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Insurance Plans

Blue Cross Blue Shield
Association

Case Management Society
of American

National Association of
Insurance Commissioners

National Business Coalition
on Health

Pharmaceutical Care
Management Association

Marianne Fazen, PhD
Board Chairperson

Alan P. Spielman
President and CEO

November 30, 2010

Elizabeth Fowler, Director of Policy
Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Attention: OCIO-9986-NC
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Director Fowler:

This letter comments on the Request for Information (RFI) published in the *Federal Register* on November 17 concerning the Federal external review process. These comments are offered on behalf of URAC, an independent, nonprofit organization promoting health care quality through accreditation, education and measurement programs. URAC accreditation is recognized by 46 states, the District of Columbia and five federal agencies including the Centers for Medicare and Medicaid Services and the Department of Labor.

Under technical guidance released by the Department of Labor on August 23, 2010 directed at non-grandfathered, self-insured group health plans that are subject to federal external review process requirements, such health plans are required to utilize accredited Independent Review Organizations (IROs) for the determination of external appeals. URAC offers a highly regarded accreditation program specific to external review processes: URAC Independent Review Organization Accreditation.

URAC recently revised its IRO Accreditation standards to align with the requirements of the National Association of Insurance Commissioners (NAIC) Uniform Health Carrier External Review Model Act accreditation program standards. The revised standards, Version 5.0, will be submitted for approval by URAC's Board of Directors later this month.

The revised IRO standards (in draft form) are included as a resource to the Office of Consumer Information and Insurance Oversight (OCIO) and Employee Benefits Security Administration (EBSA) to use in the development of the Federal external review process and related Request for Proposals. Where URAC standards specifically address questions posed in the RFI, those standards are highlighted below.

Qualified Organizations and Staff

RFI Question (1) What accreditation standards currently apply to IROs?

URAC Independent Review Organization Standards currently apply to IROs. URAC's Health Standards Committee reviews and updates the standards pursuant to market changes and emerging quality assurance issues on a regular basis. Version 5.0 of the standards will be published in early 2011 once they are approved by the URAC Board of Directors.

RFI Question (2) What credentialing standards do IROs require for medical and legal reviewers? Is credentialing required or voluntary?

IR 1 - Reviewer Credentialing Program

The organization establishes and implements a reviewer credentialing program that:

- (a) Establishes selection criteria for reviewers;
- (b) Requires verification of all credentials specified in the credentialing program:
 - (i) Prior to assigning reviews to a newly-hired reviewer; and
 - (ii) Thereafter no later than scheduled expiration for those credentials that expire;

For credentials that expire, includes a written policy and/or documented procedure for not assigning cases to a reviewer whose credentials are verified as inactive or have not been re-verified prior to scheduled expiration.

IR 2 - Reviewer Credentials Verification

At a minimum, the reviewer credentialing program shall address verification of professional credentials, including:

- (a) Primary source verification of the requisite licensure or certification required for clinical practice;
- (b) If a reviewer is an M.D., D.O. or D.P.M and is board certified, then primary source verification of the reviewer's board certification(s);
- (c) History of sanctions and/or disciplinary actions; and
- (d) Professional experience including:
 - (i) Length of time providing direct patient care; and
 - (ii) Dates indicating when the direct patient care occurred.
 - (iii) Identifying a reviewer's professional affiliation, privileging or participation with:
 - (iv) Health benefit plans of insurance issuers or group health plans; and Facilities.

IR 3 - Credential Status Changes

The organization implements a written policy and/or documented procedure to:

- (a) Require staff to notify the organization in a timely manner of an adverse change in licensure or certification status, including board certification status; and
- (b) Implement corrective action in response to adverse changes in licensure or certification status, including board certification status.

IR 4 - Reviewer Qualifications

Per IR 1(a), the organization establishes criteria for the qualification of reviewers. Such criteria will specify that for all cases the organization selects reviewers who:

- (a) Have current, non-restricted licensure or certification as required for clinical practice in a state of the United States;
- (b) At a minimum, are clinical peers of the attending provider; and

- (c) Have a scope of licensure or certification and professional experience that typically manages the medical condition, procedure, treatment, or issue under review.

IR 5 - Internal Review: Additional Reviewer Qualifications for Appeals

Per IR 1(a), the organization establishes criteria for the qualification of reviewers. At a minimum, such criteria will specify that for appeals conducted as part of the internal review process the organization selects reviewers who:

- (a) Meet the requirements specified in IR 4;
- (b) If an M.D. or D.O., has board certification by a medical specialty board approved by the American Board of Medical Specialties (ABMS) or the American Osteopathic Association (AOA); and
- (c) If a D.P.M., has board certification by the American Board of Podiatric Surgery (ABPS) or the American Board of Podiatric Orthopedics and primary Podiatric Medicine (ABPOPPM).

IR 6 - External Review: Additional Reviewer Qualifications

Per IR 1(a), the organization establishes criteria for the qualification of reviewers. At a minimum, such criteria will specify that for all external review cases the organization selects reviewers who:

- (a) Meet the requirements as specified in IR 4;
- (b) Meet the requirements as specified in IR 5;
- (c) Have at least five (5) years full-time equivalent experience providing direct clinical care to patients; and
- (d) Have clinical experience within the past three (3) years.

IR 26 – Benefit Coverage/Rescission/Legal Case Processing

When processing a case regarding administrative or legal issues, the organization and its reviewer(s) consider all information necessary to render a decision, such as the applicable health benefit plan contract, other relevant health benefit plan materials and documents, and applicable state or federal law or regulation.

Interpretive Information/Commentary (Guidance to accreditation reviewers).

- Rescission reviews are within the scope of this standard. Organizations conducting these types of reviews are required by compliance standard Core 4 to review relevant state or federal law or regulation, which would include Section 2712 “Prohibition on Rescissions” from federal PL 111-148.
- Non-medical necessity determinations of benefit coverage or reimbursement decision reviews are within the scope of this standard.
- Due process and other legal case processing unrelated to medical necessity determinations are within the scope of this standard.
- Lawyers with health insurance experience can review the cases within the scope of this standard. See definition of “reviewer,” which includes legal case reviewer qualifications.
- Though various companies and states will indicate what information can be considered when rendering a review determination, URAC seeks to establish a minimum threshold and support a national baseline with regards to the information considered for a review.

Scope of Standards

Cases referred to the IRO for independent review involving administrative and/or legal issues, including:

- Non-medical necessity benefit determinations;

- Reimbursement decisions;
- Rescission issues;
- Due process;
- Non-medical necessity legal reviews.

RFI Question (3) What procedures are currently used by IROs to assure that reviewers do not have conflicts of interest with disputing parties?

IR 7 – Defining Reviewer Conflict of Interest

Prior to executing a contract to provide review services, the organization verifies what constitutes reviewer conflict of interest according to applicable state or federal law or regulation as well as the contracting entity, including clarification of the following situations with regards to conflict of interest:

- (a) A reviewer has a contract to provide health care services to enrollees of a health benefit plan of an insurance issuer or group health plan that is the subject of a review; and
- (b) A reviewer has staff privileges at a facility where the recommended health care service or treatment would be provided if the health carrier’s previous non-certification is reversed.

IR 8 - Reviewer Conflict of Interest Attestation

For each case they accept, reviewers attest that they do not have a conflict of interest as follows:

- (a) The reviewer does not accept compensation for review activities that is dependent in any way on the specific outcome of the case;
- (b) To the best of the reviewer’s knowledge, the reviewer was not involved with the specific episode of care prior to referral of the case for review; and
- (c) The reviewer does not have a material professional, familial, or financial conflict of interest regarding any of the following:
 - (i) The referring entity;
 - (ii) The insurance issuer or group health plan that is the subject of the review;
 - (iii) The covered person whose treatment is the subject of the review and the covered person’s authorized representative, if applicable;
 - (iv) Any officer, director or management employee of the insurance issuer that is the subject of the review;
 - (v) Any group health plan administrator, plan fiduciary, or plan employee;
 - (vi) The health care provider, the health care provider’s medical group or independent practice association recommending the health care service or treatment that is the subject of the review;
 - (vii) The facility at which the recommended health care service or treatment would be provided; or
 - (viii) The developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended for the covered person whose treatment is the subject of the review.

Infrastructure

RFI Question (5) Please describe the type of data collection systems that IROs currently use to conduct analyses, reporting, and tracking of appeals and grievances.

IR 15 - Review Database

The organization maintains a database on all reviews and is able to report, at a minimum, the following information for each case:

- (a) The unique identifier assigned to the case;
- (b) The name of the referring entity;
- (c) The state relevant to the case under review;
- (d) The contract relevant to the case under review;
- (e) If available, the insurance issuer or group health plan relevant to the case under review;
- (f) The date the organization received the request to conduct a review from the referring entity;
- (g) The date the organization received the initial information packet from the referring entity;
- (h) If applicable, the date by which additional information beyond what was forwarded in the initial information packet is due to be received in order to resume the review process;
- (i) Whether it is an internal or external review and if an internal review, whether it is an appeal or not;
- (j) Whether the case relates to medical necessity and medical appropriateness, experimental or investigational treatment, administrative or legal, issue or a combination of these categories;
- (k) A description of the issue to be resolved;
- (l) Whether the case was expedited or not;
- (m) The date by which the organization must communicate the determination to the requisite parties.
- (n) The organization's determination regarding the case;
- (o) The date the organization's determination was made; and
- (p) The date the organization's determination was communicated to the requisite parties.

IR 16 - Review File Documentation

For each case, the organization maintains a file that includes:

- (a) The unique identifier assigned to the review case;
- (b) The name, credentials and specialty of the reviewer(s) and/or unique identifier for the reviewer(s);
- (c) Reviewer attestation regarding conflict of interest;
- (d) The specific question or issue to be resolved by the review process;
- (e) Whether the case relates to medical necessity and medical appropriateness, experimental or investigational treatment, administrative or legal issue, or a combination of these areas;
- (f) Whether the case is expedited or not;
- (g) Clinical evidence and information considered during the review;
- (h) References to any applicable medical literature/research data or national clinical criteria upon which the reviewer's determination was based; and

- (i) Documentation of all correspondence and communication between the organization, the reviewer(s) and any other party regarding the case, including a copy of the final determination letter.

RFI Question (9) What considerations must be taken into account to smoothly transition from the current Federal interim external review process to a possible new permanent Federal external review process?

To ensure a smooth transition from the interim process to a permanent process, URAC recommends that OCIIO and EBSA maintain the accreditation requirement for IROs. In doing so, OCIIO and EBSA can ensure that IROs contracting with the Federal government to conduct external reviews meet current industry benchmarks and have policies and procedures in place to protect the interests of the patient through the external review process.

In addition, OCIIO and EBSA should recognize URAC's Health Utilization Management (HUM) accreditation programs. While IRO accreditation focuses on the processes and credentials of independent organizations conducting benefits and clinical reviews, HUM accreditation ensures the health plan or third party administrator internal medical necessity reviews are in compliance with industry standards and federal regulations.

For example, URAC's HUM program ensures the following:

- Requires internal health plan processes for reviewing medical necessity appeals of denied claims are timely, evidence-based and reviewed by licensed clinical peers;
- Requires that medical necessity denials are only rendered by licensed physicians,
- Requires toll-free complaint lines be made available between 9:00 am to 5:00 pm in every time zone where reviews are conducted;
- Requires that review staff respond to requests from patients, facility personnel, attending or ordering physician or other health personnel of specific utilization management requirements and procedures;
- Requires that licensed health professionals are available to non-clinical administrative staff while performing non-clinical initial screenings;
- Maintains separate timelines for prospective, retrospective and concurrent reviews;
- Ensures treating physicians are ensured access to peer reviewers during the review process so that all clinically relevant information is taken into account during medical necessity reviews; and
- Requires plans to provide patients with timely written clinical rationales when care is denied based on medical necessity and accept requests for appeals verbally and in writing from the consumer and/or treating provider.

URAC's HUM standards also ensure that requests for expedited review of denied care are processed within timelines established by the Department of Labor.

URAC suggests that the Department of Labor explore how Health Utilization Management accreditation might be utilized as a compliance and oversight tool to further strengthen

consumer protection and access to needed health care services as a mechanism to avoid inappropriate denials of medically necessary care.

URAC's overriding goal in both the IRO and HUM accreditation programs is consumer protection. In keeping with that mission, URAC separately investigates consumer complaints against accredited companies. Consumers and providers can lodge a complaint against an accredited company by visiting: <http://webapps.urac.org/complaint/>.

Data Collection

RFI Question (13) What data are currently collected by IROs for tracking appeals and conducting analyses?

IR 15 - Review Database

The organization maintains a database on all reviews and is able to report, at a minimum, the following information for each case:

- (a) The unique identifier assigned to the case;
- (b) The name of the referring entity;
- (c) The state relevant to the case under review;
- (d) The contract relevant to the case under review;
- (e) If available, the insurance issuer or group health plan relevant to the case under review;
- (f) The date the organization received the request to conduct a review from the referring entity;
- (g) The date the organization received the initial information packet from the referring entity;
- (h) If applicable, the date by which additional information beyond what was forwarded in the initial information packet is due to be received in order to resume the review process;
- (i) Whether it is an internal or external review and if an internal review, whether it is an appeal or not;
- (j) Whether the case relates to medical necessity and medical appropriateness, experimental or investigational treatment, administrative or legal, issue or a combination of these categories;
- (k) A description of the issue to be resolved;
- (l) Whether the case was expedited or not;
- (m) The date by which the organization must communicate the determination to the requisite parties.
- (n) The organization's determination regarding the case;
- (o) The date the organization's determination was made; and
- (p) The date the organization's determination was communicated to the requisite parties.

RFI Question (14) What steps are taken to ensure confidentiality and security protections of patient information?

CORE 15 - Information Confidentiality and Security

The organization provides for data confidentiality and security of its information system(s) (electronic and paper) by implementing written policies and/or documented procedures that address:

- (a) Assessment of the potential risks and vulnerabilities to the confidentiality, integrity and availability of information systems;
- (b) Prevention of confidentiality and security breaches; and
- (c) Detection, containment and correction of confidentiality and security violations.

CORE 16 - Confidentiality of Individually-Identifiable Health Information

The organization implements written policies and/or documented procedures to protect the confidentiality of individually-identifiable health information that:

- (a) Identifies how individually-identifiable health information will be used;
- (b) Specifies that individually-identifiable health information is used only for purposes necessary for conducting the business of the organization, including evaluation activities;
- (c) Addresses who will have access to individually-identifiable health information collected by the organization;
- (d) Addresses oral, written or electronic communication and records that are transmitted or stored;
- (e) Address the responsibility of organization employees, committee members and board members to preserve the confidentiality of individually-identifiable health information; and
- (f) Requires employees, committee members and board members of the organization to sign a statement that they understand their responsibility to preserve confidentiality.

Evaluation

RFI Question (15) Do IROs (or subcontractors) currently conduct evaluations of their operations? Do such evaluations include an assessment of how easy it is for consumers to access and use the external review process in a timely manner? Do evaluations result in quality improvement initiatives? If so, what are some examples of quality improvement initiatives undertaken by IROs?

IR 17 - Performance Monitoring

The organization monitors its performance regarding review procedures according to its written policies and/or documented procedures, whereby:

- (a) Prior to communicating a review determination with a referring entity:
 - (i) The medical director (or equivalent designate) conducts and documents a quality check for at least the first two (2) cases conducted by a reviewer new to the organization; and

- (ii) The organization conducts a quality check and if a review does not meet the organization's quality standards, then each issue and its outcome are documented;
- (b) The medical director (or equivalent designate) conducts and documents random quality checks;
- (c) The organization conducts and documents random regulatory compliance checks for each state that it does business in;
- (d) The organization conducts and documents random compliance checks among the current contracts that are within the scope of this accreditation;
- (e) At least quarterly, the organization generates reports to track and trend against measures of acceptable levels of performance with regards to:
 - (i) Review timelines;
 - (ii) Routine quality checks per standard element (a)(ii);
 - (iii) Random quality checks per standard element (b);
 - (iv) Random compliance checks per standard elements (c) and (d);
 - (v) Client complaints; and
- (f) As needed, the organization implements action plans to correct identified problems and meet acceptable levels of performance for measures.

URAC appreciates the opportunity to respond to the RFI and provide input in the Federal external appeals process. URAC's goal through its IRO Accreditation program is to set a minimum standard of consumer protections for participants, beneficiaries, and enrollees who appeal medical necessity, treatment, and coverage decisions. By utilizing accredited IROs to conduct external reviews under the Federal process, OCIO and EBSA can ensure that IROs meet established industry benchmarks for patient protection. If we can answer any questions about URAC accreditation or our standards for IROs, please feel free to contact Michele Johnson, Director of Federal Relations at mjohnson@urac.org or by calling (202) 962-8835.

Thank you for your consideration.

Sincerely,



Alan P. Spielman
President & CEO

Attachments:

URAC Independent Review Accreditation (Version 5.0, Draft Standards for Board Approval)

DRAFT Independent Review Organization Standards, v5.0

For December URAC Board Review and Approval

Expires 12/16/10

The table below reflects the proposed draft standards. The standard names are highlighted as follows: **Yellow** reflects standards applicable to all types of reviews, **blue** identifies standards applicable to internal reviews only and **green** are applicable to external reviews.

Standard	Applies to Internal Review (IR): Peer Clinical Review	Applies to Internal Review (IR): Appeals	Applies to External Review (ER)
Version 3.0 CORE Standards Applicable to all organizations applying for accreditation			
CORE 1 - Organizational Structure	X	X	X
CORE 3 - Policy and Procedure Maintenance, Review and Approval	X	X	X
CORE 4 - Regulatory Compliance	X	X	X
CORE 6 - Delegation Review Criteria	X	X	X
CORE 7 - Delegation Review	X	X	X
CORE 8 - Delegation Contracts	X	X	X
CORE 9 - Delegation Oversight	X	X	X
CORE 11 - Written Business Agreements	X	X	X
CORE 12 - Client Satisfaction	X	X	X
CORE 13 - Information Management	X	X	X
CORE 14 - Business Continuity	X	X	X
CORE 15 - Information Confidentiality and Security	X	X	X
CORE 16 - Confidentiality of Individually-Identifiable Health Information	X	X	X
CORE 25 - Job Descriptions	X	X	X
CORE 26 - Staff Qualifications	X	X	X
CORE 27 - Staff Training Program	X	X	X
CORE 28 - Staff Operational Tools and Support	X	X	X
CORE 31 - Senior Clinical Staff Requirements	X	X	X
CORE 32 - Senior Clinical Staff Responsibilities	X	X	X
CORE 33 - Financial Incentive Policy	X	X	X
CORE 38 - Consumer Safety Mechanism	X	X	X
(Continued on following page.)			

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Standard	Applies to Internal Review (IR): Peer Clinical Review	Applies to Internal Review (IR): Appeals	Applies to External Review (ER)
Reviewer Credentialing & Qualifications			
IR 1 - Reviewer Credentialing Program	X	X	X
IR 2 - Reviewer Credentials Verification	X	X	X
IR 3 - Credential Status Changes	X	X	X
IR 4 - Reviewer Qualifications	X	X*	X*
		*By reference in IR 5	*By reference in IR 6
IR 5 - Internal Review: Additional Reviewer Qualifications for Appeals		X	X*
			*By reference in IR 6
IR 6 - External Review: Additional Reviewer Qualifications			X
Conflict of Interest			
IR 7 - Defining Reviewer Conflict of Interest	X	X	X
IR 8 - Reviewer Conflict of Interest Attestation	X	X	X
IR 9 - Reviewer Attestation Regarding Experience and Knowledge	X	X	X
IR 10 - External Review: Reviewer Attestation Regarding Experience			X
IR 11 - External Review: Independent Review Policy			X
IR 12 - External Review: Defining Organizational COI			X
IR 13 - External Review: Organizational COI Attestation			X
IR 14 - External Review: Organizational COI Transparency Process			X
Tracking, Monitoring & Reporting			
IR 15 - Review Database	X	X	X
IR 16 - Review File Documentation	X	X	X
IR 17 - Performance Monitoring	X	X	X
IR 18 - Summary Reports for External Entities	X	X	X
Independent Review Process			
IR 19 - Initial Case Assessment	X	X	X
IR 20 - Review of Additional Information	X	X	X
IR 21 - External Review: Additional Information Processing			X
IR 22 - Time Frames for External Reviews			X
IR 23 - Expedited Review Process	X	X	X
IR 24 - Medical Necessity/Appropriateness Case Processing	X	X	X
IR 25 - Experimental/Investigational Case Processing	X	X	X
IR 26 - Benefit Coverage/Rescission/Legal Case Processing	X	X	X
IR 27 - Decision Notice	X	X	X

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Core Standards, Version 3.0 for proposed Independent Review Organization (IRO) v5.0

CORE 1 - Organizational Structure

The *organization* has a clearly defined organizational structure outlining direct and indirect oversight responsibility throughout the *organization*. [2]

CORE 3 - Policy and Procedure Maintenance, Review and Approval

The *organization*: [--]

- (a) Maintains and complies with written policies and documented procedures that govern core business processes of its operations related to the scope of the accreditation; [M]
- (b) Maintains the ability to produce a master list of all such policies and procedures; [2]
- (c) Reviews written policies and documented procedures no less than annually and revises as necessary; [3]
- (d) Includes the following on the master list or on all written policies and documented procedures: [--]
 - (i) Effective dates, review dates, including the date of the most recent revision; **and** [2]
 - (ii) Identification of approval authority. [2]

CORE 4 - Regulatory Compliance

The *organization* implements a regulatory compliance program that: [--]

- (a) Tracks applicable laws and regulations in the jurisdictions where the *organization* conducts business; [M]
- (b) Ensures the *organization's* compliance with applicable laws and regulations; **and** [M]
- (c) Responds promptly to detected problems and takes corrective action as needed. [4]

CORE 6 - Delegation Review Criteria

The *organization* establishes and implements criteria and processes for an assessment prior to the *delegation* of functions. [3]

CORE 7 - Delegation Review

Prior to *delegating* functions to another entity, the *organization*: [--]

- (a) Establishes and implements a process to conduct a review of the potential contractor's written policies and documented procedures and capacity to perform delegated functions; **and** [3]
- (b) Outlines and follows criteria and processes for approving *contractors*. [3]

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CORE 8 - Delegation Contracts

The *organization* enters into *written agreements* with *contractors* that: [--]

- (a) Specify those responsibilities *delegated* to the *contractor* and those retained by the *organization*; [2]
- (b) Require that services be performed in accordance with the *organization's* requirements and URAC standards; [M]
- (c) Require notification to the *organization* of any material change in the *contractor's* ability to perform *delegated* functions; [4]
- (d) Specify that the *organization* may conduct surveys of the *contractor*, as needed; [2]
- (e) Require that the *contractor* submit periodic reports to the *organization* regarding the performance of its *delegated* responsibilities; [3]
- (f) Specify recourse and/or sanctions if the *contractor* does not make corrections to identified problems within a specified period; [2]
- (g) Specify the circumstances under which activities may be further *delegated* by the *contractor*, including any requirements for obtaining permission from the *organization* before any further *delegation*; **and** [4]
- (h) Specify that, if the *contractor* further *delegates* organizational functions, those functions shall be subject to the terms of the *written agreement* between the *contractor* and the *organization* and in accordance with URAC standards. [M]

CORE 9 - Delegation Oversight

The *organization* establishes and implements an oversight mechanism for delegated functions within the scope of accreditation that includes: [--]

- (a) A periodic review (no less than annually) of the *contractor's* written policies and documented procedures and documentation of quality activities for related delegated functions; [2]
- (b) A process to verify (no less than annually) the *contractor's* compliance with contractual requirements and written policies and documented procedures; **and** [M]
- (c) A mechanism to monitor financial incentives to ensure that quality of care or service is not compromised. [3]

CORE 11 - Written Business Agreements

The *organization* maintains signed *written agreements* with all *clients* describing the scope of the business arrangement. [2]

CORE 12 - Client Satisfaction

The *organization* implements a mechanism to collect or obtain information about *client* satisfaction with services provided by the *organization*. [3]

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CORE 13 - Information Management

The *organization* implements information system(s) (*electronic* and paper) to collect, maintain and analyze information necessary for organizational management that: [--]

- (a) Provides for *data integrity*; [M]
- (b) Includes a plan for storage, maintenance and destruction; **and** [2]
- (c) Includes a plan for *interoperability*: [--]
 - (i) Between internal information systems; **and** [Leading Indicator]
 - (ii) With external entity information systems. [Leading Indicator]

CORE 14 - Business Continuity

The *organization* implements a business continuity plan for program operations, including information system(s) (*electronic* and paper) that: [--]

- (a) Identifies which systems and processes must be maintained and the effect an outage would have on the *organization's* program; [3]
- (b) Identifies how business continuity is maintained given various lengths of time information systems are not functioning or accessible; [3]
- (c) Is tested at least every two years; **and** [3]
- (d) Responds promptly to detected problems and takes corrective action as needed. [3]

CORE 15 - Information Confidentiality and Security

The *organization* provides for data confidentiality and security of its information system(s) (*electronic* and paper) by implementing written policies and/or documented procedures that address: [--]

- (a) Assessment of the potential risks and vulnerabilities to the confidentiality, integrity and availability of information systems; [3]
- (b) Prevention of confidentiality and security breaches; **and** [M]
- (c) Detection, containment and correction of confidentiality and security violations. [M]

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CORE 16 - Confidentiality of Individually-Identifiable Health Information

The *organization* implements written policies and/or documented procedures to protect the confidentiality of *individually-identifiable health information* that: [--]

- (a) Identifies how *individually-identifiable health information* will be used; [M]
- (b) Specifies that *individually-identifiable health information* is used only for purposes necessary for conducting the business of the organization, including evaluation activities; [M]
- (c) Addresses who will have access to *individually-identifiable health information* collected by the *organization*; [M]
- (d) Addresses oral, written or *electronic* communication and records that are transmitted or stored; [M]
- (e) Address the responsibility of *organization* employees, committee members and board members to preserve the confidentiality of *individually-identifiable health information*; **and** [M]
- (f) Requires employees, committee members and board members of the *organization* to sign a statement that they understand their responsibility to preserve confidentiality. [M]

CORE 25 - Job Descriptions

The *organization* has written job descriptions for *staff* that address requirements pertinent to the scope of the positions' roles and responsibilities: [--]

- (a) Required education, training, and/or professional experience; [2]
- (b) Expected *professional competencies*; [2]
- (c) Appropriate *licensure/certification* requirements; **and** [2]
- (d) Current scope of roles and responsibilities. [2]

CORE 26 - Staff Qualifications

Staff meets qualifications as required in written job descriptions. [3]

CORE 27 - Staff Training Program

The *organization* has an ongoing training program that includes: [--]

- (a) Initial orientation and/or training for all *staff* before assuming assigned roles and responsibilities; [2]
- (b) Training in current URAC standards as appropriate to job functions; [2]
- (c) Conflict of interest; [4]
- (d) Confidentiality; [M]
- (e) Documentation of all training provided for *staff*; **and** [2]
- (f) Ongoing training, at a minimum annually, to maintain *professional competency*. [2]

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CORE 28 - Staff Operational Tools and Support

The *organization* provides *staff* with: [--]

- (a) Written policies and/or documented procedures appropriate to their jobs; [2]
- (b) *Clinical decision support tools* as appropriate; **and** [2]
- (c) Regulatory requirements as related to their job function. [2]

CORE 31 - Senior Clinical Staff Requirements

The *organization* designates at least one senior clinical *staff* person who has: [--]

- (a) Current, unrestricted clinical *license(s)* (or if the *license* is restricted, the *organization* has a process to ensure job functions do not violate the restrictions imposed by the State licensure board); [M]
- (b) Qualifications to perform clinical oversight for the services provided; [M]
- (c) Post-graduate experience in direct patient care; **and** [M]
- (d) *Board certification* (if the senior clinical *staff* person is an M.D. or D.O.). [3]

CORE 32 - Senior Clinical Staff Responsibilities

A senior clinical *staff* person's program responsibilities include: [--]

- (a) Provides guidance for clinical operational aspects of the program; [3]
- (b) Is responsible for oversight of clinical decision-making aspects of the program; [M]
- (c) Has periodic consultation with practitioners in the field; **and** [3]
- (d) Ensures the organizational objective to have qualified clinicians accountable to the *organization* for decisions affecting *consumers*. [M]

CORE 33 - Financial Incentive Policy

If the *organization* has a system for reimbursement, bonuses or incentives to *staff* or health care providers based directly on *consumer* utilization of health care services, then the *organization* implements mechanisms addressing how the *organization* will ensure that *consumer* health care is not compromised. [M]

CORE 38 - Consumer Safety Mechanism

The *organization* has a mechanism to respond on an urgent basis to situations that pose an immediate threat to the health and safety of *consumers*. [M]

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Reviewer Credentialing & Qualifications

IR 1 - Reviewer Credentialing Program

The *organization* establishes and implements a *reviewer* credentialing program that: [--]

- (a) Establishes selection criteria for *reviewers*; [4]
- (b) Requires verification of all credentials specified in the credentialing program: [--]
 - (i) Prior to assigning reviews to a newly-hired reviewer; **and** [M]
 - (ii) Thereafter no later than scheduled expiration for those credentials that expire; [M]
- (c) For credentials that expire, includes a written policy and/or documented procedure for not assigning cases to a reviewer whose credentials are verified as inactive or have not been re-verified prior to scheduled expiration. [4]

Interpretive Information/Commentary

- For standard element (b)(ii), credentials that expire include those items identified in IR 2(a) and (b). The one exception to this would be for IR 2(b) (i.e., board certification) for an MD, DO or DPM who was “grandfathered” into a lifetime board certification. This exception, where it exists, must be documented in the credentialing file.
- For standard element (b)(iii), credentials that can change over time include those items identified in IR 2(c), (d) and (e).
- For standard element (b)(iii), establishing auto-notification with a credentialing source such as the NPDB or FSMB qualifies as annual re-verification; whereas, reviewers provide the information needed to update credentials cited in IR 2(c) and (d).
- For standard element (c), the intent is for organizations to suspend assigning cases to a reviewer when a credential needed to conduct a review has expired or is otherwise inactive. The same process applies when the organization has not re-verified the credential prior to scheduled expiration. *
- * Documentation of this action, should it occur, must be reflected on the roster of available reviewers for the time period the suspension is in effect. The roster cover sheet and requisite page can be filed in the reviewer’s credentialing file or a single “suspension file” kept for reference and verification of this standard.

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IR 2 - Reviewer Credentials Verification

At a minimum, the *reviewer* credentialing program shall address verification of professional credentials, including: [--]

- (a) *Primary source verification* of the requisite *licensure* or *certification* required for clinical practice; [M]
- (b) If a reviewer is an M.D., D.O. or D.P.M and is *board certified*, then *primary source verification* of the reviewer's *board certification(s)*; [M]
- (c) History of sanctions and/or disciplinary actions; **and** [M]
- (d) Professional experience including: [--]
 - (i) Length of time providing direct patient care; **and** [M]
 - (ii) Dates indicating when the direct patient care occurred. [M]
- (e) Identifying a reviewer's professional affiliation, privileging or participation with: [--]
 - (i) *Health benefit plans* of insurance issuers or *group health plans*; **and** [4]
 - (ii) *Facilities*. [4]

Interpretive Information/Commentary

- For standard element (a), there are instances where certification – not licensure – is required to engage in clinical practice. By way of example, some behavioral health social workers must be certified. Note therefore that this element *does not* include board certification for physicians, but rather the minimum licensure or certification needed for clinical practice. Please reference standard element (b), which addresses board certification as it applies to reviewer credentials verification.
- Organizations must know a reviewer's professional experience and be able to evaluate the potential for a reviewer to conduct reviews at any level (e.g., internal peer clinical review, internal appeal and external review); therefore, details concerning professional experience as indicated in element (d) are required.
- Standard element (d)(i) is expressed as a full-time equivalent ("FTE"), which is typically defined as 37.5-40 hours or more per week.
- Standard element (e) supports determining conflict of interest due to these professional relationships. Please reference IR 7 - Defining Conflict of Interest for more information.

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IR 3 - Credential Status Changes

The *organization* implements a written policy and/or documented procedure to: [--]

- (a) Require *staff* to notify the *organization* in a timely manner of an adverse change in *licensure* or *certification* status, including *board certification* status; **and** [M]
- (b) Implement corrective action in response to adverse changes in *licensure* or *certification* status, including *board certification* status. [M]

Interpretive Information/Commentary

- Organizations will need to define what is meant by “timely manner” as indicated in standard element (a). Generally speaking, within 1-2 business days is considered “timely” given a change in the status of a reviewer’s credentials.
- In this particular standard, element (a) includes board certification status as well as licensure or certification required to engage in clinical practice.
- For standard element (b), please reference IR 1(c) for one of the steps comprising corrective action. There are other aspects of corrective action, such as follow up activities that the organization will want to include as part of this process.
- Note that the scope of IR 3(b) includes any adverse change, not just that the credential is no longer active as outlined in IR 1(c). Please reference IR 1(b)(iii), which calls for a “credentials monitoring process.” For instance, a license or certification needed to practice may still be active, but may have changed due to a restriction placed on it. Such a restriction could be discovered as part of this monitoring process.

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IR 4 - Reviewer Qualifications

Per IR 1(a), the *organization* establishes criteria for the qualification of *reviewers*. Such criteria will specify that for all *cases* the *organization* selects *reviewers* who: [--]

- (a) Have current, non-restricted *licensure* or *certification* as required for clinical practice in a state of the United States; [M]
- (b) At a minimum, are *clinical peers* of the *attending provider*; **and** [M]
- (c) Have a scope of *licensure* or *certification* and professional experience that typically manages the medical condition, procedure, treatment, or issue under review. [M]

Interpretive Information/Commentary

- For standard element (a), there are instances where certification – not licensure – is required to engage in clinical practice. By way of example, some behavioral health social workers must be certified. Note therefore that this element *does not* include board certification, but rather the minimum licensure or certification needed for clinical practice. Please reference IR 5 and IR 6, which addresses board certification requirements for reviewers.
- Standard element (b) indicates that the selected reviewer will at a minimum, be a “clinical peer” of the attending provider (see URAC’s definition for this term), which means that the reviewer is in the same licensure category as the attending.
- Note that even with the minimum licensure or certification to practice, the reviewer must be of the type that would typically manage the care situation under review per standard element (c). By way of example, an oncologist would be selected to review a request for certification of cancer treatment, even if the attending provider is a primary care physician (PCP) or generalist. Where the organization selects the reviewer, in particular with external reviews, URAC will verify appropriate peer reviewer selection.
- The selected reviewer attests to having current, relevant experience and/or knowledge for the case under review [IR 4(d)]. This attestation can be combined with the reviewer conflict of interest attestation required by standard IR 8.

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IR 5 - Internal Review: Additional Reviewer Qualifications for Appeals

Per IR 1(a), the *organization* establishes criteria for the qualification of *reviewers*. At a minimum, such criteria will specify that for *appeals* conducted as part of the *internal review* process the *organization* selects *reviewers* who: [--]

- (a) Meet the requirements specified in IR 4; [M]
- (b) If an M.D. or D.O., has board certification by a medical specialty board approved by the American Board of Medical Specialties (ABMS) or the American Osteopathic Association (AOA); **and** [M]
- (c) If a D.P.M., has board certification by the American Board of Podiatric Surgery (ABPS) or the American Board of Podiatric Orthopedics and primary Podiatric Medicine (ABPOPPM). [M]

IR 6 - External Review: Additional Reviewer Qualifications

Per IR 1(a), the *organization* establishes criteria for the qualification of *reviewers*. At a minimum, such criteria will specify that for all *external review cases* the *organization* selects *reviewers* who: [--]

- (a) Meet the requirements as specified in IR 4; [M]
- (b) Meet the requirements as specified in IR 5; [M]
- (c) Have at least five (5) years full-time equivalent experience providing direct clinical care to *patients*; **and** [3]
- (d) Have clinical experience within the past three (3) years. [3]

Interpretive Information/Commentary

- For standard element (c), information about a reviewer's professional experience is collected as part of the credentialing program requirements as outlined in standard IR 2(d) and attested to by the reviewer per IR 9. Full-time equivalent ("FTE") is typically defined as 37.5-40 hours or more per week.
- The 2008 NAIC Uniform Health Carrier External Review Model Act indicates "...through clinical experience in the past three (3) years," physicians or other health care professionals are considered experts in their clinical areas (Section 10.D(4)(a) found on page 76-21 of the Model Act). Recent clinical experience is one of several important considerations when selecting a reviewer.
 - Verification of clinical experience is addressed in standard IR 2(d).
 - As part of a compliance program and in order to meet standard Core 4, organizations will need to verify whether recent clinical practice is a requirement by state or federal law or regulation and how it is defined.
 - In addition, the reviewer conducting the external review must be an expert in the treatment of the covered person's medical condition that is the subject of the external review; and
 - Be knowledgeable about the recommended health care service or treatment through recent or current actual clinical experience treating patients with the same or similar medical condition of the covered person, (which is addressed in the reviewer's attestation).

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Conflict of Interest

IR 7 – Defining Reviewer Conflict of Interest

Prior to executing a contract to provide review services, the *organization* verifies what constitutes *reviewer conflict of interest* according to applicable state or federal law or regulation as well as the contracting entity, including clarification of the following situations with regards to *conflict of interest*: [--]

- (a) A *reviewer* has a contract to provide health care services to enrollees of a *health benefit plan* of an insurance issuer or *group health plan* that is the subject of a *review*; **and** [4]
- (b) A *reviewer* has staff privileges at a *facility* where the recommended health care service or treatment would be provided if the health carrier's previous non-certification is reversed. [4]

Interpretive Information/Commentary

- The elements (a) and (b) are not required exclusions, but rather, need to be clarified before executing a contract.
- Element (a) includes participation in advisory groups that provide guidance to the various programs that support a provider network, including credentialing, medical policy and quality management committees. However, under these standards participation in an insurance issuer's or group health plan's board of directors or any sub-committee of that board is considered a conflict of interest for an individual clinical practitioner. *
- The term "enrollees" in standard element (a) is synonymous with "covered person."
- For external review in particular, elements (a) and (b) may be determined by state or federal law or regulation.
- Note that standard element (a) *is not* referring to situations where a reviewer is conducting reviews for an insurance issuer or group health plan, which is considered a conflict of interest under these standards; please reference IR 8(c)(ii) along with its supporting interpretive information for further clarification.
- * In addition, having a role in management – in particular, as a medical director at any level of any department of an insurance issuer or group health plan – is also considered to be a "material professional" conflict of interest for a reviewer. Again, reference IR 8(c)(ii) along with its supporting interpretive information for more information.
- The presence of a conflict of interest may vary from state to state and among clients.
- This standard is implemented on a going-forward basis, such that written policies and/or documented procedures must be in effect at the time an organization submits its application for initial accreditation or reaccreditation. For every contract initiated after that submittal date, URAC will examine client-specific documentation that these reviewer conflict of interest issues were determined and agreed upon between the organization and its clients. Refer to the following bullet for examples of this documentation. *
- * For the purposes of desktop review, documentation defining reviewer conflict of interest includes state or federal law or regulation, contract language, contract addendum, letter of understanding (LOU) or memorandum of understanding (MOU) between the parties. A template copy of the reviewer attestation is also submitted for desktop.

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IR 8 - Reviewer Conflict of Interest Attestation

For each case they accept, *reviewers* attest that they do not have a *conflict of interest* as follows: [--]

- (a) The *reviewer* does not accept compensation for *review* activities that is dependent in any way on the specific outcome of the *case*; [M]
- (b) To the best of the *reviewer's* knowledge, the *reviewer* was not involved with the specific episode of care prior to referral of the case for *review*; **and** [M]
- (c) The *reviewer* does not have a material professional, familial, or financial *conflict of interest* regarding any of the following: [--]
 - (i) The *referring entity*; [M]
 - (ii) The insurance issuer or *group health plan* that is the subject of the *review*; [M]
 - (iii) The *covered person* whose treatment is the subject of the *review* and the *covered person's authorized representative*, if applicable; [M]
 - (iv) Any officer, director or management employee of the insurance issuer that is the subject of the *review*; [M]
 - (v) Any group health plan administrator, plan fiduciary, or plan employee; [M]
 - (vi) The health care *provider*, the health care *provider's* medical group or independent practice association recommending the health care service or treatment that is the subject of the *review*; [M]
 - (vii) The *facility* at which the recommended health care service or treatment would be provided; **or** [M]
 - (viii) The developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended for the *covered person* whose treatment is the subject of the *review*. [M]

Interpretive Information/Commentary

- Acceptable means for reviewers to "...attest that they do not have a conflict of interest..." for each case they accept includes: electronic signature, wet signature, electronic or wet mark in a checkbox where the identity of the reviewer can be determined (e.g., by name and/or unique identifier).
- For element (a), the operative word is "episode of care," where for a particular patient a reviewer may not conduct a review if s/he was previously involved in any way with the given episode of care under review. URAC uses "episode of care" and "specific case" to mean the same thing. See also URAC's definition of "conflict of interest."
- For element (c), in order to have a financial conflict of interest, a reviewer would have ownership interest of greater than 5% in a particular entity as listed in the sub-elements for this standard (i)-(vii). See also URAC's definition of "conflict of interest."
- For element (c):
 - Refer to standards IR 2(e)(i) and IR 7(a) when addressing IR 8(c)(ii).
 - In addition, for IR 8(c)(ii) and (iv), if a reviewer conducts reviews for an insurance issuer or group health plan that is the subject of a review, or participates in management, including supervises others on behalf of the insurance issuer or group health plan (i.e., a medical director at any level of any department), or participates on the insurance issuer's or group health plan's board of directors or

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any subcommittee of the board, then *this is considered a conflict of interest* pursuant to this standard.

- For IR 8(vi), refer to standards IR 2(e)(ii) and IR 7(b).
- Given the nuances in the areas related to conflict of interest, it is prudent for an organization to ensure a clear understanding with regards to these areas between the organization and each of its clients.
- In cases where the insurance issuer or group health plan is not known to the organization, then it is presumed that there is no conflict of interest with the insurance issuer or group health plan [IR 8(c)(ii)].

IR 9 - Reviewer Attestation Regarding Experience and Knowledge

For each *case* they accept, *reviewers* attest to: [--]

- (a) Having a scope of *licensure* or *certification* that typically manages the medical condition, procedure, treatment, or issue under review; **and** [M]
- (b) Current, relevant experience and/or knowledge to render a determination for the *case* under review. [M]

IR 10 - External Review: Reviewer Attestation Regarding Experience and Knowledge

For each *external review case* they accept, *reviewers* attest to meeting identified minimum requirements for direct patient care experience related to: [--]

- (a) Length of time providing direct patient care; **and** [M]
- (b) How recent the reviewer's relevant direct patient care experience is. [M]

Interpretive Information/Commentary

- The information required by this standard is applicable to those review cases where there are minimum requirements related to a reviewer's experience with direct patient care (e.g., length of time and how recent the experience is).
- These issues can be addressed in the same attestation addressing conflict of interest [IR 8].
- Please reference standard IR 4(d) where reviewers attest to current, relevant experience and/or knowledge for the case under review.
- URAC does not prescribe the mode of delivery for the attestation, which can be hard copy or electronic.

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IR 11 - External Review: Independent Review Policy

The *organization* establishes a written policy applicable to *external reviews* whereby: [--]

- (a) In selecting a *reviewer*, the *organization* does not allow the *covered person*, the *covered person's authorized representative*, if applicable, or the insurance issuer or *group health plan* to choose or control the choice of the physician(s) or other health care professional(s) to be selected to conduct the review; [M]
- (b) In reaching a conclusion, the *reviewer* is not bound by any decisions or conclusions reached during the insurance issuer's or *group health plan's utilization review* process or internal grievance process; [M]
- (c) In rendering a review decision, the *organization* bases its decision upon the conclusion of the *reviewer(s)*; [M]
- (d) The *organization* verifies that a *reviewer* does not have a *conflict of interest* with an assigned *case*; [M]
- (e) The *organization* does not accept compensation for *external independent review* activities that is dependent in any way on the specific outcome of the *case*; [M]
- (f) The *organization* will not knowingly accept a case with which it has an organizational *conflict of interest*; **and** [M]
- (g) Pursuant to standard IR 13, the *organization* notifies the *referring entity* should it discover at any point prior to or during the external review process that it has an organizational *conflict of interest*. [M]

Interpretive Information/Commentary

- Upon desktop review, the organization's written policy will be reviewed for compliance with this standard. If any other written policy or documented procedure appears to conflict with this policy, then it will be cited as an issue upon desktop and/or onsite review.
- During the onsite review, the organization's leadership will be interviewed to verify their understanding of the policy and determine what steps would be taken if an organizational conflict of interest was discovered during the course of handling a review [IR 12].
- It *is not* the intent of standards IR 9, 10, 11 and 12 to have the organization (i.e., IRO) conduct an assessment of potential organizational conflict of interest for every external review case that is referred to it; instead, these issues are worked out *prior to* executing contracts and referring external review cases to the organization. *
- * By way of example, if the contracting entity determines that an organization's prior involvement with a specific episode of care under review in and of itself constitutes an organizational conflict of interest, then preferably this would be screened for by the referring entity or its designate *prior to* referring the external review case to the organization. These processes can be worked out up front given a mutual understanding of what constitutes a conflict of interest. Refer also to standard IR 12(b). Note if the case is redacted, then there is no way to determine prior involvement with the case under review. **
- ** However, given the possibility that the organization may discover at any point in the review process that an organizational conflict of interest exists, URAC has established standard IR 13 whereby the case is returned to the referring entity. Continued processing occurs only after full disclosure and written consent is obtained by the requisite parties.

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IR 12 - External Review: Defining Organizational Conflict of Interest

Prior to executing a contract to provide *external review* services, the *organization* verifies what constitutes an organizational *conflict of interest*: [--]

- (a) According to applicable state or federal law or regulation; [M]
- (b) According to the contracting entity; **and** [M]
- (c) Including clarification whether a relationship between the *organization* and an insurance issuer's or *group health plan's* parent company, sister companies or subsidiaries constitutes an organizational conflict of interest. [M]

Interpretive Information/Commentary

- For element (c), the nature of the relationship between an insurance issuer or group health plan and its parent/sister/subsidiary companies may come into play. For instance, the presence or absence of a controlling interest between the insurance issuer or group health plan and one of these other entities, such as the parent company, would be a factor in determining conflict of interest.
- This standard is implemented on a going-forward basis, such that written policies and/or documented procedures must be in effect at the time an organization submits its application for initial accreditation or reaccreditation. For every contract initiated after that submittal date, URAC will examine client-specific documentation that these conflict of interest issues were determined and agreed upon between the organization and its clients. Refer to the following bullet for examples of this documentation. *
- * For the purposes of desktop review, the organization's current conflict of interest attestation [IR 12] will be a primary document for URAC to examine. Other documentation defining organizational conflict of interest includes state or federal law or regulation, contract language, contract addendum, and letter of understanding (LOU) or memorandum of understanding (MOU) between the parties.
- For purposes of the onsite review, URAC will review specific written agreements between the organization and its clients that address these prospective organizational conflict of interest issues. Organization management will be interviewed on how this process is carried out and documented.

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IR 13 - External Review: Organizational Conflict of Interest Attestation

The *organization* attests to its known organizational *conflicts of interest* prior to or as part of executing a contract for *external review* services. As part of that attestation, the *organization* definitively identifies whether it: [--]

- (a) Is owned or controlled, or is a subsidiary of or in any way owned or controlled by, or exercises control with an insurance issuer or group health plan, a national, state or local trade association of issuers or plans, or a national, state or local trade association of health care providers; [M]
- (b) Conducts *internal review* and if so, discloses the names of those entities for which it conducts *internal review* so that the referring entity has the opportunity to forward these cases to a different *organization* for external review; **and** [M]
- (c) Has a material professional, familial, or financial *conflict of interest* regarding any of the following: [--]
 - (i) An insurance issuer; [M]
 - (ii) Any officer, director or management employee of an insurance issuer; [M]
 - (iii) Any group health plan administrator, plan fiduciary, or plan employee; [M]
 - (iv) A medical group or independent practice association; [M]
 - (v) A facility providing health care service and treatments; **and** [M]
 - (vi) The developer or manufacturer of a drug, device, procedure, or other therapy. [M]

Interpretive Information/Commentary

- As part of the desktop review, the organization submits a copy of its current organizational conflict of interest attestation. URAC will verify that all standard elements are definitively addressed one way or the other (i.e., a relationship does or does not exist). If certain elements are not addressed, then the organization will be requested to amend its attestation in order to come into compliance with that particular element of the standard.
- All elements in this standard must be addressed one way or the other in the organization's conflict of interest attestation.
- This standard is implemented on a going-forward basis, such that written policies and/or documented procedures must be in effect at the time an organization submits its application for initial accreditation or reaccreditation. These documents must indicate who will review the attestation in order to keep it current, how often this will be done including what will trigger an update, and when there are any changes they are shared with clients.
- The attestation required by this standard needs to be current, complete (i.e., address all elements), and documented on the organization's letterhead as well as signed and dated by the requisite principal(s) of the company.
- For every contract initiated after the accreditation application submittal date, URAC will examine client-specific documentation indicating that this attestation was shared with clients and organizational conflict of interest issues were worked out between the organization and its clients (see also IR 11).
- For IR 12(c)(i), the organization is expected to identify the insurance issuer or group health plan for which it does reviews. This transparency with its external review clients allows a state/ state commissioner to clarify if this is considered an organizational conflict of interest and if so, screen for it prior to referring the case. *

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- * Note that per IR 8(c)(ii) and (iv), however, if a *reviewer* conducts reviews for an insurance issuer or group health plan that is the subject of a review, or participates in management, including supervising others on behalf of the insurance issuer or group health plan (i.e., a medical director at any level of any department), or participates on the insurance issuer's or group health plan's board of directors or any subcommittee of the board, then *this is considered a conflict of interest* at the reviewer level.

IR 14 - External Review: Organizational COI Transparency Process

If the *organization* discovers that an organizational *conflict of interest* does exist, then the *organization* returns the *case* to the *referring entity* unless, after full disclosure of the *conflict of interest*, the *organization* obtains written consent to conduct the *external review* from the *covered person, insurance issuer or group health plan*, and the *referring entity*. [M]

Interpretive Information/Commentary

- It *is not* the intent of standards IR 10, 11, 12 and 13 to have the organization (i.e., IRO) conduct an assessment of potential organizational conflict of interest for every external review case that is referred to it; instead, these issues are worked out *prior to* executing contracts and referring external review cases to the organization.
- By way of example, if the contracting entity determines that an organization's prior involvement with a specific episode of care under review in and of itself constitutes an organizational conflict of interest, then preferably this would be screened for by the referring entity or its designate *prior to* referring the external review case to the organization. Refer also to standard IR 10(b).
- However, given the possibility that the organization may discover at any point in the review process that an organizational conflict of interest exists, URAC has established standard IR 13 whereby the case is returned to the referring entity. Continued processing occurs only after full disclosure and written consent is obtained by the requisite parties.
- For IR 12(b)(i), the organization is expected to identify the insurance issuer or group health plan for which it does reviews. This transparency with its external review clients allows a state/ state commissioner to clarify if this is considered an organizational conflict of interest and if so, screen for it prior to referring the case.
- Note that per IR 8(c)(ii) and (iv), however, if a *reviewer* conducts reviews for an insurance issuer or group health plan that is the subject of a review, or participates in management, including supervising others on behalf of the insurance issuer or group health plan (i.e., a medical director at any level of any department), or participates on the insurance issuer's or group health plan's board of directors or any subcommittee of the board, then *this is considered a conflict of interest* at the reviewer level.

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Tracking, Monitoring & Reporting

IR 15 - Review Database

The *organization* maintains a database on all *reviews* and is able to report, at a minimum, the following information for each *case*: [--]

- (a) The unique identifier assigned to the *case*; [M]
- (b) The name of the *referring entity*; [2]
- (c) The state relevant to the *case* under *review*; [2]
- (d) The contract relevant to the case under review; [2]
- (e) If available, the insurance issuer or *group health plan* relevant to the *case* under *review*; [2]
- (f) The date the *organization* received the request to conduct a *review* from the *referring entity*; [2]
- (g) The date the *organization* received the initial information packet from the *referring entity*; [2]
- (h) If applicable, the date by which additional information beyond what was forwarded in the initial information packet is due to be received in order to resume the review process; [2]
- (i) Whether it is an *internal* or *external review* and if an *internal review*, whether it is an *appeal* or not; [2]
- (j) Whether the *case* relates to medical necessity and medical appropriateness, experimental or investigational treatment, administrative or legal, issue or a combination of these categories; [2]
- (k) A description of the issue to be resolved; [2]
- (l) Whether the case was expedited or not; [4]
- (m) The date by which the organization must communicate the determination to the requisite parties. [2]
- (n) The *organization's* determination regarding the *case*; [M]
- (o) The date the *organization's* determination was made; **and** [M]
- (p) The date the *organization's* determination was communicated to the requisite parties. [M]

Interpretive Information/Commentary

- These data elements support the performance monitoring addressed in standard IR 16 as well as the summary reporting for external entities outlined in standard IR 17.

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IR 16 - Review File Documentation

For each *case*, the *organization* maintains a file that includes: [--]

- (a) The unique identifier assigned to the review *case*; [M]
- (b) The name, credentials and specialty of the *reviewer(s)* and/or unique identifier for the *reviewer(s)*; [M]
- (c) *Reviewer* attestation regarding *conflict of interest*; [M]
- (d) The specific question or issue to be resolved by the review process; [3]
- (e) Whether the *case* relates to medical necessity and medical appropriateness, experimental or investigational treatment, administrative or legal issue, or a combination of these areas; [3]
- (f) Whether the *case* is expedited or not; [M]
- (g) Clinical evidence and information considered during the *review*; [4]
- (h) References to any applicable medical literature/research data or national clinical criteria upon which the *reviewer's* determination was based; **and** [4]
- (i) Documentation of all correspondence and communication between the *organization*, the *reviewer(s)* and any other party regarding the *case*, including a copy of the final determination letter. [M]

Interpretive Information/Commentary

- Acceptable means for reviewers to "...attest that they do not have a conflict of interest..." for every case they accept includes: electronic signature, wet signature, electronic or wet mark in a checkbox where the identity of the reviewer can be determined (e.g., by name and/or unique identifier). In order to meet standard element (c), the reviewer attestation would need to be included or referenced as part of the file documentation for every case the organization accepts.
- Please refer to IR 25 addressing the contents of a decision notice, which includes documentation of peer-to-peer conversation attempts and contacts if required per standard element IR 25(c). This decision notice or "final determination letter" is part of the minimum file documentation outlined in standard element IR 15(i).
- Action plans to correct identified problems [IR 16(f)] can reside in the review case file or in a separate file. Either way, an action plan designed to correct problems with a specific case needs to reference the unique identifier for that case.
- During the onsite review, URAC will use a report consisting of data elements outlined in IR 14 to select cases for every level of review that the organization conducts (e.g., internal peer clinical review, internal appeal and external review). URAC will also use this report to select expedited appeals if conducted.

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IR 17 - Performance Monitoring

The *organization* monitors its performance regarding *review* procedures according to its written policies and/or documented procedures, whereby: [--]

- (a) Prior to communicating a *review* determination with a *referring entity*: [--]
 - (i) The medical director (or equivalent designate) conducts and documents a quality check for at least the first two (2) cases conducted by a *reviewer* new to the *organization*; **and** [M]
 - (ii) The *organization* conducts a quality check and if a review does not meet the organization's quality standards, then each issue and its outcome are documented; [M]
- (b) The medical director (or equivalent designate) conducts and documents random quality checks; [M]
- (c) The *organization* conducts and documents random regulatory compliance checks for each state that it does business in; [M]
- (d) The *organization* conducts and documents random compliance checks among the current contracts that are within the scope of this accreditation; [M]
- (e) At least quarterly, the *organization* generates reports to track and trend against *measures* of acceptable levels of performance with regards to: [--]
 - (i) Review timelines; [M]
 - (ii) Routine quality checks per standard element (a)(ii); [M]
 - (iii) Random quality checks per standard element (b); [M]
 - (iv) Random compliance checks per standard elements (c) and (d); [M]
 - (v) Client complaints; **and** [M]
- (f) As needed, the *organization* implements action plans to correct identified problems and meet acceptable levels of performance for *measures*. [M]

Interpretive Information/Commentary

- Any concern about medical decision-making quality or consistency that is internally identified or communicated to the IRO from patients, providers, or clients, including government regulators [IR 15(e)(v)], is addressed via an action plan as required in the standard [IR 15(f)].
 - This guide language was added per discussion at a previous HSC meeting in response to concerns that the July Board had raised regarding the quality and consistency of reviews. The October Board will be notified of this added language.
- For element (a)(ii), the organization needs to document a quality check *only if* it results in finding a quality issue. This “documentation by exception” practice is standard in the industry.
- Whenever the medical director (or equivalent designate) conducts a quality check, it is documented per standard elements (a)(i) and (b).
- The random quality check indicated in element (b) and random regulatory compliance check in (c) can be made before or after communicating a review determination with a referring entity. These processes, including how the review cases are randomly selected as well as when and how many are done, is determined by the organization

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and clearly documented. Contractual requirements may drive certain aspects of this process.

- An “equivalent designate” – mentioned in standard elements (a)(i) and (b) – has the same or higher licensure level as the medical director.
- The “new reviewer” quality checks indicated in standard element (a)(i) are not included in the random quality checks required by (b).
- For standard element (d), a stratified random selection of cases may be an effective strategy given that organizations often use template contracts upon which executed contracts are based. In this way, selecting a few contracts of one type for a compliance check reflects performance on all contracts of that type.
- It is not the intent of standard element (d) for the organization to randomly select cases for every contract, but rather randomly select cases from all current contracts covered by this accreditation.
- The intent of element (e) is for the organization to know when it is not meeting its established levels of acceptable performance.
- The intent of element (f) is for the organization to take action when problems are identified and acceptable levels of performance are not met.
- Action plans to correct identified problems [IR 16(f)] can reside in the review case file or in a separate file. Either way, an action plan designed to correct problems with a specific case needs to reference the unique identifier for that case.

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IR 18 - Summary Reports for External Entities

For the current year and any given calendar year within the past three (3) full consecutive years, the *organization* is capable of reporting in aggregate by contract: [--]

- (a) If applicable, on *internal reviews*: [--]
 - (i) The total number of *reviews*; [M]
 - (ii) The number of each type of review (i.e., standard or expedited) and average length of time for resolution of each type; [M]
 - (iii) The number of each type of review outcome (e.g., upheld, reversed or partially upheld and reversed); **and** [M]
- (b) If applicable, on *external reviews*: [--]
 - (i) The number of requests for *external review* and their outcome, including the number resolved upholding the *adverse determination* or *final adverse determination*, the number resolved reversing the *adverse determination* or *final adverse determination* and the number reflecting a combination thereof; [M]
 - (ii) The number of each type of review (i.e., standard or expedited) and average length of time for resolution of each type; [M]
 - (iii) The number of each category of cases (i.e., medical necessity/appropriateness, experimental/investigational, administrative/legal, or a combination thereof); **and** [M]
 - (iv) Where the *organization* is allowed by state or federal regulation or contract to contact the insurance issuer or *group health plan*, the number of *external reviews* that were terminated as the result of a reconsideration by the insurance issuer or *group health plan* of its adverse determination or final adverse determination after the organization forwarded additional information received from the covered person or the covered person's authorized representative. [M]

Interpretive Information/Commentary

- Upon desktop review, URAC will examine related written policies and documented procedures for producing the reports required by the standard. At a minimum, template reports containing no data, but outlining the format and contents of a report pursuant to this standard will be reviewed at desktop.
- During the onsite review, the organization will provide the URAC reviewer with a list of its contracts and the level of review performed for each one (e.g., internal peer clinical review, internal appeal review and external review). The URAC reviewer will select two (2) to three (3) reports for the organization to run during the onsite.
 - If an organization has only one contract, then all reports will be based upon data pertaining to that one contract.
 - Reports will reflect a quarterly reporting period and if this is not feasible, then they will constitute at least one (1) month's worth of data.
 - Contracts will be selected for reporting such that to the extent possible, all levels of review are reported on at least once (e.g., internal peer clinical review, internal appeal review and external review).
 - If an organization conducts expedited reviews, but has not had the opportunity to do one, then this will not be held against the organization.

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- For element (b)(iv), if the organization is not allowed to contact the insurance issuer or group health plan, then this is not a reportable data element for states where this contact is prohibited.

Independent Review Process

IR 19 - Initial Case Assessment

Upon accepting a *case* from a *referring entity*, the *organization* identifies: [--]

- (a) The specific question or issue to be resolved by the review process; [3]
- (b) Whether the *case* relates to medical necessity and medical appropriateness, experimental or investigational treatment, administrative or legal issue, or a combination of these areas; [3]
- (c) Whether the *case* is expedited or not; [3]
- (d) Applicable state or federal law or regulation as well as contract requirements, including: [--]
 - (i) The information that must be taken into consideration as part of reviewing the case; [3]
 - (ii) The process, including time frame, for securing additional information if it should be determined that case documentation is incomplete; [3]
 - (iii) Time frames applicable to steps in the review process, including communication of the review determination; **and** [3]
 - (iv) Identification of the parties to receive notification of the review determination. [3]

Interpretive Information/Commentary

- It is the intent of this standard for the organization to identify the state and federal laws and regulations as well as contract requirements applicable to a case that it accepts.
- For the qualifications used to select a reviewer, please refer to standards IR 4, 5 and 6.

IR 20 - Review of Additional Information

At the direction of the *referring entity* and given additional information to conduct a review of a non-certification, the *organization* may use the same *reviewer* or one similarly qualified to render another review determination. [3]

Interpretive Information/Commentary

- This standard does not apply to certifications; additional information is not used to reverse a certification.

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IR 21 - External Review: Additional Information Processing

As required by state or federal law or regulation or contractual requirements, the *organization* implements mechanisms to request and accept any additional information that may assist in rendering a determination. If additional information is provided by the *covered person* or *attending provider*, then the *organization* provides a copy to the insurance issuer or *group health plan* to provide this entity with the opportunity to reverse the decision that is the subject of the *external review*. Once the insurance issuer or *group health plan* issues a reversal in writing, the *external review* process is terminated. [4]

Interpretive Information/Commentary

- Refer to standard element IR 17(b)(iv), which requires that the organization be prepared to report on the external review process described in this standard.
- The organization must submit a written policy and/or documented procedure for this standard for desktop review if it conducts external review and per state or federal law or regulation is permitted to have contact with the insurance issuer or group health plan that is the subject of the review; otherwise, this standard is not applicable.
- For the onsite review, if this standard is applicable, then the organization identifies cases where this procedure was carried out; URAC will verify implementation from this selection. Organizations will not be penalized if they have external review contracts that allow for additional information processing and yet the situation has not yet occurred.
- This standard reflects language found in the NAIC Model Act (Section 8.G on page 76-13 and Section 10.G on page 76-22).

Scope of Standards

- This standard does not apply to expedited reviews.

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IR 22 - Time Frames for External Reviews

The *organization* completes an external review according to the following time frames (unless superseded by applicable law or regulations): [--]

- (a) An expedited review is completed as soon as possible, but in no event more than 72 hours after receipt of the request for an expedited external review; [M]
- (b) A non-expedited review is completed within 45 calendar days after receipt of the request for an external review; **and** [M]
- (c) The time frame starts upon receipt of the request for a review and ends once the organization issues a determination to all requisite parties as required by contract, law or regulation. [M]

Edits

- URAC's Board indicated that it was uncomfortable not having time frames specified in the standards for external review. The proposed timelines align with federal requirements pursuant to the PPACA, Public Law 111-148 "Technical Release" on August 23, 2010.
- Per the Affordable Care Act, a health plan must comply with the state process if it provides for an external review process that meets, at a minimum, the consumer protections set forth in the interim final regulations.

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IR 23 - Expedited Review Process

The *organization* provides for an expedited review process that: [--]

- (a) Is available in *cases* for which the time frame for completion of a non-expedited review would seriously jeopardize: [--]
 - (i) The life or health of the *covered person*; **or** [M]
 - (ii) The *covered person's* ability to regain maximum function; **and** [M]
- (b) Includes written policies and/or documented procedures for: [--]
 - (i) Acting upon expedited *cases* received and/or processed after hours; **and** [M]
 - (ii) Issuing a determination in writing within forty-eight (48) hours after the date of providing notice, if that initial notice was not provided in writing. [M]

IR 24 - Medical Necessity/Appropriateness Case Processing

When processing a *case* regarding medical necessity and appropriateness, the *organization* and its *reviewer(s)* consider information pertinent to the *case* that will include the following as available, unless otherwise prohibited by state or federal law or regulation: [--]

- (a) The *covered person's* medical records; [M]
- (b) The *attending provider's* recommendation; [M]
- (c) The terms of coverage under the *covered person's health benefit plan*; [3]
- (d) Information accumulated regarding the *case* prior to its referral for *review*, including rationale for prior review determinations; [4]
- (e) Information submitted to the *organization* by the *referring entity, covered person or attending provider*; [M]
- (f) Clinical review criteria and/or medical policy developed and used by the insurance issuer or *group health plan*; **and** [3]
- (g) *Medical or scientific evidence*. [3]

Interpretive Information/Commentary

- The scope of this standard includes long term care reviews.
- Though various companies and states will indicate what information can be considered when rendering a review determination, URAC seeks to establish a minimum threshold and support a national baseline with regards to the information considered for a review.

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IR 25 - Experimental/Investigational Case Processing

When processing a *case* regarding the experimental or investigational nature of a proposed treatment, the *organization* and its *reviewer(s)* consider the following, unless otherwise prohibited by state or federal law or regulation: [--]

- (a) All the information listed in IR 21; **and** [4]
- (b) Whether: [--]
 - (i) The recommended or requested health care service or treatment has been approved by the Federal Food and Drug Administration, if applicable, for the condition; **or** [4]
 - (ii) *Medical or scientific evidence or evidence-based clinical practice guidelines or criteria* demonstrate that the expected benefits of the recommended or requested health care service or treatment is more likely than not to be beneficial to the covered person than any available standard health care service or treatment and the adverse risks of the recommended or requested health care service or treatment would not be substantially increased over those of available standard health care services or treatments. [4]

Interpretive Information/Commentary

- Though various companies and states will indicate what information can be considered when rendering a review determination, URAC seeks to establish a minimum threshold and support a national baseline with regards to the information considered for a review.
- This standard reflects language in the NAIC Model Act (Section 10.I(5) on page 76-24).

IR 26 – Benefit Coverage/Rescission/Legal Case Processing

When processing a *case* regarding administrative or legal issues, the *organization* and its *reviewer(s)* consider all information necessary to render a decision, such as the applicable *health benefit plan* contract, other relevant *health benefit plan* materials and documents, and applicable state or federal law or regulation. [4]

Edits

- Greater clarification regarding the full scope of this standard is needed; therefore, the title was expanded and additional interpretive information was added.
- Lawyers with experience in health insurance are the primary type of reviewers for these types of administrative/legal cases, so the definition of “reviewer” was expanded to accommodate this.

Interpretive Information/Commentary

- Rescission reviews are within the scope of this standard. Organizations conducting these types of reviews are required by compliance standard Core 4 to review relevant state or federal law or regulation, which would include Section 2712 “Prohibition on Rescissions” from federal Bill PL 111-148.
- Non-medical necessity determinations of benefit coverage or reimbursement decision reviews are within the scope of this standard.

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- Due process and other legal case processing unrelated to medical necessity determinations are within the scope of this standard.
- Lawyers with health insurance experience can review the cases within the scope of this standard. See definition of “reviewer,” which includes legal case reviewer qualifications.
- Though various companies and states will indicate what information can be considered when rendering a review determination, URAC seeks to establish a minimum threshold and support a national baseline with regards to the information considered for a review.

Scope of Standards

- Cases referred to the IRO for independent review involving administrative and/or legal issues, including:
 - Non-medical necessity benefit determinations;
 - Reimbursement decisions;
 - Rescission issues;
 - Due process;
 - Non-medical necessity legal reviews.

Definition

Reviewer(s): The individual (or individuals) selected by the organization to consider a case.

Selection of the reviewer(s) for a case must be conducted in accordance with standards IR 1 through IR 6.

All reviewer(s) who are health care practitioners must have the following qualifications:

- Active U.S. licensure;
- Recent experience or familiarity with current body of knowledge and medical practice;
- At least five (5) years experience providing health care;
- If the reviewer is an M.D. or D.O., board certification by a medical specialty board approved by the American Board of Medical Specialties or the American Osteopathic Association.
- If the reviewer is a D.P.M., board certification by the American Board of Podiatric Surgery

All reviewer(s) who are health insurance lawyers conducting rescission, benefit interpretation, reimbursement or other administrative/legal review, must have the following qualifications:

- Active U.S. licensure as a lawyer, which may need to be specific to the state with jurisdiction over review;
- Recent experience or familiarity with current body of knowledge and health insurance practice;
- At least five (5) years experience providing legal services regarding health insurance matters.

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IR 27 - Decision Notice

At a minimum, the *organization* sends to the *referring entity* a notice of the determination that includes: [--]

- (a) A description of the issue to be resolved; [M]
- (b) A description of the qualifications of the *reviewer(s)*; [M]
- (c) If required, documentation of *peer-to-peer conversation* attempts and contacts; [M]
- (d) A *clinical rationale* or explanation for the determination; **and** [M]
- (e) Specific citations to supporting evidence or references per the *organization's* policy. [M]