital Association Guide to the Health Care Field* — an annual

publication of the American Hospital Association, 840 North Lake Shore Drive, Chicago, IL 60611

—*Encyclopedia of Associations* — an annual publication of Gale Research Company, Book Tower, Detroit, MI 48826, covering all types of associations, including those pertinent to health-care delivery areas.

—*National Trade & Professional Associations of the United States and Canada*, published by Columbia Books, Inc., Room 601, 734 Fifteenth St., N.W., Washington, DC 20005

—*The Guide to Biomedical Standards* — an annual publication of the Quest Publishing Company, P.O. Box 4141, Diamond Bar, CA 91765

—*The Directory of Visual Aids for Hospital Safety Programs* — an annual publication of the Quest Publishing Company, P.O. Box 4141, Diamond Bar, CA 91765

—*Biomedical Safety & Standards Newsletter* — a monthly publication of the Quest Publishing Company, P.O. Box 4141, Diamond Bar, CA 91765

The following are representative professional organizations which have published various standards of care, safety, etc., applicable to health-care delivery. Interested readers can write directly to the appropriate organization for catalogs and price lists of available publications.

American Dental Association
211 East Chicago Avenue
Chicago, IL 60611

American Heart Association
7320 Greenville Avenue
Dallas, TX 75231

American Hospital Association
840 North Lake Shore Drive
Chicago, IL 60611

American Medical Association
535 North Dearborn Street
Chicago, IL 60610

American National Standards Institute
1430 Broadway
New York, New York 10018

American Nurses' Association
2420 Pershing Road
Kansas City, MO 64108

American Society for Artificial Internal Organs
3600 Spruce Street
Philadelphia, PA 19104

American Society for Testing and Materials
1916 Race Street
Philadelphia, PA 19103

Association for the Advancement of Medical Instrumentation
1500 Wilson Boulevard, Suite 417
Arlington, VA 22209

Factory Mutual System
Factory Mutual Public Relations and Publications

1151 Boston-Providence Turnpike
Norwood, MA 02062

Intersociety Commission for Heart Disease Resources

44 East 23rd Street, Suite 316
New York, New York 10010

Institute of Electrical and Electronic Engineers

345 E. 47th Street
New York, New York 10017

Instrument Society of America
400 Stanwix Street
Pittsburgh, PA 15222

Joint Commission on Accreditation of Hospitals
645 North Michigan Avenue
Chicago, IL 60611

National Committee for Clinical Laboratory Standards

771 E. Lancaster Avenue
Villanova, PA 19085

National Council on Radiation Protection and Measurements
P.O. Box 30175

Washington, D.C. 20014

National Electrical Manufacturers Association
155 East 44th Street

New York, New York 10017

National Fire Protection Association
470 Atlantic Avenue

Boston, MA 02210

National Sanitation Foundation
N.S.F. Building,

Ann Arbor, MI 48105

Underwriters' Laboratories
1285 Walt Whitman Road

Melville, N.Y. 11746

Manufacturers' Publications

Manufacturers of drugs and medical therapeutic and diagnostic devices and products customarily print and distribute a wide variety of promotional, educational and instructional literature. Designed primarily for physicians, such material contains specific recommendations and advice on the part of the manufacturer (and, therefore, often self-serving and self-protecting) as to accepted indications and recognized contraindications for the use of the drug or product, approved methods of usage, pertinent warnings against misuse, potential side effects, procedures for patient monitoring, reported risks and hazards, and known adverse interactions with other drugs or products, etc. Writings from these sources therefore, may well be accepted by a court, arbitration panel or a malpractice screening panel as a "standard" against which the conduct of a defendant health-care provider can be judged.

Sources for descriptive and warning literature published by manufacturers include: the releases from the manufacturer's sales and advertising department, the material the manufacturer provides its "detail" staff who call upon physicians and hospitals, the advertisements placed in professional periodicals, the "package inserts" and other labelling required by the FDA, and the many instructional and descriptive brochures, pamphlets, "warning letters" and other written material commonly mailed to physicians and hospitals.

A most useful source book of manufacturer's recommendations in the area of prescription drugs is the annual publication of Medical Economics, Inc. (Oradell, NJ 07649) entitled *Physician's Desk Reference*. More familiarly known as *PDR*, this

compendium of over 2,500 commonly used prescription drugs has been published annually since 1947 and is distributed without charge to almost every practicing physician and hospital in the U.S., as well as sold to many nonmedical personnel. Each annual issue of *PDR* and the quarterly cumulative supplements for a given year provide detailed information concerning listed drugs and the manufacturer's recommendations, usually in the same language and wording as the package insert approved by the Federal Food and Drug Administration as the official labelling of the product. *PDR* also provides a convenient source of the names and addresses of most U.S. pharmaceutical manufacturing companies with names of the person or departments to whom inquiries for further information should be addressed.

Legislative Enactments

Many federal, state, county and municipal statutes cover health-care delivery. Often, they specify rules, regulations and codes of conduct that must be adhered to by law with deviation therefrom preventing the obtaining of certain benefits otherwise available or constituting a criminal offense. One such example, frequently quoted in hospital malpractice actions, is Public Law 89-97 (Title 20, Code of Federal Regulations, Chapter III, part 405) which outlines the minimal standards that must be adhered to by hospitals desirous of participating in the Medicare Program and in receipt of payments for hospitalized Medicare patients.

Federal guidelines for medical care delivery for Professional Standards Review Organizations' consideration have been prepared in preliminary form in an 815 page volume by the American Medical Association detailing screening criteria for admission, treatment and evaluation of care for Medicare and Medicaid hospitalized patients. (The deadline for the final version is June 30, 1976.)

Strict guidelines defining the number of required services and benefits that must be provided under federal law for Health Maintenance Organizations have also been promulgated under the 1973 HMO Act.

One example of a municipal legislative enactment affecting health-care delivery is the little known amendment of 1947 to section 112 of the Sanitary Code of the City of New York which limits the collection and use of donor sperm in artificial insemination in New York City only to physicians licensed to practice in the State of New York and which, further, specifies in detail the physical and other examinations required by law on every prospective sperm donor, the medical disorders which forbid the use of donor sperm, and the records which the physician who performs an artificial insemination must keep.

State medical, dental, nursing, and other "Professional Practice" laws generally define in detail the minimally acceptable standards of education and training required for licensure, outline the scope of professional practice permitted, and recently have begun to include in the requirements for licensure maintenance evidence of accomplishment of continuing professional education.

In addition to those statutes which set forth the generally controlling principles of the law, myriads of regulations are published by the various administrative agencies charged with implementing the law and most often constitute "binding" standards to be rigidly followed.

Impending new Federal regulations or amendments or changes in existing regulations are published in the *Federal Register*, and the source for current "official" regulations is the *Code of Federal Regulations*, both available on subscription basis from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

State, county and municipal statutes, rules and regulations affecting health-care delivery generally can be obtained from the office of the Secretary of State, the Attorney General, the State Department of Public Health, local Boards of Health, the office of the Mayor or County Administrator or from other state or local governmental agencies.

Government Agency Publications

In addition to the so-called "official" regulations promulgated by those federal and state governmental agencies that implement existing legislative enactments, many governmental agencies publish a variety of material that, although not "binding" by law, still constitutes a governmentally approved "standard" that may have considerable probative force when introduced into evidence.

The *Monthly Catalog, United States Publications*, (available on yearly subscription from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402) presents monthly a listing of all pamphlets, bulletins, books and other publications currently issued by U.S. governmental departments, agencies and bodies. Listed first under the name of the issuing agency with availability, source and price, the publications are also indexed by subject, and a cumulative annual index provides easy reference to particular subject areas. A similar, but considerably abridged publication, *Selected U.S. Government Publications*, is available without charge on written request from the Superintendent of Documents.

The *American Statistics Index Annual and Retrospective Edition* published by Congressional Information Service, 4720 Montgomery Lane, Suite 600, Washington, DC 20014, provides a comprehensive

guide and index to the statistical publications of the U.S. Government, including many pertaining to health-care delivery.

Catalogs and other publication listings, some of which concern health-care delivery, may be obtained from individual government agencies such as the Federal Food and Drug Administration (5600 Fishers Lane, Rockville, MD 20852), the Federal Communications Commission, the Department of Health, Education and Welfare and the Occupational Safety and Health Administration in Washington, DC.

The Special Equipment Requirements Division of the Veterans Administration publishes minimal standards for medical and hospital equipment submitted to purchase for their medical clinics, hospitals and other facilities. Further information on specific items may be obtained from the Supply Service, Veterans Administration, 810 Vermont Avenue, N.W., Washington, DC 20420.

Medical Books

Medical text books, reviews, progress reports, monographs and other treatises comprise another large category of published material that can be referred to as expressions of a "standard of medical or hospital care," potentially admissible as evidence in malpractice actions.

Textbooks on general medicine, surgery and the various specialties often provide source descriptions of generally approved or recognized medical and surgical diagnostic and therapeutic procedures and techniques for their performance. For a listing of standard reference works in this area that can be expected to be accepted in legal proceedings as "authoritative" the reader is referred to the article by Attorney Steven H. Mackauf originally printed in 2 *Medicolegal News* 5-8 (October, 1974), subsequently reprinted in 1 *American Journal of Law & Medicine* 133-146 (March 1975) and updated in 1 *American Journal of Law & Medicine* 320-322 (Fall, 1975).

To locate medical books possibly of courtroom use in defining "standards of care," the most complete listing of medical book publications is that of the "National Library of Medicine Current Catalog," an ongoing monthly publication with annual cumulative index available on purchase from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 and kept for reference in most larger medical libraries.

Almost as complete in scope of medical book publications is *Bowker's Medical Books in Print* (R.R. Bowker Company, 1180 Avenue of the Americas, New York, NY 10030) listing currently available medical books by subject matter and author. Another privately published source of books in the health-care delivery area is the series compiled by Medi-Facts Publishing

Company, 2337 Lemoine Avenue, Fort Lee, NJ 07024 of separate annual volumes covering books of interest and use by physicians, dentists, nurses, veterinarians, and pharmacists.

The *Hospital Literature Index* (quarterly publication with annual cumulative index) of the American Hospital Association, 840 North Lake Shore Drive, Chicago, IL 60611, indexing the periodical literature on hospital medical care development and delivery also contains regular description of new book acquisitions of the American Hospital Association's Library.

Some book titles suggest that the contents are specifically directed to definitions of "standards of care." In example are two recent releases: *Guidelines for Graded Exercise Testing and Exercise Prescription* (Lea & Febiger, 600 S. Washington Square, Philadelphia, PA, 1975) and *Patient Care Standards*, that presents in outline form a recommended series of standards of nursing care procedure and observation (The C.V. Mosby Company, 11836 Westline Industrial Drive, St. Louis, MO 63141, 1975).

In the adverse drug reaction area, the following are potentially useful sources of acceptable methods of drug prescription and recommended patient monitoring:

Techniques of Medication — A Manual on the Administration of Drug Products (Martin et al.)

J.B. Lippincott Company
E. Washington Square
Philadelphia, PA 19105

Hazards of Medication — A Manual of Drug Interactions, Incompatibilities, Contraindications and Adverse Effects (Martin et al.)

J.B. Lippincott Company
E. Washington Square
Philadelphia, PA 19105

The Pharmacologic Basis of Therapeutics (Goodman and Gilman)

The Macmillan Company
866 Third Avenue
New York, New York 10022

Drug Interactions — Clinical Significance of Drug-Drug Interactions and Drug Effects on Laboratory Results (Hansten)

Lea & Febiger
600 S. Washington Square
Philadelphia, PA 19106

AMA Drug Evaluations

Publishing Sciences Group, Inc.
411 Massachusetts Avenue
Acton, MA 01720

Medical Periodicals

The medical periodical literature contains in printed form original articles, review and progress reports, case presentations, editorials, letters to the editor and other information that comprise another large source of medical and hospital "standards of care."

The number of medical and paramedical periodicals and journals published on a regular basis is tremendous and ever expanding so that use of one or more of the

currently available bibliographic biomedical periodical reference tools is essential to locate those publications that may be pertinent to a particular standard of care.

The backbone of any search of world medical periodical literature is found in the comprehensive citations listed in the monthly issues of *Index Medicus* and the annual alphabetized *Cumulated Index Medicus*. These massive compilations have been published since 1960 by the National Library of Medicine. They are available on subscription from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 and contained in almost every sizable medical library. Application of computer techniques currently enables selective retrieving from the vast store of material contained in *Index Medicus* and other bibliographic keys to medical periodical literature. The most expansive and readily available of the computerized services is the "Medical Literature Analysis and Retrieval Systems" (MEDLARS) of the National Library of Medicine that provides computer-compiled bibliographies from the biomedical citations listed in *Index Medicus* since January, 1964.

For specialized medical bibliographic searching, the reader should consult the following additional periodical indexing and abstract services:

Hospital Literature Index

American Hospital Association
840 North Lake Shore Drive
Chicago, IL 60611

Hospital Abstracts

(Monthly Survey of World Literature)
Department of Health and Social Security
Her Majesty's Stationery Office
London, England

Abstracts of Hospital Management Studies

The Cooperative Information Center for
Hospital Management Studies
The School of Public Health
The University of Michigan
Ann Arbor, MI 48106

Nursing Literature Index

Glendale Adventist Medical Center
P.O. Box 871
Glendale, CA 91209

Index to Dental Literature

American Dental Association
211 E. Chicago Avenue
Chicago, IL 60611

Annual Year Books (21 Separate Subject Headings)

Year Book Medical Publishers
35 East Wacker Drive
Chicago, IL 10036

Current Contents

Institute for Scientific Information
325 Chestnut Street
Philadelphia, PA 19106

Excerpta Medica (World Literature Abstracts under Separate Subject Headings)

Associated Scientific Publishers
P.O. Box 211
Amsterdam, The Netherlands
(American Elsevier Publishing Company
52 Vanderbilt Avenue
New York, NY 10017)

Science Citation Index

Institute for Scientific Information
325 Chestnut Street
Philadelphia, PA 19106

In adverse drug reaction cases, the following are helpful sources to locate pertinent medical journal articles:

Drug Interactions — An Annotated Bibliography with Selected Excerpts 1967-1971 (Also, same title for 1970-1971)

Superintendent of Documents
U.S. Government Printing Office
Washington, D.C. 20402

Toxicity Bibliography

Superintendent of Documents
U.S. Government Printing Office
Washington, D.C. 20402

Clin-Alert

Science Editors, Inc.
4169 Westport Road
Louisville, KY 40207

The Medical Letter on Drugs and Therapeutics

56 Harrison Street
New Rochelle, NY 10801

Adverse Reaction Titles

Excerpta Medica Foundation
Associated Scientific Publishers
P.O. Box 211
Amsterdam, The Netherlands
(American Elsevier Publishing Company
52 Vanderbilt Avenue
New York, NY 10017)

For medical journals that frequently publish, in whole or in part, articles defining the use of prescription drugs, particularly adverse reactions, drug interactions and recommended monitoring procedures, the following are suggested source references:

Journal of the American Medical Association
535 North Dearborn Street
Chicago, IL 60610

New England Journal of Medicine
10 Shattuck Street
Boston, MA 02115

FDA Drug Bulletin
US Department, HEW, Public Health Service
5600 Fishers Lane
Rockville, MD 20852

Drug Therapy

Biomedical Information Corporation
919 Third Avenue
New York, NY 10022

Current Prescribing
Oradell, NJ 07649

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