

The

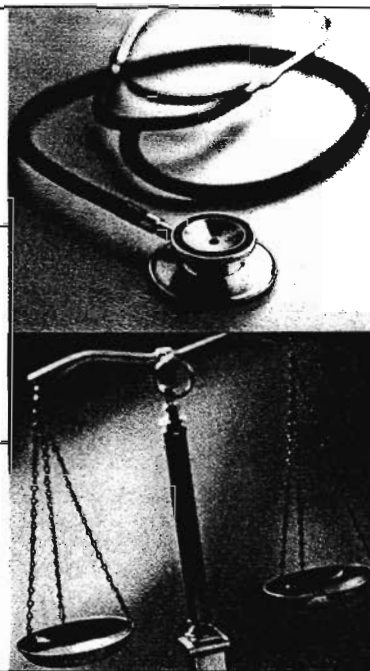
Utilization

Management

Guide

Third

Edition



PROMOTING QUALITY HEALTH CARE

Acknowledgments

Executive Editor: Garry Carneal, JD, MA

Managing Editors: David H. Reiter, Esq. and Howard Burde, Esq.

Assistant Editor: Jacquelyn A. Lombos

The Utilization Management Guide, Third Edition, is the product of a cumulative effort from a host of writers, editors, research assistants, and support staff. No book of this scope could possibly be published without such outstanding support. In addition to the dedicated individuals whose biographies appear in this Guide, we would be remiss to not only mention but also express our eternal thanks to this special group of individuals.

Our first thanks go out to the staff at URAC, especially to Jackie Lombos, Brigitte Schnorr, and Regina Xerez-Burgos, whose superlative efforts saw this project through from beginning to end by coordinating, organizing, drafting, editing, and laying out this entire Guide. We greatly thank URAC's accreditation reviewers Claire Barrett, Chris Brown, Christine Leyden, Donna Merrick, Sue Ohr, Susan Stern, and Bonnie Sturges for their assistance as well.

Mr. Burde wishes to personally extend his thanks as well to Myra Callahan and Dawn Bachetti of Blank Rome who typed and copy edited many sections of this Guide provided by Blank Rome and were most diplomatic in their grammatical criticism. Of course, we also extend our appreciation to several law students and young lawyers who assisted with this Guide's research, including Mandara Meyers, Holly Fernandez, Penelope Jones, Leasa Woods, and Michael Lorelli. Finally, Mr. Burde wishes to greatly thank all his partners at Blank Rome who willingly, if not always knowingly, contributed the firm's resources to this effort.

Important Note to Readers:

In this Guide, URAC has attempted to survey, analyze, and summarize all the state laws and regulations that pertain to both health utilization management and workers' compensation utilization management. In addition, this publication also includes a chapter on such federal programs as Medicaid and Medicare. While URAC has tried to address all facets of this material, by design this publication does not cover every state and federal utilization review or utilization management provision. Nor for this matter should this publication be used as a substitute for a review of the actual laws and regulations of each state. URAC recommends consulting the state laws and the appropriate government officials for definitive answers to questions of a regulatory nature. Please note that the views expressed in the *The Utilization Management Guide* are those of the individual authors. They do not necessarily represent the views and positions of URAC.

All rights reserved. Reproduction in whole or part without written permission from URAC is prohibited.



©2005 URAC
1220 L Street, Suite 400, Washington, D.C. 20005
☎ (202) 216-9010 ☎ (202) 216-9006
🌐 www.urac.org

About URAC

URAC, an independent, nonprofit organization, is a well-known leader in promoting health care quality through its accreditation and certification programs. As a nonprofit industry neutral organization, URAC's Certificate of Accreditation serves as a seal of approval to assure both regulators and consumers a health care provider is meeting a superior standard of quality care. Through its broad-based governance structure and an inclusive standards development process, URAC ensures that all stakeholders are represented in establishing meaningful quality measures for the entire health care industry.

Since its inception in 1990, URAC has accredited over 2,700 office and Internet sites doing business in all 50 states and three foreign countries. URAC-accredited organizations provide health care services to over 150 million Americans. Currently, URAC offers over 18 different accreditation and certification programs. These programs cover a wide range of health care operations ranging from integrated health plan offerings to specialty carve out services such as utilization management and other medical management functions to include the following:

Clinical Accreditation and Certification Programs:

- Case Management
- Claims Processing
- Consumer Education and Support
- Core
- Credentials Verification Organization
- Disease Management
- Health Call Center
- Health Network
- Health Plan
- Health Provider Credentialing
- Health Utilization Management
- Independent Review
- Vendor Certification
- Workers' Compensation Utilization Management

Health IT Accreditation Programs:

- Health Web Site
- HIPAA Privacy – for Covered Entity or Business Associate
- HIPAA Security – for Covered Entity or Business Associate

Other URAC Quality Benchmarking Programs:

- Consumer Satisfaction Commendation

Because of URAC's broad-based standards and rigorous accreditation process, purchasers and consumers look to URAC accreditation as an indication that a health care organization has the necessary structures and processes to promote high quality care and preserve patient rights. In addition, regulators in 35 states and three federal agencies recognize URAC's accreditation standards in the regulatory process.

Along with their mission to promote and maintain quality health care for the general public, URAC is engaged in several research projects to assess and identify new approaches to improve performance measurement in a variety of health care settings. In addition, URAC also authors many cutting-edge publications on health care delivery systems, HIPAA Privacy and Security regulations, and offers over 40 days of educational conferences, workshops, and seminars annually on issues ranging from accreditation to best practices.

About the Authors

David H. Reiter, J.D.

Legislative Counsel for Government Policy and Legal Affairs, URAC

David H. Reiter currently serves as URAC's Legislative Counsel for Government Policy and Legal Affairs. For 14 years, Mr. Reiter practiced trial law in the District of Columbia and Maryland state and federal court systems. During this period he also provided Of Counsel work regarding internal and external litigation matters for a national and international patent and trademark law firm in Washington, D.C. In the year 2000, he left private practice for a position with Cable and Wireless, U.S.A., an International Internet Technology company, where he assisted with their ISO audit of their international data center. Immediately prior to his coming to URAC, Mr. Reiter worked at both The Center for Biologics Evaluation and Research, and The Center for Drug Evaluation and Research with the U.S. Food and Drug Administration. Mr. Reiter received his B.A. in Economics from the George Washington University Columbian College in Washington, D.C., and his J.D. from Suffolk School of Law in Boston, MA. He is also an active member of the American Health Lawyers Association.

Howard A. Burde, J.D.

Partner, Blank Rome LLP

Howard A. Burde is Chair of the Health Law Group of Blank Rome LLP. His practice includes providing advice on complex health, health insurance and managed care law issues to institutional providers, health insurers, managed care organizations and governments.

Prior to joining Blank Rome, Mr. Burde served as Deputy General Counsel to Governors Tom Ridge and Mark Schweiker, where he served as legal counsel for Commonwealth of Pennsylvania responsible for the Departments of Health, Public Welfare and Aging, as well as for the Health Related Professional Boards, the Medical Professional Liability Catastrophe Loss Fund, and all managed care, health insurance, and health and human service issues. Mr. Burde is Editor in Chief and primary author of *The Health Laws of Pennsylvania* (PBI, 2000) as well as numerous peer reviewed articles. Mr. Burde is on the Boards of the *Journal of Health Law* and *The BNA Health Law Reporter*. Mr. Burde is a frequent speaker on health law topics to audiences including the American Health Lawyers Association, the Utilization Review Accreditation Commission, the Health Care Financial Management Association, and the Milbank Memorial Fund.

Mr. Burde graduated from Duke University, B.A. magna cum laude, 1984 and was a Baccalaureate Speaker at the Duke University Graduation. He received his J.D. degree in 1988 from the University of Virginia School of Law and was a founder of the Virginia Health Law Forum.

Garry Cameal, JD, MA

Garry Cameal is a leading expert in health care quality, including issues pertaining to the quality and regulation of health care and medical management operations. Since 1996, Mr. Cameal has served as President & CEO of URAC, a non-profit, independent organization. Currently, URAC offers 16 accreditation programs in both the clinical and health information technology arenas. Previously, Mr. Cameal has served as the Vice President of Legal and State Affairs at the American Association of Health Plans (AAHP) and Legislative Counsel for Health Policy for the National Association of Insurance Commissioners (NAIC).

Karen L. Cavalli, Esquire

Karen L. Cavalli is Senior Counsel with Independence Blue Cross in Philadelphia, Pennsylvania and concentrates her practice in the areas of managed care, health and insurance law. She received her B.A. from Muhlenberg College and her J.D. from the Widener University School of Law, where she served as president of the Health Law Society and managing editor of the *Society of Healthcare Attorneys of the Hospital Association of Pennsylvania's Health Law Newsletter*. While in law school, she studied international health law at the Padua International Law

Institute in Padua, Italy. She has authored numerous articles and lectured on managed care topics, such as regulatory compliance and utilization review. In 2002, she served on the Blue Cross Blue Shield Association's Utilization Management Task Force and was a featured speaker on the topic of extraterritorial considerations for state utilization review laws, at the Blue Cross Blue Shield Association's 36th Annual Lawyers Conference.

Guy D'Andrea

Mr. D'Andrea has worked in health care policy for over 12 years. He is the founder of Discern LLC, a consulting firm focusing on health care compliance and project management. For seven years, Mr. D'Andrea led product development and government affairs for URAC, a private accreditation organization. Prior to joining URAC, Mr. D'Andrea held positions in health care policy and legislation at the American Association of Health Plans (now AHIP), the American Managed Care and Review Association, and the Maryland Association of HMO's.

Mr. D'Andrea is a frequent speaker on the topic of health care quality and oversight, and has authored numerous articles on accreditation and compliance issues. He

received his undergraduate degree from Cornell University and is currently working towards dual Masters of Business Administration degrees from Columbia University and the London Business School.

Pam Foster

Pam Foster has worked in the managed health care industry since 1986. Her most recent work with AdvancePCS, purchased by Caremark in January 2004, included responsibility for drug prior authorization and appeals' profitability as well as for product regulatory compliance. She served on the DMAA (Disease Management Association of America) Board for three years and led the AdvancePCS disease management programs to full NCQA compliance in 2002. She is a Master's prepared nurse, graduated from Johns Hopkins University, who prior to joining AdvancePCS, worked for three large managed care companies directing utilization, case management, network development and disease management activities. Ms. Foster is an active NCQA surveyor with a strong commitment to quality healthcare delivery.

Liza Greenberg, RN, MPH

Liza Greenberg, RN, MPH, is a health care consultant with a special interest in patient safety, quality, prevention and public health. She formerly was Vice President of Research and Quality Initiatives at URAC, a nonprofit national accreditation organization for health care. Ms. Greenberg's responsibilities at URAC included development of new research initiatives on performance measurement and health improvement for managed care organizations. She also staffed development of URAC's case management and disease management accreditation standards. Ms. Greenberg received her BA and BSN from the University of Pennsylvania, and an MPH from the Johns Hopkins University School of Hygiene and Public Health.

Lori Harris-Stevens, RN, MHA

Lori Harris-Stevens is Vice President of Accreditation for URAC. Ms. Harris-Stevens joined URAC in 1997 as an Accreditation Reviewer. In addition to her accreditation reviewer responsibilities, Ms. Harris-Stevens was the primary URAC staff person assigned to the development and implementation of the Health Call Center Standards. Ms. Harris-Stevens is a Registered Nurse with over 20 years of experience in health care, 14 of which were in the managed care arena. Before working in the managed care industry, Ms. Harris-Stevens had extensive experience in both the public and private health care sectors. Ms. Harris-Stevens has a Masters degree in Health Administration.

Valerie Nosek, RN, BSN, CPHQ

Valerie Nosek has over five years' experience as an Accreditation Reviewer at URAC for accreditation programs including Health Utilization Management, Workers' Compensation Utilization Management, Case Management, Health Provider Credentialing, Credentials Verification Organization and Claims Processing. Her career in managed care includes seven years of varied experience in the development and management of utilization management, case management and quality programs for

general health and workers' compensation programs, during which time she coordinated successful URAC Health Utilization Management Accreditation. Additional experience includes two years in HMO quality management, focusing on provider quality issues and consumer grievance resolution.

Susan Prest, MA, LP

Susan Prest is president of Prest & Associates, Inc., a Madison, Wisconsin based, URAC accredited independent review organization specializing in the independent review of psychiatric, addictions medicine and behavioral health care cases. Ms. Prest is the current president of the National Association of Independent Review Organizations (NAIRO). She is a graduate of the University of California at Berkeley, a licensed psychologist with twenty-six years of experience as an administrator and clinician specializing in mental health and substance abuse managed care. Ms. Prest is a nationally recognized expert on independent review and managed care.

John D. Shire

John D. Shire practices with the Health Law Group of Blank Rome LLP. Mr. Shire concentrates his practice in health care transactions, health care regulatory matters, health care operations, health information compliance, and technology contracts. Mr. Shire represents hospital systems, physician practices, managed care organizations, imaging centers, and private equity investors in health care-related businesses. Mr. Shire is a co-author of *How Government and Industry Pharma Compliance Guidance Impacts Attorney Advice For All Health Care Clients*, Health Lawyers News, Vol. 7 No. 8 (August 2003), and has contributed as an author and researcher for two major health care resources, *The Guide to Medical Privacy and HIPAA* (Thompson Publishing Group, 2002) and *The Health Laws of Pennsylvania* (PBI Press 2000). Mr. Shire is a graduate of the Dickinson School of Law, where he was an associate editor of the *Dickinson Law Review*. He received his B.A. degree, cum laude, from Bucknell University. Mr. Shire is admitted to practice in Pennsylvania, New Jersey, and Maryland.

Patricia M. Wagner

Patricia M. Wagner is an associate with Epstein Becker & Green, where she practices in the firm's National Health Law Practice. Ms. Wagner counsels clients on a full range of legal and regulatory issues. Ms. Wagner's experience includes advising clients on a variety of health regulatory matters including issues related to compliance with: the HIPAA Privacy Rule; HIPAA portability provisions; ERISA claims regulations; and other state and federal regulatory requirements. Ms. Wagner also has experience with litigation of federal and state healthcare antitrust matters.

The Utilization Management Guide: 3rd Edition**Table of Contents**

Foreword.....	11
1.0: Executive Summary	13
2.0: Recent Trends in UM	16
2.1 Introduction	16
2.2 The Value Equation	16
2.3 Integration or Segmentation	16
2.4 Health Information Technology	16
2.5 The Patient Safety Factor	17
2.6 The Role of Clinical Guidelines	19
2.6.1 Standardization vs. Customization	20
2.6.2 Pre-Review Screening.....	20
2.7 Evidence-Based Medicine.....	20
2.8 Predictive Modeling	21
2.9 Outcomes.....	21
2.10 Regulatory Changes.....	22
2.10.1 DOL Regulations	22
2.10.2 Independent (External) Review.....	22
2.10.3 HIPAA Privacy and Security.....	23
2.10.4 Same-state licensure.....	23
2.11 Other Contributions	23
2.12 The Conceptual Challenges.....	24
2.13 Conclusion.....	26
3.0: An Overview of State Health UM Regulation	29
3.1 Introduction	29
3.2 Definition of Utilization Management.....	29
3.3 The Structure and Process of UM Regulation.....	29
3.4 Components of UM Regulation	30
3.4.1 Applicability	30
3.4.2 Scope and Content.....	30
3.5 General Jurisdictional Considerations	32
3.6 Application of State UM Regulations	33
3.7 UM Certification Exemptions for ERISA Plans.....	33
3.8 Regulatory Accreditation Recognitions.....	33
3.9 Extraterritorial Enforcement.....	33
3.10 Conclusion.....	34
4.0: The Landscape of Utilization Review Programs for Workers' Compensation Programs.....	37
4.1 Introduction	37
4.2 Workers' Compensation Insurance	37
4.3 Workers' Compensation Managed Care Fundamentals	37
4.4 Rising Costs	37
4.5 Regulatory Oversight.....	38
4.5.1 Workers' Compensation Managed Care	38

4.5.2	Workers' Compensation Utilization Management	39
4.5.3	Oversight Through Traditional Insurance Regulation	40
4.6	Conclusion.....	40
5.0:	Utilization Review in the Medicare and Medicaid Programs	42
5.1	Introduction	42
5.2	Medicare.....	42
5.3	Quality Improvement Organizations- External Utilization Review	42
5.4	Medicare Modernization Act	43
5.4.1	Organization Determinations	44
5.4.2	Standard Time Frames for Organization Determinations	44
5.4.3	Written Notification by Medicare Advantage Organizations	45
5.4.4	Expediting Determinations	45
5.4.5	Defining the Medical Exigency Standard	45
5.4.6	Action Following Denial for Expedited Review	46
5.4.7	Action on Expedited Determinations	46
5.4.8	Notification of the Result of an Expedited Organization Determination	46
5.5	Appeals.....	46
5.6	Reconsideration	47
5.6.1	Good Cause Extension.....	47
5.6.2	Opportunity to Submit Evidence.....	47
5.6.3	Reconsideration- Reviewer and Clinical Standards	47
5.6.4	Time Frames for Reconsiderations.....	47
5.7	Reconsideration by Independent Review Entity.....	47
5.7.1	Forwarding Adverse Reconsiderations to the Independent Review Entity	47
5.8	Administrative Law Judge (ALJ) Hearings	48
5.8.1	Determination of Amount in Controversy	48
5.9	Departmental Appeals Board (DAB) Review	48
5.10	Judicial Review.....	48
5.11	Notice of Discharge and Medicare Appeal Rights (NODMAR).....	49
5.11.1	Requesting Immediate Quality Improvement Organization (QIO) Review of Inpatient Hospital Care.....	49
5.12	Medicaid	49
5.12.1	Medicaid Fee-for-Service	49
5.12.2	Inpatient Services	49
5.12.3	Drug Use Review	50
5.13	Medicaid Managed Care	50
5.14	Conclusion.....	51
6.0:	Utilization Management Under ERISA Plans.....	53
6.1	Introduction	53
6.2	Background on ERISA	53
6.3	Fiduciary Status	53
6.4	ERISA Claims Procedure	54
6.4.1	Claims for Benefits.....	54
6.4.2	Reasonable Claims Procedures	55
6.4.3	Initial Determinations	55
6.4.4	Timeframes, Delays, Additional Information.....	55

6.5	Notices of Claims Determinations.....	56
6.6	Appeals of Claims Determinations	56
6.6.1	Timelines for Appeals	56
6.6.2	Manner and Content of Notification of Benefit Determination on Review	57
6.7	Remedies.....	57
6.8	Preemption Issues	57
6.9	Conclusion.....	58
7.0:	Utilization Management Legal Update: An Overview of the ERISA Preemption Issue	59
7.1	Introduction	59
7.2	UM Liability.....	59
7.2.1	The Wickline Case.....	59
7.2.2	The Wilson Case	59
7.3	Introduction to the ERISA Preemption Issue.....	60
7.4	The Preemption Analysis Regarding Direct Agency and Vicarious Liability Claims	60
7.5	The U.S. Supreme Court Narrows ERISA Preemption	61
7.6	“Any Willing Provider” Actions.....	61
7.7	ERISA Preemption of Tort Claims.....	61
7.7.1	Mixed Eligibility Determinations: Treatment versus Administrative Decisions.....	62
7.8	ERISA Preemption Revisited	62
7.9	Conclusion.....	64
8.0:	Pharmacy Benefit Management: Drug Utilization Review.....	66
8.1	Introduction	66
8.2	What are Pharmacy Benefit Managers (PBM's)?	66
8.3	Need for PBM's.....	67
8.4	PBM Services.....	67
8.5	Formulary Development	67
8.6	PBM Utilization Tools.....	68
8.7	The Relationship of Pharmacy UM and Medical UM.....	69
8.8	PBM Regulation	69
8.9	The Future	70
9.0:	Independent Review	71
9.1	Introduction	71
9.2	What Is Independent Review?	72
9.2.1	Background	72
9.2.2	Independent Review Organizations.....	72
9.2.3	The Independent Review Process	72
9.3	Legal and Regulatory Challenges	74
9.4	Benefits of Independent Review	74
9.5	Independent Review Issues to be Resolved.....	75
9.6	Recommendations for Independent Review	76
9.7	Conclusion.....	76
10.0:	URAC Health Utilization Management Standards: Pathways to Building a UM Program	78
10.1	Establish a Utilization Management Program Model	78
10.1.1	Non-clinical Administrative Staff	78
10.1.2	Initial Clinical Reviewers	78
10.1.3	Peer Reviewers	79

10.1.4 Appeal Reviewers	79
10.2 Select Clinical Review Criteria	79
10.3 Select UM Software.....	80
10.4 Develop Job Descriptions.....	80
10.5 Develop Policies and Procedures	80
10.5.1 UM Review Process	81
10.5.2 Confidentiality and Conflict of Interest.....	81
10.6 Delegation – Yes or No?	81
10.7 Develop Orientation and Training Program Descriptions	81
10.8 Develop Quality Management Program	82
10.8.1 QM Program Description-	82
10.8.2 Annual Quality Improvement Initiatives	82
10.8.3 Auditing Process	83
10.9 Regulatory Compliance	83
10.10 Conclusion.....	83
11.0: Promoting Patient Safety Through Medical Management	86
11.1 Medical Management Has a Role in Patient Safety	86
11.1.1 The Environment	86
11.1.2 Potential Patient Safety Roles For Medical Management Programs.....	86
11.2 The Role of Health Information Technology.....	87
11.3 Next Steps: A Systems Based Approach for Patient Safety	88
11.4 Looking Ahead	88
11.5 Resources for Patient Safety.....	89
How to Use This Survey: Methodology and Template.....	90
State-by-State Health UM Surveys.....	94
State-by-State Workers' Compensation UM Surveys.....	263
Core Standards.....	296
Health UM Standards.....	301
Workers' Compensation UM Standards.....	307
State Regulatory Contacts for Health UM.....	312
State Regulatory Contacts for Workers' Compensation.....	318
States That Recognize URAC Accreditation.....	321
Online URAC Directory of Accredited Organizations.....	322

9.0: Independent Review¹

Susan Prest, M.A., L.P.

9.1 Introduction

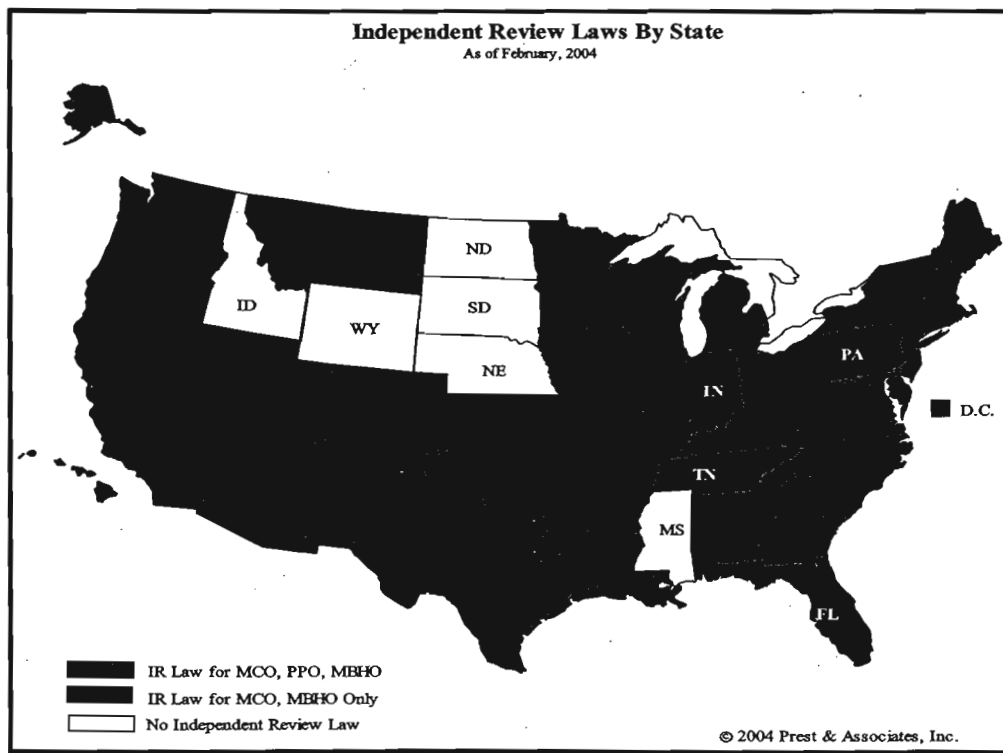
Independent medical review has become both an important and integral part of our health care system. Independent review's emergence upon the American health care scene is one of the most important developments in patient and consumer protection in the past decade. Physicians, health plans, employers, state and federal regulators, patient and consumer advocacy groups all agree that independent review, and not lawsuits, is the best means of resolving health care disputes.

In the year 2000 the overwhelming majority, or 92%, of all insured employees were in managed care plans; up from 54% in 1993.² With the dramatic increase in consumers who receive their health care through managed care plans has come an increase in number of disagreements over what services the health plans³ would or should cover. In response to these rising concerns about the impartiality of health plan benefit coverage decisions, coupled with the lack of progress with a Patients' Bill of Rights at the federal level, 44 states and the District of Columbia have

enacted independent review laws. As shown in Figure 1, there are only 6 states that have still not yet enacted independent review laws (Idaho, Mississippi, Nebraska, North Dakota, South Dakota and Wyoming).

In March of 2002, The Henry J. Kaiser Family Foundation commissioned a study prepared by the Georgetown University Institute for Health Care Research and Policy⁴ whose subject included one of the first comprehensive analyses of state independent review programs. The study found that independent review was becoming widely recognized as an important mechanism for consumer protection. It also demonstrated extensive state activity in the area of independent review and its success in resolving disputes between individuals and their health plans. In fact, independent review organizations (IRO's) are currently receiving high marks for quality, performance, and integrity. Yet, with all of the activity, optimism, and widespread support for independent review, the programs are used infrequently. There are only about

Figure 1. Independent Review Laws By State



4,000 documented requests for an independent review annually. Thus, careful attention needs to be paid in order to preserve the integrity and viability of independent review and to take advantage of its full potential.

9.2 What Is Independent Review?

URAC defines independent review, also called external review, as a process, independent of all affected parties, to determine if a health care service is medically necessary, medically appropriate, experimental, or investigational.⁵ It is a formal and unbiased process for the resolution of disputes involving adverse medical benefit determinations and is usually conducted by a medical expert or panel of medical experts who are not affiliated with the health plan. These expert medical reviewers must be qualified to perform the review and are usually associated with an independent review organization approved by the state. It may typically (but not always) occur after all utilization management and benefit appeal mechanisms available within the health benefits plan have been exhausted.

A primary goal of an independent review is to assure the patient, attending physician, and other treating clinicians that after a treatment recommendations and coverage decisions will be reviewed by a qualified and truly independent expert medical reviewer. In most cases the independent review process has the power to overrule the health plan's denial of benefits. However, the laws vary on whether the decisions are binding although they are binding in most states. Recent data shows that approximately 50% of the coverage disputes at the state level result in a finding on behalf of the insured.⁶

9.2.1 Background

In 1978, Michigan became the first state to establish an independent review program. Subsequently throughout the 1990's a large number of states began to enact patient protection legislation in earnest. By March 2000, 33 states had either legislated or enacted independent review laws. In that same year, URAC began its formal accreditation program for external review organizations (ERO's now IRO's) by accrediting the first 5 independent review organizations. The standards employed by URAC, both then and now, address a consumer's concerns that insurance appeal decisions are based on financial considerations or poor medical judgment, rather than what is best for the patient. Currently, 22 independent review organizations are fully accredited by URAC.⁷

Today independent review organizations operate in all the 50 states and their performance is earning them excellent ratings. Despite this fact the debate over patient protections still continues. In fact, most health care consumers are unaware of independent review laws and how to access the appeals process.

Founded in 2001 by the majority of URAC accredited independent review organizations, the National Association of Independent Review Organizations (NAIRO) is a trade association dedicated to protecting the integrity of independent medical review. Recognizing both legislative growth in this area, and in furtherance of their objectives, NAIRO, has called for the preservation of the integrity and viability of independent review.⁸

9.2.2 Independent Review Organizations

An independent review organization (IRO) is an entity that conducts independent external reviews of adverse health care determinations. Independent review organizations maintain panels of licensed, credentialed, and board-certified physicians who are experts in their areas of review. By design, independent review organizations are fully independent from all parties involved with an appeal. In light of their purpose IRO's should not have any financial, professional or contractual ties with the involved health plans, hospitals, providers, patients or manufacturers.

Generally independent review organizations usually contract with state regulatory agencies to conduct impartial reviews of disputed denials of health care benefits. Depending on the particular state, IRO's are subject to not only the rules and regulations set by the contracting agencies, but may be required by the state to be accredited by a nationally recognized accrediting body. URAC accredits independent review organizations by using standards that assure IRO's: are free from conflicts of interest; maintain established qualifications for physician reviewers; address medical necessity and experimental treatment issues; have reasonable time periods for standard and expedited reviews; and maintain an appeals processes. A URAC IRO accreditation means the organization provides a fair and impartial review process that benefits to both patients and physicians who have grievances with their MCO.⁹

9.2.3 The Independent Review Process

Independent review laws provide insureds with a process to challenge adverse medical determinations made by their health plans. While health plans are required to establish internal formal grievance procedures, it is usually after all the health plan's internal appeal mechanisms are exhausted that the insured or enrollee can proceed through the state independent review process, if one is available. There are exceptions to this rule. Sometimes requests for an independent review may be made before the internal appeal process has been exhausted if the request involves life threatening conditions, or the health plan waives the exhaustion requirement.

There is a great deal of variation among the states regarding legislation, and which state administrative

agency is responsible for regulating independent review. as (See Table 1).

In general, despite the many variations between states, the independent review process usually follows several basic steps. First, the enrollee must file a written request with the specific state agency that regulates independent or external review. The filing must be accomplished within a specific time period that follows the date of receiving notice of a health plan's final adverse determination. At that point the state governing authority determines if the case is either a *standard review* or an *expedited review* and if the request for an independent review is appropriate. Once that decision is made, the case is then assigned to an independent review organization.

Second, after filing for an independent review the state may chose either an IRO, or compose a panel of physicians to conduct the appeal review. While Hawaii offers appeal by IRO, Vermont's Department of Insurance offers a review panel by maintaining an internally selected panel of in-state psychiatrists to review psychiatric and addictions medicine state level appeals. In New Mexico the Superintendent of Insurance compiles and maintains a list of physicians available to perform independent reviews. Some states will also add an additional requirement that an external independent review organization be certified by the state in order to provide independent reviews.

Third, IRO decision time frames are determined by whether the appeal falls under a standard, expedited, or experimental or investigational review. A standard review must be completed within 30 days of the date that the request for the review is filed with the state regulating department. An expedited review may be requested if the patient has a medical condition where waiting for the completion of a standard review would jeopardize the life or health of the patient or would interfere with the patient's ability to regain maximum function or if the patient has not been discharged from inpatient care. Expedited review decisions normally must be completed within 24 to 72 hours from the time the review is requested. If an adverse determination is made by a health plan on the basis that the recommended care is considered experimental or investigational, the enrollee may request an independent review as well. The enrollee's treating physician must certify that standard treatments have not been effective, or are not appropriate, or that there is no available standard treatment covered by the health plan that is more beneficial than the recommended treatment.

In addition to notification and time frame requirements, IRO's are required to provide toll-free telephone access for consumers and providers. Upon receipt of an

independent review request, the organization will screen the case to determine if a conflict of interest exists for either the expert medical reviewer or the independent review organization. This will also determine whether the case is a standard or an expedited review, whether the case relates to a clinical or administrative issue, whether the case refers to medical necessity or experimental/investigational treatment, and whether the issue may be appropriately resolved through the independent review process. Independent review organizations also will require that their reviewers do not accept any type of compensation based on the reviewer's opinion or the outcome of the review.

Each IRO establishes and implements procedures for the selection and credentialing of reviewers following either the applicable state requirements, URAC standards, or both. A medical expert or panel of medical experts who are considered to be peers of the attending provider and who have the proper scope of licensure and professional experience to complete the review are selected. The organization provides these medical reviewers with a file containing the necessary information to complete the review. This documentation normally includes the patient's medical records, the attending health care professional's recommendation, applicable clinical review criteria, medical and scientific evidence determined to be relevant and appropriate to the case, terms of coverage, consulting reports, and any other relevant documentation. Any decisions made will be criteria or evidence-based using both scientific and medical evidence. When more than one reviewer is used, IRO's will provide an opportunity for the reviewers to discuss the case. In these circumstances, the majority decision prevails.

For every IRO decision made by the IRO, each reviewer must provide a written opinion to the independent review organization. In reaching their opinion, the reviewer is not bound by any decisions or conclusions reached during the health plan's internal review process. The report must contain a description of the reason for the review request, the date that the review request was received from the state regulator, the date the review was conducted, the principal reasons, and rationale for the determination and references or practice guidelines considered in reaching the decision.

After a final decision, a written notice to either uphold or reverse the health plan's adverse determination is sent to the appropriate parties as designated by the state statutes or regulations. With the exception of three jurisdictions (i.e., the District of Columbia, Oklahoma, and Oregon), independent review decisions are binding on the health plan and the enrollee to the extent that the parties have other remedies available under applicable federal or state

Table 1: State Departments* Regulating Independent Review**As of February, 2004**

Department of Insurance		Department of Health	Other State Department	No Independent Review Organization
Alaska	Nevada	Alabama	California, Department of Managed Care (HMO's only)	Idaho
Arizona	New Hampshire	Delaware		Mississippi
Arkansas	New Mexico	District of Columbia		Nebraska
California	New York	Florida		North Dakota
Colorado	North Carolina	Georgia		South Dakota
Connecticut	Ohio	Massachusetts		Wyoming
Hawaii	Oregon	Minnesota		
Illinois	South Carolina	Montana		
Indiana	Tennessee	New Jersey		
Iowa	Texas	Oklahoma		
Kansas	Utah	Pennsylvania		
Kentucky	Vermont	Rhode Island		
Louisiana	Virginia			
Maine	Washington			
Maryland	West Virginia			
Michigan	Wisconsin			
Missouri				

* The term "department" is used to refer to agencies, commissions, administrations or other such terms. ©2004 Prest & Associates, Inc.

law. In some states the health plan or the enrollee may appeal by seeking judicial or administrative review of the binding independent review decision. For example, in Alaska the person who is aggrieved by a final decision at the state level may appeal the decision to the superior court. In Iowa, the enrollee or the enrollee's treatment provider acting on behalf of the enrollee may appeal the review decision by the independent review organization by filing a petition for judicial review.

In terms of who pays for the independent review process, it is the health plan against whom a request for an independent review is filed that usually pays the costs consistent with the fee schedule of the independent review organization. These fees vary widely and are dependent upon a number of factors including the number of reviewers that are used to review a case, state fee cap requirements, and complexity of the medical review. The fees are reported to range from a low of \$350 to a high of \$2000 with the median cost of a review of \$700 to \$900.

9.3 Legal and Regulatory Challenges

During the last few years independent review has survived most of its major legal challenges. One of these was a 5 to 4 decision by the U.S. Supreme Court in Rush Prudential HMO Inc., v Moran. In Rush the Supreme Court found that an Illinois HMO Act which called for mandated independent review was not preempted by the Employee Retirement Income Security Act of 1974 (ERISA).¹⁰ As the Court explained, external review laws regulate insurance and therefore are not preempted by ERISA. Rush is significant because it means that patients in employer-sponsored health plans who live in the 42 states with external review laws can obtain an independent physician review of treatment denials. Unfortunately, the ruling did not apply to the large number of employees who are

covered under "self-insured" plans. "Self-insured" plans do not have to comply with state insurance regulations.¹¹ Moreover, the facts in Rush preceded the effective date of the ERISA claims benefit regulations and, therefore, future decisions may hold that a specific reduced legal scheme preempts state independent review laws.

According to a National Committee for Quality Assurance (NCQA) study,¹² as of July 31, 2003, most health plans are subject to state independent review laws to varying degrees. But, as shown in Table 1, the fact is that these state independent review laws apply inconsistently across managed care products such as managed care organizations (MCO's), preferred provider organizations (PPO's), and managed behavioral healthcare organizations (MBHO's).

9.4 Benefits of Independent Review

According to an American Association of Health Plans (AAHP) report titled *Independent Medical Review of Health Plan Coverage Decisions: A Framework for Excellence*, "(f)or the consumers of American health care, the widespread enactment of independent medical review is perhaps the most important development of the past decade."¹³ Although once lobbied against by most health plans, independent review has gained a wide range of acceptance as ultimately benefiting both members and health plans together. Some examples of these benefits are:

- 1) *Reduction of costly litigation.* As reported by The New York Times, states with mandatory independent review laws can expect reduced litigation. When an external review sides with the patient, plans almost always back down and are unwilling to bear the legal risk of continuing to deny coverage for the disputed treatment. On the other hand, few patients or their

lawyers wish to waste both the time and the money by going to court and arguing against a plan that has won approval from independent physicians.¹⁴ According to Terese Giorgio, Senior Director, Corporate Programs for IPRO, Inc., a New York based URAC accredited independent review organization, independent review will continue to offer a fair and impartial venue for enrollees and insurers to resolve their disputes without seeking expensive and time-consuming legal recourse.

- 2) *Enhanced health plan credibility.* Health plans welcome the opportunity to restore the public's faith in the health plans appeal process that independent review can provide. Health plans are aware that the public holds generally negative views about managed care and independent review is credited with enhancing health plans credibility.
- 3) *Consumer satisfaction.* Independent review gives consumers the accountability they want. It addresses their concerns that appeal decisions are sometimes based on financial considerations or poor medical judgment, rather than what is truly best for the patient.
- 4) *Quality Improvement.* Independent review shows the promise of improving medical care. As Winifred S. Hayes, Ph.D., President of HayesPlus, a URAC accredited independent review organization based in Lansdale, PA has communicated to the author, the role of independent (medical) review has grown as health plans and hospitals recognize its value in enhancing quality of care, addressing health outcome problems and medical errors, and developing and applying medical policy.

9.5 Independent Review Issues to be Resolved

- 1) *Lack of public awareness.* Consumers enrolled in health plans are generally unfamiliar with their plan's internal review process and are unaware of any independent review program available in their states. Even though all but six states have enacted laws requiring independent review, the number of such reviews being requested is small and infrequent. The Kaiser Family Foundation in a report released in March 2002¹⁵ demonstrated that consumers were granted relief through independent review 50% of the time they chose to use the process. Even so, very few consumers have turned to independent review.
- 2) *Lack of standardization and consistency of independent review between states.* Independent reviews vary considerably between states. There is variation in the types of disputes that are accepted, the process, time frames and whether to allow access to specialty expert

medical review panels such as behavioral health care independent review organizations. For example, in some states independent review requirements apply to all types of health plans while in other states they apply only to some types of health plans. Creating consistency in the application of important standards across the nation with uniform and standardized independent review processes would protect the viability and integrity of independent review. In response to this concern Steven B. Larsen, Esq., former Commissioner of Insurance for the State of Maryland, in his article, *It's Time to Fix State External Review Laws*¹⁶ recommends the creation of a uniform right to external review to ensure that health plans and their members are subject to a more predictable and equitable process. He also calls for some form of administrative review of external review decisions to ensure compliance with statutory standards.

- 3) *State licensing or domicile requirement for reviewers.* Same-state licensure limits the range of medical expertise available to the client/patient. It limits an IRO's ability to be competitive in certain marketplaces as not all IRO's have sufficient reviewers available for coverage in all 50 states.
- 4) *Lack of statutory immunity for independent review organizations and their reviewers for review activities conducted in good faith.* According to Dr. Hayes, "The biggest threat to independent review is litigation, especially in those states that do not indemnify the IRO and its' reviewers."
- 5) *Exclusion of certification of specialty behavioral health independent review organizations.* 12 of the 44 states that certify independent review organizations exclude the certification of specialty behavioral health independent review organizations. The primary reason given by states for this exclusion is clerical. They say it interferes with the state's process of assigning cases by rotation among independent review organizations.¹⁷ Many states have solved this clerical problem without compromising patient protection and patient rights. Other states only certify one or a limited number of independent review organizations. These states do not include specialty behavioral health independent review organizations on their restricted panels. Only Vermont and Minnesota have separate review panels for mental illness and substance abuse.

In consideration of these and other issues requiring attention and resolution the National Association of Independent Review Organizations (NAIRO) recommended ten key elements for inclusion in any

Patients' Bill of Rights legislation or regulation concerning independent review as discussed in more detail below.¹⁸

9.6 Recommendations for Independent Review

NAIRO recommends the following ten key elements for inclusion in Patients' Bill of Rights legislation or state laws and regulations concerning independent review.

- 1) A reviewer's opinions should be supported by best available scientific evidence and nationally recognized clinical guidelines and consensus statements.
- 2) Standardization of external review processes, timeframes, methods, and credentialing requirements throughout the U.S. using a private standard setting organization (i.e., adopt URAC standards, including a minimum of 72 hours for expedited reviews, except in extreme emergencies).
- 3) Require reviewers to hold an unrestricted license to practice medicine or other clinical discipline in one of the 50 US states (no same-state licensing or domiciliary requirements for the reviewers).
- 4) Guarantee anonymity of the reviewers.
- 5) Provide statutory immunity for IRO's and reviewers for review activities conducted in good faith.
- 6) Do not exclude single-service IRO's.
- 7) Conflict of interest standards should be case-specific.
- 8) Upon request, the patient has the right to see the reviewer's original reports.
- 9) Review outcomes that are binding on the plan. Member must go through the external review process before litigating.
- 10) Fund a plan to educate the patient regarding his/her rights to external review.

9.7 Conclusion

Independent review is in a unique position to dramatically improve the quality of health care available to all Americans for many years to come. It has gained wide recognition as a successful tool to resolve disputes involving denial of medical benefits. It is now one of the most actively regulated areas impacting health plan and managed care operations. Although there are many issues that still require attention in order to preserve the viability and integrity of independent review, there is general agreement by qualified physicians that independent review is here to stay and should be the accountability cornerstone in any patient protection proposal.

Currently there is important work being done in both the private and public sector by organizations such as the America's Health Insurance Plans (AHIP), the

Department of Labor (DOL), the National Association of Health Underwriters (NAHU), the National Association of Insurance Commissioners (NAIC), the National Association of Independent Review Organizations (NAIRO), the National Committee for Quality Assurance (NCQA), URAC, The Henry J. Kaiser Family Foundation, Georgetown University Institute for Health Care Research and Policy, Congress, the courts and other organizations in the area of independent review. With the unique cooperation evident among these organizations it appears that independent review will continue to take its place as an important national and state patient and consumer protection.

1 The term "independent review" as used in this article refers to independent medical review which is also referred to as external review, external independent review, and other similar terms.

2 *Patient's Rights*, The Henry J. Kaiser Family Foundation, 2003.

3 The term "health plan" as used in this article refers to array of managed care programs and insurers providing health care insurance or benefits coverage.

4 *Assessing State External Review Programs and the Effects of Pending Federal Patients' Rights Legislation*, prepared for The Henry J. Kaiser Family Foundation by Georgetown University, Institute for Health Care Research and Policy, March, 2000, Revised May, 2002 [hereinafter "Kaiser report"].

5 URAC, *Accredited Independent Review Organizations*, March 1, 2004, www.urac.org/prog_accred_orgs.asp [hereinafter "URAC website"].

6 Kaiser report at 3.

7 URAC, *Independent Review Organization, Accreditation Standards Summary, Accreditation Overview*, March 1, 2004, www.urac.org/prog_accred_IRO.

8 *Preserving the Integrity and Viability of Independent Medical Review*, National Association of Independent Review Organizations (NAIRO), 2001 [hereinafter "NAIRO white paper"].

9 URAC *Core Standards, Version 1.1 and Independent Review Standards, Version 2.0*.

10 *Rush Prudential HMO, Inc. v Moran*, 230 F.3d 5959 (7th cir. 2000), cert. granted, 121S.Ct. 2598 (U.S. June 29, 2001)(No. 00-1021).

11 Jay Fisher, *U.S. Supreme Court rules in Rush Prudential Inc. v. Moran case*, The Academy of Orthopaedic Surgeons Bulletin, Vol. 5, No. 4, August 2002.

12 *External Review (IRO) Laws By State*, NCQA, July 31, 2003, www.ncqa.org

13 *Independent Medical Review of Health Plan Coverage Decisions: A Framework for Excellence*, an American Association of Health Plans (AAHP) survey, April, 2001.

14 Michael M. Weinstein, *Will Patients' Rights Fix The Wrongs?* The New York Times, June 24, 2001, Section 4 at 1.

15 Kaiser report at 3.

16 Steven B. Larsen, Esq., and Saul Ewing, LLP, *It's Time to Fix State External Review Laws*, HMO & Health Plans, January, 2004.

17 The state of Washington wrote, "Yes, we certify IROs to operate in Washington State. However, our laws, specifically require that an IRO be able to perform "a full range" of reviews, so no specialty IRO's are allowed." The state of Oregon simply states that they are following the Washington state law. The state of Indiana wrote, "Indiana HMO's are required to rotate through a list of IRO's certified by the Department of Insurance. In order for the rotation process to work efficiently Indiana is choosing to certify only full-service review organizations."

18 NAIRO white paper at 5.