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Foreword

John D. Blum Loyola University Chicago, School of Law, jblum@luc.edu

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Foreword

Health law in the 1990s is akin to a sailboat forced to cope with unpredictable and frequent wind shifts. In the early part of the decade, the health law craft was buffeted by the gales of health reform, forcing it to tack against a head wind of dramatic velocity. But no sooner had the government's health reform stalled when the winds shifted toward managed care and private sector reform. In 1997, health law is still sailing through waters churned by the cross winds of managed care; the gusts are not only coming from the private sector, but also from government. This, the sixth volume of the *Annals of Health Law*, clearly illustrates the current significance of regulation as government struggles to provide guidance and prevent abuses in the unsettled seas of managed care.

It seems fair to characterize 1997 as the year in which fraud and abuse regulations, old and new, lurked behind every corner of our evolving health system. Of the nine articles in this volume of the Annals, five concern some aspect of health care fraud and abuse enforcement. Robert Salcido's article deals with the use of the Medicare Anti-Kickback Statute by the government in false claims prosecutions. Salcido argues that the government's use of the False Claims Act to essentially do what the Anti-Kickback Statute was intended for is an inappropriate strategy. Authors Michael Mustokoff, Jody Werner, and Michael Yecies critically examine the use of the False Claims Act as a vehicle to address quality of medical care issues in the context of false billing, concluding that the False Claims Act is not the appropriate mechanism to pursue problems of quality. David Hoffman concludes quite to the contrary, writing that the use of the False Claims Act by the government to recover monies paid for substandard care is completely appropriate, highlighting the governments' prosecution in the Tucker House II Colleen Faddick examines the implications of the 1996 Health Insurance Portability and Accountability Act on fraud and abuse, arguing that the new law, together with the increased enforcement in this area, should spur providers into creating compliance programs. The Thomas Bartrum and Edward Bryant piece deals specifically with corporate compliance programs,

examining key areas these programs need to address, and the broader implications of such programs.

Two articles in the volume focus on government regulatory concerns about market changes that have been driven by managed care. In the piece by Edward Hirshfeld, the author examines FTC/DOJ antitrust guidelines for physician joint venture networks. The article by Eric Tower explores a more recent concern of regulators, the duty of hospital directors to obtain a fair price in the conversion of nonprofit acute care facilities. Tower argues that other than traditional duties of loyalty and fair dealing, directors have very little guidance about fair pricing in a conversion situation.

The other two articles in this volume are illustrative of the breadth of health law, and the fact that issues that predate the managed care revolution are still very much alive. Authors Scott Saylor and Steven Thomas examine the United States Supreme Court decision of *Medtronic, Inc. v. Lohr* concerning the issue of state tort law preemption under the 1976 Medical Device Amendments. While the Supreme Court did not uphold the preemption, Saylor and Thomas argue that this decision applied to the specific facts, and may not prevent preemption of state tort claims involving products that receive FDA premarket approval. The article by Vassyl Lonchyna concerns the application of DNR orders in the operating room. Lonchyna argues that there is a lack of clear hospital policy about whether medical staff are obligated to honor DNR orders for surgical procedures, or whether routine resuscitation should be pursued.

As you the reader sail through the seas of health care, it is my hope that you will find this volume to be a helpful compass, at least for some of your journey. We have tried in each issue of the Annals to focus on current trends and provide content that is applied and practical to the health law practitioner, and hopefully we have succeeded in that effort in Volume 6. I want to thank the National Health Lawyers Association and their Executive Vice President Marilou King for continued support in producing this volume, as well as our many peer reviewers. I am indebted to this edition's Senior Editor, Thomas Bartrum, for all his efforts in making Volume 6 a reality. I also wish to thank our Executive Editor, Marilyn Hanzal, for her hard work on this and the previous five issues of the Annals, and wish her safe sailing as she sets off on the waters of health law practice. I am confident that the winds of health care will continue to swirl in un-

predictable and interesting ways, and so I look forward to working on more new and challenging issues in Volume 7.

John D. Blum Editor-in-Chief