



**Promoting Quality Health Care
Through Accreditation, Education & Measurement**

May 27, 2009

Ms. Charlene Frizzera
Acting Administrator
Centers for Medicaid & Medicaid Services
Department of Health and Human Services
Attention: CMS-4140-NC
P.O. Box 8017
Baltimore, MD 21244-8010

Re: CMS-4140-NC; 42 CFR Parts 144 and 146

Dear Acting Administrator Frizzera:

URAC is pleased to submit its comments in response to your *Request for Information Regarding the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA)*, as published in the Federal Register on April 28, 2009.

As you may be aware, URAC was founded 19 years ago by representatives of provider groups, insurers, health care purchasers, consumers, and regulators to develop and enforce industry standards for proper utilization management of health care services. We accredit over 200 purveyors of utilization management services across the country, including dozens who review the necessity of mental health services. Our utilization management programs are more widely recognized by governmental purchasers and regulators than any other managed care accrediting program in the United States. For more information about URAC and its governmental recognitions, please refer to appendix A of this letter. Also attached for your information are the Health Utilization Management Accreditation Standards, Version 6.0, in appendix B.

As a nationally recognized health care accreditation organization with wide ranging expertise which includes leadership in accrediting behavioral health networks, as well as utilization review and worker's compensation programs, our standards help organizations achieve a high bar on the quality of services rendered to their beneficiaries.

In response to the Departments' request for industry feedback on the six specific areas identified in the Federal Register notice, URAC is pleased to respond to items 3, 4, and 5 as cited below, providing the relevant URAC accreditation standards as requested.

A. Request for Industry Standards Relating to Medical Necessity and Denial of Coverage

“3. What information, if any, regarding the criteria for medical necessity determinations made under the plan (or coverage) with respect to mental health or substance use disorder benefits is

currently made available by the plan? To whom is this information currently made available and how is it made available? Are there industry standards or best practices with respect to this information and communication of this information?

4. *What information, if any, regarding the reasons for any denial under the plan (or coverage) of reimbursement or payment for services with respect to mental health or substance use disorder benefits is currently made available by the plan? To whom is this information currently made available and how is it made available? Are there industry standards or best practices with respect to this information and communication of this information?"*

URAC Response:

URAC's Health Utilization Management Accreditation Standards, Version 6.0, contain detailed requirements for both oral discussion and written disclosure of the underlying clinical rationale for a decision to deny payment for a requested covered service to the patient, attending physician, or other ordering provider or facility. This denial is known as a Non-Certification decision. The relevant URAC standards, HUM 15, HUM 16, HUM 22, HUM 23, HUM 24, HUM 26, HUM 27, and HUM 28, related guidance for interpreting HUM 22 and HUM 23, and required content for notification letters, appeals, and written responses to requests for additional clarification of the clinical rationale for non-certification, are provided below. The full set of URAC Health Utilization Management Accreditation Standards, Version 6.0, are provided in Appendix B.

■ **HUM 15 – Peer-to-Peer Conversation Availability**

Health professionals that conduct peer clinical review are available to discuss review determinations with attending physicians or other ordering providers.

■ **HUM 16 – Peer-to-Peer Conversation Alternate**

When a determination is made to issue a *non-certification* and no *peer-to-peer conversation* has occurred:

(a) The organization provides, within one business day of a request by the attending physician or ordering provider, the opportunity to discuss the non-certification decision:

(i) With the clinical peer reviewer making the initial determination; or

(ii) With a different clinical peer, if the original clinical peer reviewer cannot be available within one business day); and

(b) If a peer-to-peer conversation or review of additional information does not result in a certification, the organization informs

■ **HUM 22 – Written Notice of Non-Certification Decisions and Rationale**

For non-certifications, the organization issues written notification of the non-certification decision to the patient and attending physician or other ordering provider or facility rendering service that includes:

- (a) The principle reasons for the determination not to certify;
- (b) A statement that the clinical rationale used in making the non-certification decision will be provided, in writing, upon request; and
- (c) Instructions for:
 - (i) Initiating an appeal of the non-certification; and
 - (ii) Requesting a clinical rationale for the non-certification.

Interpretive Guidance:

- A principal reason statement that is non-specific, i.e., “care not found to be medically necessary” does not meet the intent of HUM 22(a).
- Non-certification notification will be timely, will be provided in writing and will include the information needed to provide the basis for an appeal.
- The health literacy /education level and linguistic needs of the population served should be considered when developing the non-certification letter templates to patients/members.
- HUM 22a: The principal reason for the non-certification determination should include a general clinical or non-clinical statement as to why the UM organization said “no” to the request. For example, “care could be provided in a less acute setting,” “insufficient diagnostic work-up,” and “conservative treatment not tried nor ruled out,” etc.
- HUM 22a: A general statement such as “care is not medically necessary” does not meet the intent of the principal reason requirement.
- HUM 22b: if the organization provides the clinical rationale in the non certification notification letter then the offer for the clinical rationale in writing would not be required. Remember that the clinical rationale is the specific reason why services are not being authorized specific to the consumer.
- HUM 22b: Some state regulatory requirements may require that the clinical rationale be provided in the letter. Reference the state regulatory requirements for all states in which the Utilization Management Organization conducts business.
- HUM 22b: URAC recognizes in certain circumstances (e.g., a potentially suicidal patient), it may not be appropriate to send the clinical rationale directly to the patient. For these exceptions, URAC will allow the UM organization to send the rationale to the provider, and have the provider discuss the clinical rationale with the patient. Note that this exception applies to clinical rationale, not principal reason. The letter to the patient should refer him or her to the physician or other ordering provider.

- HUM 22c: The non-certification letter must include the process to request an appeal and the clinical rationale (if not provided in the letter). Some states have specific appeal language requirements and it would be prudent to check with regulatory compliance for guidance.
- In some organizations, such as HMO's and PPOs, the patient may not be financially responsible for the non-certification of services, therefore, a written notification letter may not be required to be sent to the patient.
- The clinical rationale provides additional clarification of the clinical basis for a non-certification decision, and specific reasons why the patient's symptoms did not meet the clinical review criteria. The principal reason for the non-certification determination should include a clinical or non-clinical statement as to why the Utilization Management Organization said "no" to the request. For example, "care could be provided in a less acute setting", "insufficient diagnostic work-up", and "conservative treatment not tried nor ruled out", etc. are examples of acceptable documentation. A general statement such as "care is not medically necessary" does not meet the intent of the principal reason requirement. The principal reason for the non-certification determination should include a specific clinical or non-clinical statement.

■ **HUM 23 Clinical Rationale for Non-Certification Requirements**

Upon request from the patient, attending physician, or other ordering provider or facility rendering service, the organization provides specific clinical rationale upon which the non-certification was based.

Interpretive Guidance:

- The clinical rationale provides additional clarification of the clinical basis for a non-certification decision, and specific reasons why the patient's symptoms did not meet the criteria.
- URAC recognizes in certain circumstances (e.g., a potentially suicidal patient), it may not be appropriate to send the clinical rationale directly to the patient. For these exceptions, URAC will allow the UM organization to send the rationale to the provider, and have the provider discuss the clinical rationale with the patient. Note that this exception applies to clinical rationale, not principal reason. The letter to the patient should refer him or her to the physician or other ordering provider.
- Clinical rationale provides supporting documentation specific to the patient under review, for a non-certification decision. Simply referring to clinical criteria is not sufficient to meet the standard.
- The organization can provide the clinical rationale in the non-certification letter, in which case this standard would not be applicable. The organization's policy and/or written procedures should indicate that the rationale is provided.

■ **HUM 24 – Reversal of Certification Determinations**

The organization does not reverse a certification determination unless it receives new information that is relevant to the certification and that was not available at the time of the original certification.

■ **HUM 26 – Scope of Review Information**

The organization, when conducting routine prospective review, concurrent review, or retrospective review:

- (a) Accepts information from any reasonably reliable source that will assist in the certification process;
- (b) Collects only the information necessary to certify the admission, procedure or treatment, length of stay, or frequency or duration of services.
- (c) Does not routinely require hospitals, physicians, and other providers to numerically code diagnoses or procedures to be considered for certification, but may request such codes, if available.
- (d) Does not routinely request copies of all medical records on all patients reviewed;
- (e) Requires only the section(s) of the medical record necessary in that specific case to certify medical necessity or appropriateness of the admission or extension of stay, frequency or duration of service, or length of anticipated inability to return to work; and
- (f) Administers a process to share all clinical and demographic information on individual patients among its various clinical and administrative departments that have a need to know, to avoid duplicate requests for information from enrollees or providers.

■ **HUM 27 – Prospective and Concurrent Review Determinations**

For prospective review and concurrent review, the organization bases review determinations solely on the medical information obtained by the organization at the time of the review determination.

■ **HUM 28 – Retrospective Review Determinations**

For retrospective review, the organization bases review determinations solely on the medical information available to the attending physician or ordering provider at the time the medical care was provided.

B. Request for Information on the Scope of Out-of-Network Coverage

“5. To gather more information on the scope of out-of-network coverage, the Departments are interested in finding out whether plans currently provide out-of-network coverage for mental

health and substance use disorder benefits. If so, how is such coverage the same as or different than out-of-network coverage provided for medical and surgical benefits?”

URAC Response:

URAC’s **Health Plan Accreditation Standards, Version 6.0**, contains a standard, provided below, P-NM 4, which calls for a health plan to implement written policies to ensure members’ access to non-network providers when a covered service is not available from in-network providers, or in emergencies.

■ P-NM 4 - Out of Network and Emergency Services

To the extent it is contractually responsible, the *organization* implements written policies that assure *consumers’* access to:

- (a) Covered services that are not available from *participating providers*; **and**
- (b) Emergency care, both within and outside the *organization’s* service area.

Interpretive Guidance:

- Organizations have an obligation to provide for consumers’ medical care, even when necessary care is not available within the provider network, or when the consumer has a medical emergency.
- The organization’s policies regarding emergency services must address events both within and outside the organization’s service area.
- Note: All elements of the standard are mandatory.
- To be effectively implemented, written policies and/or documented procedures that meet the intent of this standard must be understood not only by network management staff, but also by any employee of the organization that may be called upon to explain to the consumer the policy regarding consumer access to emergency services or providers of services not available within the network.
- Consumer documents should include information about how to obtain emergency care, including the organization’s policy on when and how to directly access emergency care services.

CONCLUSION

URAC appreciates this opportunity to provide our health care accreditation expertise and standards to help the Departments ensure MHPAEA is implemented in a manner that achieves this new statute’s intent, and best serves the interests and needs of U.S. health care consumers. We hope our comments have been helpful, and invite you to learn more about URAC’s accreditation standards, governmental recognitions, operational reviews and additional resources by accessing the policy maker portal on the URAC website (<http://www.urac.org/policyMakers/resources/>).

Please do not hesitate to contact URAC Vice President for Government Relations, Product Development and Education John DuMoulin (jdumoulin@urac.org, 202/962-8836) and URAC Government Relations Director Mara Osman (mosman@urac.org, 202/962-8838) if further URAC input or assistance is required.

Thank you for consideration of these comments.

APPENDIX A

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, education and measurement. Our strategic priorities are to:

- Enhance Continuity of Care;
- Encourage Transparency: Cost & Performance/Quality Data;
- Engage Consumers in their Health Care Management;
- Enhance Operational Management Effectiveness; and
- Engender Support for Evidence-Based Decision-Making

To support these goals, 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:

- 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
- Mail Service Pharmacy
- Medicare Advantage Deeming
- Pharmacy Benefit Management
- Specialty Pharmacy

- Vendor Certification
- Wellness
- Workers' Compensation Pharmacy Benefit Management
- Workers' Compensation Utilization Management

Government Recognition of URAC Accreditation

Federal and state policymakers recognize the value of private accreditation to promote cost-efficiency and to ensure that their constituencies receive quality health care. 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.

Many states have found URAC's accreditation standards helpful in meeting regulatory requirements for managed care plans and other health care organizations and functions. Thirty-nine states and the District of Columbia currently reference accreditation through statute, regulation, agency publication, Request for Proposal or contract language, making URAC the most recognized national managed care accreditation body at the state level.

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 committees review the submitted comments, make 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.

URAC Accreditation Review Process

The URAC accreditation review process begins with applicants for accreditation submitting material through AccreditNet, URAC's secure online application system. When an application

arrives, a reviewer is assigned to conduct an assessment of the submitted documentation for compliance with URAC standards. Any standard that appears non-compliant is noted and communicated to the client with a recommended course of action to meet the standard. Then an onsite review is conducted for each applicant.

URAC staff reviewers are clinical experts who provide application support through the entire accreditation process, including a sharing of best practices during the onsite review. The objective of the onsite review is to verify operational compliance with URAC standards. URAC reviewers, for example, interview the applicant’s staff and review a statistically valid sampling of relevant documentation, including specific quality information. With respect to quality data, URAC accepts nationally recognized measures, such as HEDIS measures to evaluate plan performance and CAHPS data to evaluate consumer satisfaction. URAC may also consider other credible, CMS-recognized quality measures such as the Wisconsin MEDDIC-MS and MEDDIC-MS SSI Performance Measures.

The findings from an applicant’s onsite review are anonymously presented to the URAC committees that make the accreditation determinations through an Executive Summary report. Committee members include industry peers and experts such as physician providers, plan physicians, quality management professionals, information technology experts, pharmacists and security/privacy officials. Levels of accreditation are awarded in accordance with corporate policy and URAC’s accreditation scoring methodology. Applicants receive an official notification letter with their accreditation status and a certificate of accreditation.

URAC Accreditation Standards-At-A-Glance

URAC accreditation programs are comprised of modules, or sets of standards. The Core Organizational Quality Standards serve as the foundation of URAC accreditation, and this module is part of each URAC accreditation program, with the exception of URAC’s Health Information Technology accreditations. The Core standards address several key organization functions that are important for any health care organization:

URAC Core Organizational Quality Standards	
Organizational Structure Defined	Communication Practices Monitored
Policies and Procedures Articulated	Confidentiality Maintained
Clinical Oversight	Access to Services
Staff Qualifications Defined	Promotes Consumer Safety
Staff Credentialing Enforced	Promotes Consumer Satisfaction
Robust Staff Training	Rigorous Complaints and Appeals
Rigorous Information Management	Quality Management Program Defined
Rigorous Regulatory Compliance	
Delegation to Business Partners Monitored	Robust Quality Improvement Projects
HIT Business Continuity Plans (2009)	Health Literacy (2009)

URAC Health Utilization Management Accreditation is URAC’s premier program. Pioneered in 1990, it presented the first-ever industry standards for utilization management and transformed the industry. URAC Health Utilization Management Standards serve as the basis for many states’ laws and regulations and are the most widely recognized utilization management standards at the state and federal level. The standards address key issues in medical necessity decisions:

URAC Health Utilization Management Standards	
Review Criteria	Time Frames for Initial UM Decision
Accessibility of Review Services	Notice of Non-Certification Decisions
On-site Review Services	Notice of Certification Decisions
Initial Screening	UM Procedures
Initial Clinical Review	Information Upon Which UM is Conducted
Peer Clinical Review	
Peer-to-Peer Conversation	Appeals Considerations

FEDERAL RECOGNITIONS (In Detail)

1. Centers for Medicare and Medicaid Services (CMS) recognize URAC Medicare Advantage Health Plan Accreditation for the Medicare Advantage (MA) Program.

CMS granted URAC deemed status in May 2006 for both local PPO and HMO health plans approved under its Medicare Advantage Deeming Program. Deemed status is official recognition by the nation’s third largest payer that URAC accreditation meets or exceeds CMS’s own regulatory standards for plan quality in six areas: quality assessment and improvement; confidentiality and accuracy of enrollee records; antidiscrimination; access to services; provider participation rules; and advance directives. CMS’s approval of URAC for deeming authority was published in the Federal Register on Friday, May 26th, 2006. Deeming authority is granted based on CMS’s determination that URAC’s standards are at least as stringent as those specified under Medicare.

Should an Medicare Advantage (MA) organization receive accreditation from a CMS approved accrediting organization such as URAC, as an alternative for meeting some Medicare requirements, an MA organization may be exempt from CMS monitoring of certain requirements in subsets listed in section 1852(e)(4)(B) of the Social Security Act. In essence, the Secretary deems that the MA organization has met the Medicare requirements via its accreditation (by URAC or other accrediting organization approved by CMS).

2. The Office of Personnel Management (OPM) recognizes all URAC accreditation programs under the Federal Employee Health Benefits Program (FEHBP).

The FEHBP provides health care coverage to approximately eight million federal employees, retirees, and their dependents. Since July 2000, URAC accreditation has been listed in the annual Guide to Federal Employees Health Benefits.

3. The TRICARE/Military Health System, the Department of Defense's managed health care program, recognizes URAC Health Network (HN), Case Management (CM), Health Utilization Management (HUM), and Disease Management (DM) Accreditations.

Through TRICARE, the federal government provides health care services throughout the world to 8.7 million military personnel and their families and military retirees.

Tricare first recognized URAC's Health Network Accreditation in a 2002 Request for Proposals (RFP) (Solicitation No. MDA906-02-R-0006, Aug. 1, 2002). In 2008, TRICARE expanded its recognition of URAC's accreditation standards to include case management (CM), health utilization management (HUM), and disease management (DM). The 2008 RFP (Solicitation No. H94002-07-R-0007, March 24, 2008) requires contractors' networks and utilization and case management programs to be "accredited by a nationally recognized accreditation organization no later than 18 months after the start of health care delivery" and that the accreditations be maintained "in all geographic areas covered by the contract" and "throughout the contract and all exercised options." The RFP further requires that the contractor's disease management programs "meet national accreditation standards for disease management and chronic care management" within the 18 month time frame. TRICARE has specifically identified URAC as a nationally recognized accreditation organization.

4. The Department of Veterans' Affairs (VA) recognizes URAC Health Call Center Accreditation.

The Veterans Health Administration (VHA) has 22 regional Veterans Integrated Service Networks (VISNs) that were instituted to administer the health services for VA hospitals and clinics. (The VHA has 173 medical centers, 650 outpatient community and outreach clinics, and over 51,000 medical center beds with the VHA treating nearly one million patients a year in VA hospitals alone.) In Directive 2000-035 (October 5, 2000), the VHA established as policy that each VISN must ensure that all of its enrolled patients are provided 24x7 direct telephone access to clinical staff who are trained to provide health care advice and information. These telephone care programs/call centers must meet specified minimum standards and must get accredited by URAC or another appropriate accrediting body. URAC is currently the only accrediting body for telephone care and triage call centers.