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**COMMENTS BY**  
**THE AMERICAN ACCREDITATION HEALTHCARE COMMISSION/URAC**

**RELATED TO**

**PROPOSED RULE:**  
**CODE OF MARYLAND REGULATIONS 31.10.36:**  
**PHARMACY BENEFIT MANAGERS—APPROVAL OF AN ACCREDITING  
ORGANIZATION**

SUBMITTED MARCH 12, 2009

DELIVERED TO:  
**MARYLAND INSURANCE ADMINISTRATION**  
BY EMAIL: AGIBSON@MDINSURANCE.STATE.MD.US

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URAC GOVERNMENT RELATIONS DIRECTOR

The American Accreditation Healthcare Commission/URAC (URAC) appreciates the opportunity to comment on proposed Code of Maryland Regulations (COMAR) 31.10.36: *Pharmacy Benefit Managers – Approval of an Accrediting Organization*, regulations that would implement Maryland Chapter 279 (2008) and allow the Insurance Commissioner to deem accredited pharmacy benefit managers to be in compliance with state requirements for Pharmacy and Therapeutics Committees (Maryland Insurance Article §15-1618). URAC supports Maryland's recognition of accreditation as an alternative means for demonstrating compliance with state requirements, and recommends one modification to the proposed regulations.

Upon review of the proposed rule, URAC suggests that the Maryland Insurance Administration (MIA) add language (bolded) to Section .02: Definitions. We propose that Section .02B(1) be amended to read:

“Accrediting organization” means an entity that accredits a pharmacy benefits manager, **such as URAC**.

As the MIA is aware, URAC has worked with health care leaders and customers of pharmacy benefit management services for the past two years in order to develop quality

indicators for the industry. In July 2007, URAC released the first-ever national accreditation standards for pharmacy benefit management and drug therapy management, and has currently accredited 15 companies pursuant to these accreditation programs. In 2008, we added three new programs to our pharmacy quality management<sup>®</sup> products: Mail Service Pharmacy Accreditation, Specialty Pharmacy Accreditation, and Workers Compensation, Property and Casualty Pharmacy Benefit Management Accreditation. We have accredited 4 companies pursuant to these new programs, and 12 companies are currently in process for accreditation.

URAC looks forward to working with the MIA as it implements the state's 2008 legislation addressing pharmacy benefit managers, and appreciates Maryland's recognition of URAC leadership in the pharmacy quality management<sup>®</sup> area. Later this year, we hope to seek formal approval by the Commissioner pursuant to COMAR 31.10.36.03: *Determination of Approved Accrediting Organization*. In anticipation of this process, we have attached a crosswalk for your preliminary review (*Crosswalk: URAC Pharmacy Benefit Management Standards and Maryland Insurance Articles, §15-1614 and §15-1617*) and a copy of URAC Pharmacy Benefit Management Standards (Version 1.0, 2007).

### **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 over 25 accreditation and certification programs across the health care spectrum (i.e., Case Management, Claims Processing, Consumer Education and Support, Core Organizational Quality, Credentialing Support, Credential Verification Organization, Disease Management, Drug Therapy Management, Health Call Center, Health Content Provider, Health Network, Health Plan, Health Provider Credentialing, Health Utilization Management, Health Web Site, HIPAA Privacy, HIPAA Security, Independent Review Organization, Medicare Advantage Deeming, Pharmacy Benefit Management, Vendor Certification and Workers' Compensation Utilization Management). In 2008, URAC's Board of Directors approved four new accreditation programs: Mail Service Pharmacy, Specialty Pharmacy, Workers Compensation, Property and Casualty Pharmacy Benefit Management, and Comprehensive Wellness Accreditation.

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.

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, Case Management, Disease Management, and Utilization Management Accreditations; 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 three 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. In 2007, URAC pioneered the first comprehensive accreditation program standards applicable to the pharmacy benefit management industry: Pharmacy Benefit Management Accreditation and Drug Therapy Management Accreditation.

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. To date, 15 pharmacy benefit management companies have earned URAC accreditation, and six others are working toward that goal.

### **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. While URAC standards comprehensively address all aspects of pharmacy benefit management business, three key areas deserve 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.

#### **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.

### 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.

### Conclusion

Thank you again for the opportunity to provide comments on proposed regulation COMAR 31.10.36: *Pharmacy Benefit Managers – Approval of an Accrediting Organization*. We look forward to working with the MIA as the State moves forward with implementation of its 2008 legislation addressing pharmacy benefit managers. As previously mentioned, we have attached a crosswalk of URAC standards and Maryland pharmacy and therapeutics committee requirements for your preliminary review (*Crosswalk: URAC Pharmacy Benefit Management Standards and Maryland Insurance Articles, §§15-1614 and 15-1617*), as well as a copy of URAC Pharmacy Benefit Management Standards (Version 1.0, 2007).

Additional URAC resources are available through the policy maker portal on the URAC website (<http://www.urac.org/policyMakers/resources/>). Please do not hesitate to contact me ([mosman@urac.org](mailto:mosman@urac.org), 202/962-8838) or URAC Government Relations Specialist Kelsey Kurth ([kkurth@urac.org](mailto:kkurth@urac.org), 202/962-8824) if URAC can provide any further assistance.

Thank you for your consideration.

Best Regards,



Mara C. Osman  
Government Relations Director

Attachments: Crosswalk: URAC Pharmacy Benefit Management Standards and Maryland Insurance Articles, §15-1614 and §15-1617

URAC Pharmacy Benefit Management Standards (Version 1.0, 2007)

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