



**Member
Organizations**

American
Association of
Preferred Provider
Organizations

American College of
Physicians

America's Health
Insurance Plans

American Health
Quality Association

American Hospital
Association

American Insurance
Association

American Medical
Association

American Nurses
Association

American Psychiatric
Association

Blue Cross Blue
Shield
Association

Case Management
Society of America

National Association
of Insurance
Commissioners

Robert L. Crocker
*Board
Chairperson*

Alan P. Spielman
*President and
CEO*

**COMMENTS BY
ALAN P. SPIELMAN, PRESIDENT AND CEO
THE AMERICAN ACCREDITATION HEALTHCARE COMMISSION/URAC**

RELATED TO

**NEW HAMPSHIRE HOUSE BILL 561:
AN ACT RELATIVE TO PHARMACY BENEFIT MANAGERS**

SEPTEMBER 26, 2007

SUBCOMMITTEE ON HOUSE BILL 561
EXECUTIVE DEPARTMENTS AND ADMINISTRATION COMMITTEE
NEW HAMPSHIRE HOUSE OF REPRESENTATIVES

The American Accreditation Healthcare Commission/URAC (URAC) appreciates the opportunity to address the committee on matters related to New Hampshire House Bill 561, which would regulate the practice of pharmacy benefit management and contracts for pharmacy benefit management. For the past two years, URAC has been working with health care leaders and customers of pharmacy benefit management services to develop quality indicators for the industry, culminating in July when URAC released the first-ever national accreditation standards for pharmacy benefit management and drug therapy management. We are pleased to be here today to discuss the development and applicability of these quality benchmarks.

Overview of URAC

URAC is an independent, nonprofit organization whose mission is to promote continuous improvement in the quality and efficiency of health care management through the processes of accreditation and education. To support this goal, our Board of Directors represents the full spectrum of stakeholders interested in our health care system, including consumers, employers, health care providers, health insurers, purchasers, workers' compensation carriers and regulators.

Incorporated in 1990, URAC pioneered utilization management accreditation by creating a nationally recognized set of standards to ensure accountability in managed care determinations of medical necessity. As the health care industry evolves, URAC continues to address emerging issues: we now offer 19 accreditation and certification programs across the health care spectrum (i.e., Case Management, Claims Processing, Consumer Education and Support, Core Organizational Quality, Credential Verification Organization, Disease Management, Drug Therapy Management, Independent Review Organization, Health Call Center, Health Content Provider, Health Network, Health Plan, Health Utilization Management, Health Web Site, HIPAA Privacy, HIPAA Security, Medicare Advantage Health Plan, Pharmacy Benefits Management and Workers' Compensation Utilization Management).

Many states have found URAC accreditation standards helpful in ensuring that managed care plans and other health care organizations are meeting quality benchmarks. Thirty-eight states and the District of Columbia currently reference one or more URAC accreditation programs in their statutes, regulations, agency publications or contracts, making URAC the most recognized national managed care accreditation body at the state level. In New England, URAC accreditation is recognized in Maine (Health Utilization Management and Workers' Compensation Utilization Management); Massachusetts (Health Network, Health Plan and Health Utilization Management); New Hampshire (Health Utilization Management); Rhode Island (Health Utilization Management); and Vermont (Health Plan and Health Utilization Management).

At the federal level, four federal agencies recognize URAC accreditation. The Centers for Medicare and Medicaid Services recognize URAC Medicare Advantage Health Plan Accreditation for the Medicare Advantage (formerly Medicare+Choice) Program; the Office of Personnel Management recognizes all URAC accreditation programs under the Federal Employee Health Benefits Program; TRICARE/Military Health System recognizes URAC's Health Network Accreditation; and the Department of Veterans' Affairs recognizes URAC's Health Call Center Accreditation.

URAC Standards: Establishing Quality Benchmarks

URAC accreditation serves as a symbol of excellence in the health care industry, promoting prevailing industry standards and consumer protections. In the rapidly evolving field of health care, URAC standards are developed through a dynamic process that identifies best practices and promotes high quality performance measurement. All stakeholders in the health care arena actively participate with URAC in developing these quality benchmarks through an inclusive process that incorporates an opportunity for public comment.

URAC's standards development process begins with a period of careful research, debate and discussion among stakeholders. An initial set of standards is then proposed and made available for a public comment and review. URAC's Advisory Committee reviews the submitted comments, makes appropriate changes, and the draft standards are then beta tested with a discrete group of companies in order to ensure that they work in practice. After beta testing, the standards may be modified again, and then they are forwarded to URAC's Board of Directors for consideration and approval. URAC revises its standards through this process at least every two years.

Development of URAC Standards for Pharmacy Benefit Management

URAC's practice of bringing the entire scope of experts and stakeholders to the table ensures that we are creating contemporary standards that are both meaningful and achievable. Our most recent success is the development of comprehensive accreditation program standards applicable to the pharmacy benefit management industry: Pharmacy Benefit Management Accreditation and Drug Therapy Management Accreditation. For your review, we have attached a copy of these program standards to our testimony today.

In the last forty years, the pharmacy benefit management sector of the health care industry has evolved from providing administrative services (e.g., claims management) to offering an array of sophisticated administrative, clinical and financial management services. Whether stand-alone companies or departments within a health plan, pharmacy benefit management organizations might administer prescription drug plans for employers and government plans; provide retail pharmacy network services; operate mail-service pharmacies; offer specialty pharmacy programs; sponsor prescription drug plans for Medicare Part D; and/or provide clinical and utilization management services (e.g. drug formulary management; disease management programs; and therapeutic interchange programs). Nearly 70% of the U.S. population is covered under a medical plan that provides a prescription drug benefit managed by a pharmacy benefit management organization.

URAC ascertained that this dynamic industry and its clientele would benefit from the availability of an accreditation program from a nationally recognized accreditation entity. Pharmacy benefit management organizations earning such accreditation would validate their commitment to quality and accountability by undergoing a rigorous and periodic review that evaluates their operations and services against national standards. URAC's goals in undertaking this new accreditation initiative were to:

- Provide an objective evaluative tool for purchasers to use during vendor selection;
- Promote patient safety and access to needed drugs and pharmacies;
- Improve medication management;
- Protect and empower consumers by promoting communication, defining pharmacy benefit management terms, clarifying access rights to needed medications, and addressing grievance and appeals processes;
- Provide independent validation of organizational excellence;
- Provide continuous quality improvement-oriented processes that improve operations and enhance compliance; and
- Improve evaluation, consistency and understanding of pharmacy benefit services among key stakeholders.

In July 2006, URAC assembled a multi-stakeholder committee charged with developing requirements for the nation's first-ever accreditation programs for pharmacy benefit management. Committee members formed two working groups in order to comprehensively address the issues pertinent to this health care sector. The Operations Work Group discussed standards for operational quality; communications, customer service and disclosure; and pharmacy distribution channels. The Clinical Work Group discussed drug use management; patient safety; formulary development; and drug therapy management. URAC Pharmacy Benefit Management Advisory Committee members represented the perspectives of diverse stakeholders:

- Employers (e.g., National Business Coalition on Health, General Motors, UPS, Pitney Bose, and IBM);
- Consumers (e.g., Consumers Union and California HealthCare Foundation);
- Consultants (e.g., Gorman Health Group);
- Health plans (e.g., Coventry, Humana, AETNA, Blue Cross Blue Shield Association, Blue Shield of CA and Kaiser Permanente);
- Retail pharmacy (e.g., National Community Pharmacists Association, Rite Aid and National Association of Chain Drug Stores);
- Pharmacy benefit management organizations (e.g., CareMark, Express Scripts, Medco Health Solutions, Wellpoint Rx, MedImpact, Member Health, Resolution Health, and Prescription Solutions);
- Pharmacy professional organizations (e.g., Academy of Managed Care Pharmacy and American Pharmacists Association);
- Labor (e.g., National Education Association);
- Physicians (e.g., American College of Physicians);
- Care management organizations (e.g., Case Management Society of America and Healthways); and
- Large public purchasing groups (e.g., Office of Personnel Management and Ohio Public Employees Retirement System).

URAC then engaged in a year of standards development and testing that involved all these major stakeholder groups and a field team of expert reviewers. Initial standards underwent a public review and comment period, then field testing by twelve pharmacy benefit organizations, including United HealthCare's Prescription Solutions, Inc.; Express Scripts, Inc.; Caremark; PerformRx; MedImpact HealthCare Systems; Prime Therapeutics LLC; Catalyst Rx; Envision Pharmaceutical Services; AETNA, Inc.; and Navitus Health Solutions, LLC. The beta test group together represents fifty-two percent of the current lives covered under pharmacy benefit management programs across the nation. Following a report from the review team that conducted the beta tests, URAC's Pharmacy Benefit Management Standards Committee decided to establish two separate accreditation programs, Pharmacy Benefit Management Accreditation and Drug Therapy Management Accreditation, to more accurately reflect industry activities. (URAC reviewers found that not all pharmacy benefit management organizations engage in drug therapy management for commercial populations, so this accreditation module was modified to become a separate accreditation.) URAC made its final accreditation standards available to health plans, stand-alone pharmacy benefit management companies, and other organizations in July 2007, and numerous organizations are now working towards these new URAC accreditations.

URAC Pharmacy Benefit Management and Drug Therapy Management Standards

The national standards established in URAC's Pharmacy Benefit Management Accreditation and Drug Therapy Management Accreditation programs incorporate the input of consumers, purchasers of pharmacy benefit management services and other key stakeholders. Employer/purchasers, for example, are interested in predictable cost and employee/consumer satisfaction; common industry terms that enable comparison shopping; cost containment to allow benefit continuation; and pricing disclosures. Consumer concerns relate to privacy and access to reliable, safe and affordable medications, understandable communications, and responsive customer service.

URAC Pharmacy Benefit Management Accreditation standards comprehensively address all aspects of pharmacy benefit management business. This standards program is comprised of the following five modules:

Module 1: Core Organizational Quality

- Organizational Structure Defined
- Communication Practices Monitored
- Policies and Procedures Articulated
- Confidentiality Maintained
- Staff Qualifications defined
- Promotes Consumer Safety
- Staff Credentialing Enforced
- Promotes Consumer Satisfaction
- Robust Staff Training
- Rigorous Complaints and Appeals Process
- Rigorous Information Management
- Quality Management Program Defined
- Rigorous Regulator Compliance
- Delegation to Business Partners Monitored
- Robust Quality Improvement Projects

Module 2: Customer Services, Communication and Disclosure

- Concrete Consumer Information Disclosure
- Concrete Client Information Disclosure
- On-Going Communications Enforced
- Robust Communication Safeguards
- Client Audit Rights Maintained
- Call Center Operations Defined
- Multiple Format Communication Requirements
- Health Literacy/Cultural Sensitivity Encouraged

Module 3: Pharmacy Distribution Channels

- Scope of Distribution Channels Defined
- Access and Availability Criteria Articulated
- Quality and Safety Criteria Articulated
- Network Access and Availability Articulated
- Out-of-Network Criteria Articulated
- Robust Pharmacy Relations
- Pharmacy Contracting and Subcontracting
- Articulated Dispute Resolution
- Claims Processing Standardized

Module 4: Drug Utilization Management

- Coverage Decisions Based on Clinical Information (published-outcomes data and evidence-based data)
- Clinical Review Criteria – developed with prescribers and updated at least annually
- Drug Utilization Management Scope Defined (prospective, concurrent, and retrospective review)
- Consumer Safety Requirements
- Robust Reviewer Qualifications
- Automated Review: Algorithmic Protocol and Oversight
- Non-Formulary Exceptions
- Decision Notice Required
- Appeals Process, includes Peer Clinical Review
- Expedited and Standard Appeals Review Defined

Module 5: Formulary Development and Pharmacy and Therapeutics Committee

- Formulary decisions based on cost factors only after safety, efficacy and therapeutic need established
- Process to promote rational, clinically appropriate, safe, and cost effective drug therapy
- Process to identify consumer safety issues
- Formulary management includes review of drug therapeutic advantages based on scientific evidence and standards of practice
- Formulary must be up-to-date with optimum therapeutics
- Must have a Pharmacy and Therapeutics Committee which is representative of prescribers working with high volumes populations served
- Pharmacy and Therapeutics Committee must meet at least quarterly, review and recommend formulary updates, and consider new drugs in a timely manner
- Formulary Appeals Process, includes Peer Clinical Review

URAC's Drug Therapy Management Accreditation program contains two modules: A Core Organizational Quality module identical to that for Pharmacy Benefit Management Accreditation and a Drug Therapy Management Services module. Drug Therapy Management is a distinct service or group of services that optimizes therapeutic outcomes for individual consumers as a result of appropriate drug therapy. It is an expanding practice, as increasing numbers of care managers and pharmacists manage a range of factors in drug therapies such as drug dose, method of delivery, adverse events, and cost effectiveness. URAC's ground-breaking accreditation in this area recognizes the importance and complexity that drug therapy management plays in the health care system. The standards address the essential aspects of a drug therapy management business:

Standards for Drug Therapy Management Services

- Drug Therapy Management Program Criteria
- Staff Development and Implementation Qualifications
- Coordination of Care
- Drug Therapy Management Process Structure
- Consumer-Centered Approach
- Medication Use Communication
- Drug Therapy Management Program Consumer Education
- Population Specifications
- Consumer Identification and Recruitment
- Service Offerings

- Quality Improvement
- Shared Decision-Making with Consumers
- Requirements for Measuring program Performance
- Documentation and Outcomes Measurement
- Drug Therapy Management Program Provider Performance Feedback
- Drug Therapy Management Telephone Access
- Participating Consumer Rights and Responsibilities

While URAC standards comprehensively address all aspects of pharmacy benefit management business, I would like to highlight three key areas of special attention: (1) clinical focus of URAC standards; (2) consumer and client disclosures; and (3) safeguards to assure that pharmacy network management protects patient safety and is based on solid contracting practices.

I. Clinical Focus of URAC Standards

Clinical integrity is a prevalent theme throughout URAC's Pharmacy Benefit Management and Drug Therapy Management standards. Clinical information is subject to timely review and updates. Clinical decisions and information are developed and delivered with the involvement and oversight of appropriate clinicians to promote optimal and cost effective drug use. Clinical decisions and information are formulated through an evidence-based process. Importantly, formulary development and management is based on efficacy, safety and therapeutic need. Highlights of the clinical rigor of URAC standards are included in the appendix of this testimony.

II. Consumer and Client Disclosures

In order to promote transparency, URAC Pharmacy Benefit Management standards address consumer and client disclosures in the Customer Service, Communications, and Disclosure (CSCD) module. Standard 1 addresses the information that should be available to consumers on the post-enrollment environment in order for the consumer to understand how to utilize his/her benefits. Standards 4 and 5 pertain to the relationship between the pharmacy benefit management company and the organization that contracts for pharmacy benefit management services, and represents a balance between the needs of purchasers for information to assess the value of their pharmacy benefit management program and the need of health plans and pharmacy benefit management companies to maintain the proprietary nature of their negotiated arrangements and other business practices.

URAC standards, for instance, encourage pharmacy benefit management companies to include a description of their pricing structure and sources of revenue in their contracts with clients. This description should address how the pricing structure is defined and updated, such as rebate structure and administrative fees, as well as the source of the price updates and pricing update time cycle. For example, if drugs are priced using average wholesale price (AWP), then how AWP is defined and updated. Other possible descriptions of pricing structure are: straight pass-thru, maximum allowable charge (MAC), and usual and customary (U&C) charge. Highlights of the consumer and client disclosure elements of URAC standards are included in the appendix of this testimony.

III. Pharmacy Network Management

The Pharmacy Distribution Channel Standards module in URAC's Pharmacy Benefit

Management Accreditation program promotes sound contracting practices and patient safety in pharmacy network management. Our standards recognize written agreements with pharmacies as the fundamental building blocks of a pharmacy network, and thus require that a written agreement is in place for each pharmacy and that it include a specific list of contract elements that ensure basic protections of pharmacy providers. (These contracting criteria are also applicable to subcontractors.) Due process and an opportunity for redress of grievances is also afforded to participating pharmacies through a dispute resolution process. Highlights of the pharmacy network management elements of URAC standards are included in the appendix of this testimony.

Conclusion

As we did with Utilization Management Accreditation in 1990 and numerous accreditation programs we have developed since that time, such as Case Management Accreditation and Independent Review Accreditation, URAC has now pioneered national accreditation programs for pharmacy benefit management organizations. We offer a trusted and independent resource for monitoring the safety, effectiveness and service quality of pharmacy benefit management organizations and drug therapy management providers. These innovative programs come at a time when the pharmacy benefit management industry has evolved into an integrated model of programs for clinical value and savings, and when effective management of prescription drug benefits has become critical to the delivery of high quality health care. With the advent of consumer-focused health care, where patients make more decisions in medical benefits and services, and the continued controversy and confusion around pharmacy benefit management, the time is right for these national accreditation standards that measure pharmacy benefit management quality and provide an evaluative tool for customers of pharmacy benefit management organizations.

URAC appreciates this opportunity to inform the Committee about these new quality indicators for the pharmacy benefit management industry. We hope that our accreditation standards will be helpful to your deliberation of issues pertinent to House Bill 561. Please feel free to contact me or URAC's Government Relations Director Mara Osman (202/962-8838, mosman@urac.org) if we can be of further assistance.

Again, thank you for your time and consideration.