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Table of Contents

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CONTENTS

Foreword i

**The Hospital-Medical Staff Relationship:
An Issue of Quality Program** vii

Attendees List viii

ARTICLES

**The Hospital Board at Risk and the Need to
Restructure the Relationship with the Medical Staff:
Bylaws, Peer Review and Related
Solutions**

JOHN P. MARREN, J.D.

G. LANDON FEAZELL, J.D.

..... MICHAEL W. PADDOCK, J.D., LL.M. 179

This article argues that the current structure of the hospital governing board and medical staff relationship does not support and promote quality and patient-centered care. The fundamental flaw in the current structure is the interdependent, yet independent and discordant relationships between hospital governing boards and medical staffs. These relationships are described as cultures and fit into three types of "silos": organizational (the "structural silo"); professional (the "professional silo", including the "culture of blame"); and the fragmented quality information silo (the "informational silo"). While case law, statutory requirements and regulatory expectations clearly state that governing boards are ultimately responsible for quality of patient care, governing boards delegate these functions to medical staff without having sufficient information to measure and monitor quality. As a result, problems manifest because of these failures of oversight and compliance. Dramatic lapses in quality occur due to overuse, underuse, and misuse of healthcare services. Furthermore, the challenges and opportunities from improved quality and patient safety, as a strategic business driver, cannot be seized until the underlying structural flaws are understood and addressed. This article proposes that solutions become apparent when the various health care constituencies are educated about these cultural impacts and when multidisciplinary bodies, with board leadership and direct authority, integrate and consider quality information.

Quality Assurance and Hospital Structure:

How the Physician-Hospital Relationship Affects Quality Measures

RONALD G. SPAETH, M.B.A.
KELLEY C. PICKERING

SHANNON M. WEBB 235

Mr. Spaeth writes about the relationship between hospital administration and the physician, and how that relationship affects the quality of medical care delivered to the patient. The article focuses on the differences between the employment structure in an academic teaching hospital, and the open, independent contractor medical staff typical of a traditionally smaller community hospitals. The individual traits and nuances of these structures and how they can be distinguished from one another create dynamic differences in the approach for quality care. Peer review, credentialing, and management of adverse outcomes are just a few of the ways in which hospitals continue to strive to provide higher quality care, but the way these methods are implemented and performed in different hospital structures are dramatically different, yielding distinct results. Mr. Spaeth argues that the challenges faced by community hospitals in their effort to provide higher quality care and eliminate medical error are exacerbated because of their unique structure and the particular relationship physicians share with the hospital and its administration.

The Medical Staff Structure —

Its Role in the 21st Century GERALD M. EISENBERG, M.D. 249

Dr. Eisenberg’s paper presents a vision of the medical staff from the point of view of a practicing physician and medical staff leader. Dr. Eisenberg focuses on ways the medical staff, as an independent entity, may use the collective clinical knowledge and experience of its physician membership to enhance quality. This paper also presents Dr. Eisenberg’s unique insights regarding the interplay and conflict between hospitals and their associated medical staff in today’s complex health care delivery system. He provides several suggestions to increase cooperation between these two important components of inpatient care.

Proposed Changes to the Hospital-Medical Staff Relationship to Improve Quality of Care

ELIZABETH A. SNELSON, J.D., M.A. 265

Medical staff attorney Snelson answers the Colloquium’s charge, “What exactly has to change in the hospital-medical staff relationship for health care quality to be improved?” Her response emphasizes the logic of having clinicians vested with authority to establish policies concerning the clinical decision-making. The article discusses the cases defining the medical staff bylaws as contractual in nature, and the problem of hospital attorneys demanding unilateral amendments to bylaws. Bylaw clauses that would chill medical opinion and communication or denigrate clinical recommendations are discussed. Ms. Snelson advocates for the inclusion of the medical staff organization in exclusive contract and other clinical decision-making, and includes sample bylaw language enacting her recommendations.

No More Kidding Around: Restructuring Non-Medical Childhood Immunization Exemptions to Ensure

Public Health Protection ROSS D. SILVERMAN, J.D., M.P.H. 277

Professor Silverman’s article examines the complex challenges faced by U.S. policymakers attempting to balance the public health protections of mandatory childhood immunization programs with the legal, religious, philosophical, and practical concerns raised by permitting non-medical exemptions under the programs. The article

begins with a discussion of the history of childhood immunization programs, and continues by describing the inconsistency of enforcement of state immunization laws and exemptions. The author analyzes recent cases from New York, Wyoming, and Arkansas, and discusses how these decisions both pose threats to these programs' public health protections, while also offering insight into potential problems for other state vaccination programs. Professor Silverman concludes by advocating that states adopt an "informed refusal" approach to vaccination exemption as a way of improving immunity protections, while respecting the autonomy rights of those who wish to opt out of the program.

Off-Label or Out of Bounds?

Prescriber and Marketer Liability for Unapproved

Uses of FDA-Approved Drugs

JAMES O'REILLY, J.D.,

AMY DALAL 295

Professor O'Reilly's study of recent drug review legislation applies a historical and holistic view of promotion practices for unapproved uses of prescription drugs. He faults Congress for moving public health protections away from a strictly protective mode and toward assistance to drug marketers. He argues that the adverse health consequences of "off-label" promotion of drugs are not well understood, and that the 1997 amendments disserved the public health interest while expanding pharmaceutical company profits.

FDA's Proposed Rules on Patent

Listing Requirements for New Drug

And 30-Month Stays on ANDA Approval

(Proposed Oct. 24, 2002) YUK FUNG HUI 325

In order to close the loophole in the generic drug approval process that allows a brand name drug patent holder to delay or defeat generic drug application merely by technicality, the FDA recently proposed to modify its regulations. Those proposals affect the patent listing requirements of a new drug application, and the duration of time that a generic drug application could be put on hold in the event of a patent infringement suit. With the modified rules, the FDA expects to see an increase in the availability of generic drugs, which eventually will lead to lower drug costs. Ms. Hui discusses the contents of the proposed regulations and provides an analysis of the proposed rule's legal authority, implications on patent rights, and impact on the pharmaceutical industry.

The Bipartisan Patient Protection Act:

Greater Liability on Managed

Care Plans..... URURA MAYERS, J.D., LL.M. 341

Mrs. Mayers' article notes the substantial differences that exist between the Senate and the House of Representatives' version of the Bipartisan Patient Protection Act of 2001. While observing the remedies made available to participants, beneficiaries, or enrollees under both bills, she shows that the Senate bill places greater liability on managed care plans because it favors consumer protection, while the House of Representatives' bill does not. In order to develop an understanding of why an act of this nature is needed, Mrs. Mayers provides a brief historical overview of how managed care entities developed. She also examines the Employee Retirement Income Security Act ("ERISA") and proposes amendments to them. She concludes her article by raising an even deeper concern, and that is: what happens to individuals without access to health care coverage.

**Making the Health Insurance Flexibility
and Accountability (HIFA) Waiver
Work Through Collaborative
Governance**

BARBARA J. ZABAWA, J.D., M.P.H. 367

This paper argues that collaborative governance should be an essential component in any HIFA waiver proposal, due to the fact that the health care system is moving away from a federal and hierarchical program design and implementation towards a more local, collaborative approach. As several current collaborative projects demonstrate, collaboration may overcome barriers to health expansion program success, such as stakeholder buy-in, notice, and state access to private health coverage information. Furthermore, collaboration within the context of the HIFA waiver process may maximize the strengths of current collaborations, such as providing: (a) access to greater and more stable funding sources; (b) access to a facilitator that can collect and distribute data; and (c) an avenue for accountability. Multiple challenges in ensuring collaborative governance are reviewed. Ms. Zabawa argues that these challenges are not insurmountable if states adopt a truly collaborative approach to designing and implementing programs under the HIFA waiver; there may be hope in expanding and improving health coverage, since collaboration is the most appropriate mechanism to address the complexity of health system reform.