DEPARTMENT OF
Managed Health Care

Arnold Schwarzenegger, Governor
State of California
Business, Transportation and Housing Agency

Department of Managed Health Care
980 9th Street, Suite 500
Sacramento, CA 95814-2725
(916) 327-9333 - Phone
(916) 322-9868 - Fax
emackani@dmhc.ca.gov

December 8, 2010

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

FEDERAL EXTERNAL REVIEW PROCESS – REQUEST FOR INFORMATION

Dear Ms. Fowler:

The California Department of Managed Health Care (DMHC) is the California agency that licenses and regulates health care service plans (health plans) under the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 of Division 2 of the Health and Safety Code, commencing with Section 1340.) There are 108 health plans providing managed health care services to 21 million Californians and operating under this state licensing law.

Under California law, the DMHC, rather than the individual health plans, contracts with the independent review organization (IRO). Enrollees are eligible for an independent medical review (IMR) if they have a disputed health care service with their health plan. A disputed health care service means any health care service eligible for coverage and payment under a health plan contract that is denied, modified, or delayed by the health plan, in whole or in part based on the finding that the service or treatment is not medically necessary or is considered experimental/investigational. All other types of grievances are handled by the DMHC.

The DMHC currently contracts with MAXIMUS Federal to conduct all of its IMRs. The following comments are based, in part, on MAXIMUS Federal's response to the DMHC's request for proposal for independent medical review services.

The DMHC appreciates the opportunity to comment on the request for information (RFI) pertaining to the federal external review process. The DMHC's comments are as follows:

Qualified Organization and Staff

[1] What accreditation standards currently apply to IROs?

The DMHC requires IROs to be accredited by the Utilization Review Accreditation Commission (URAC), National Committee for Quality Assurance (NCQA), or another health care quality accreditation entity.

[2] What credentialing standards do IROs require for medical and legal reviewers? Is credentialing required or voluntary?

In addition to statutory credentialing requirements, DMHC's contracted IRO, MAXIMUS Federal, provides its own set of credentialing requirements. Both sets of requirements are discussed below.

Credentialing under the Health & Safety Code:

Health & Safety Code § 1374.32(d)(4) requires IROs to select medical professionals to review medical treatment decisions who are physicians or other providers who:

- Are clinicians knowledgeable in the treatment of the enrollee's medical condition, knowledgeable about the proposed treatment, and familiar with guidelines and protocols in the area of treatment under review.

- Are medical professionals that hold a non-restricted license in any state of the United States, and for physicians, a current certification by a recognized American medical specialty board in the area or areas appropriate to the condition or treatment under review.

- Have no history or disciplinary action or sanctions, including, but not limited to, loss of staff privileges or participation restrictions, taken or pending by any hospital, government, or regulatory body.

Credentialing under MAXIMUS Federal:

MAXIMUS Federal requires that each of its Medical Professional Reviewers (MPR) to be in active practice[1] and must meet the following minimum qualifications:

- Be board certified (not simply board eligible) in a recognized American Board of Medical Specialties (ABMS) or American Board of Orthopedic Surgery (ABOS) practice area.

- Have at least five (5) years of experience as a practicing clinician.

[1] Active practice is defined as at least 24 hours of clinical practice a week.

- Have no unexpected or identifiable lapses in employment of three (3) months or more.
- Have an active and valid license with no history of any disciplinary actions.
- Have an active DEA license.
- Have no history of sanctions or disciplinary actions.

In addition, MAXIMUS Federal reviewers must provide or comply with the following:

- The most recent five (5) year malpractice history.
- Verification of hospital affiliation, privileges, and academic appointment.
- Multiple recommendations from respected colleagues and other medical professionals.
- Be credentialed by MAXIMUS Federal's Credentialing Committee.

The MAXIMUS Federal's Credentialing Committee requires candidates to provide the following information to initiate the credentialing process:

- Curriculum vitae
- American Medical Association profile
- Medical License verification
- DEA verification
- Board certification verification
- Work history analysis
- Malpractice claim history and disciplinary action review
- Malpractice insurance coverage verification
- Hospital affiliation, privileges, and academic appointment verification
- Recommendations

Finally, MAXIMUS Federal requires its reviewers to be re-credentialed every three (3) years at a minimum.

[3] What procedures are currently used by IROs to assure that reviewers do not have conflicts of interest with disputing parties?

In addition to statutory conflict of interest requirements, but MAXIMUS Federal provides additional conflict of interest requirements. Both are discussed below.

Conflict of Interest under the Health & Safety Code:

Under Health and Safety Code section 1374.32(d)(1), an IRO is prohibited from being affiliated or a subsidiary of, or in any way be owned or controlled by a health plan or a trade association of health plans. Additionally, a board member, director, officer, or employer of the independent medical review organization cannot serve as a board member, director, or employee of a health care service plan. Similarly, a board member, director, or officer of a health plan or a trade association of health plans may not serve as a board member, director, officer, or employee of an independent medical review organization.

- Additionally, under Health & Safety Code § 1374.32(d)(6), neither the IROs, their designated experts conducting a review, nor any officer, director, or employee may have any material professional, familial, or financial affiliation with:

- The plan or any officer, director, or employee of the plan;

- The physician, medical group, independent practice association involved in the healthcare service in dispute;

- The facility or institution where either the proposed or recommended health care would be provided. An academic medical center under contract to the plan to provide services to enrollees may qualify as a contractor provided it will not provide the service and provided the center is not the developer or manufacturer of the proposed treatment;

- The development or manufacture of any drug, device, procedure, or other therapy proposed or recommended by the enrollee or plan; or

- The enrollee or the enrollee's immediate family.

Conflict of Interest under MAXIMUS Federal:

In addition to the DMHC's requirements, MAXIMUS Federal refrains from having any relationship of any kind with any California-licensed health or disability insurer that is doing business in California. MAXIMUS Federal also maintains a comprehensive Conflict of Interest Plan, which is monitored by a Director of Compliance under the direction of the Compliance Committee made up of there independent Board of Directors.

MAXIMUS Federal independently verifies its compliance with its Conflict of Interest Plan at least annually through an independent ISO registration, as part of its URAC accreditation review, as well as by separately agreed upon audits. Moreover, MAXIMUS Federal precludes any ownership, financial interest, or significant familial relationships with a government agency client, with any provider, with any drug or device manufacturer, and any party to an individual case.

MAXIMUS Federal also conducts a case specific conflict verification of its staff and consultations. A conflict of interest check occurs 1) when a new case is assigned to MAXIMUS Federal, 2) during the IMR assignment process with respect to the selected staff or consultant, 3) before the assignment, each MPR is screened for conflicts pursuant to Health & Safety Code § 1374.32(d)(5). MAXIMUS Federal also researches each MPRs professional and financial affiliations, and discusses the case file with the MPRs to avoid any conflicts of interest. Moreover, MAXIMUS Federal screens MPRs and their reviews to ensure that they are neutral, or display no general bias.

[4] What are the IROs' current capacity for performing reviews?

MAXIMUS Federal has the capacity to address all types of medical reviews. It has a panel of over 500 MPRs representing all American Board of Medical Specialties and American Osteopathic Association (AOA) specialties and subspecialties, and can handle more than 7,500 IMRs a month.[2]

Does staffing and the time necessary for performing a review differ based on the type of claim (e.g., medical necessity, experimental/investigational treatment, coverage issue, etc.)?

Staff resources can vary depending on the type of claim. For example, some claims can involve issues of coverage as well as medical necessity whereas other claims will simply involve a question of medical necessity. However, there are some basic standards that the DMHC applies that are described below.

Infrastructure

[5] Please describe the type of data collection system that IROs currently use to conduct analyses, reporting, and tracking of appeals and grievances.

MAXIMUS Federal uses an enhanced IMR Tracking System for data collection. The system includes a complete case tracking intranet application that provides a self service portal that is available over the internet to both the DMHC and other stakeholders. This allows for a secure method of initiating cases and reviewing case status via the internet, while ensuring the confidentiality and integrity of sensitive information

[6] Are the current data systems, available in a secure, 508-compliant, web-based interactive structure?

MAXIMUS Federal uses the IMR Tracking System, which is a distributed web-based application with a centralized relational database.

---

[2] 7,500 IMRs a month represents MAXIMUS Federal's average monthly client caseload in FY09.

[7] What telecommunication systems and consumer technical support systems do IROs currently maintain for consumers (e.g., Web sites, 24-hour hotlines, helpdesk, and/or translation services for non-English speakers)?

This level of consumer access and interaction is handled by the DMHC and not by MAXIMUS Federal. The DMHC provides a website (www.dmhc.ca.gov), a Help Center to take consumer phone calls (1-888-466-2219), and also translation services for non-English speakers. A consumer is provided the IRO's contact information when they need to provide non-contractual medical records to the IRO after a review has begun; however most often, this is facilitated through the DMHC staff.

[8] What is a reasonable amount of time for a contractor to become fully operational (have all systems in place to conduct external reviews) after the date of a contract award? What resources would be necessary?

The DMHC has always contracted with entities that are operational and does not have experience with contractors that have not become fully operational.

[9] What consideration 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?

The system should be developed to be user friendly and accessible to consumers, and also provide adequate information for the reviewer to make an appropriate and timely decision.

[10] Do IROs currently operate nationally or in limited geographic areas? Would IROs that currently serve local areas be able to expand their service areas to possibly include other geographic areas such as other States? Are there any local State and/or local licensing requirements?

Among other required qualifications, the DMHC requires that an IRO be prepared to ensure that they will have an office in California and demonstrate its ability to recruit California-licensed providers to conduct reviews. Additionally, the DMHC asks that IROs give California-licensed reviewers preference, if available and qualified. Thus, IROs may operate on a national level or expand their service area so long as they comply with these aforementioned requirements. There are no state or local licensing requirements for IROs in California.

[11] Are there any special considerations HHS and/or DOL should be aware of in considering a specialized contract for urgent care appeals or for experimental and investigational treatments? Would such an approach have an impact on coordination?

Often in compiling information for review, the type of review is only determined after receipt of the supporting documentation and medical records involved with the case. Requiring a consumer to pursue a review with a specialized IRO and then perhaps later need to redirect the consumer to a different IRO or contractor could delay the review and result in duplicate reviews,

especially if the consumer is working directly with an IRO and not through a regulatory agency such as the DMHC. There could be a cost for an IRO to begin one type of review only to have to shut it down and then have the review completed by a different contractor. Also, as treatments move from an experimental status to the accepted norm, it would be difficult to track and trend for those kinds of reviews over time

[12] Please describe the difference in standard operating procedures and resources (time, cost, personnel) for appeals that involve only medical necessity and those that involve both medical necessity and coverage questions.

In California, appeals that involve medical necessity, experimental/investigational status, or emergency services, are eligible for review by the IRO. All other issues involving coverage are reviewed by the DMHC staff to determine compliance with the law and with the health plan contract. Often a consumer's case may have one component that is reviewed under coverage (for example claims for services in the past where the consumer did not obtain prior authorization when required) and another component that is eligible for an external review (prospective denial based on medical necessity).

Data Collection

[13] What data are currently collected by IROs for tracking appeals and conducting analyses?

Health & Safety Code § 1397.5 requires the DMHC Director to annually publicly report a summary of grievances filed against plans by enrollees or subscribers. The summary must include the total number of grievances filed and the types of grievances filed. While it is unknown what other specific data MAXIMUS Federal may collect, the latter information is collected.

[14] What steps are taken to ensure confidentiality and security protections of patient information?

When contracting with IROs, the DMHC requires the IROs to ensure that any physical or electronic transfer and storage of medical records and confidential information is protected against unauthorized disclosure as required by federal and state law. Information about the diagnoses, treatment, health and personal identifying information of any enrollee shall be made available to reviewers and other personnel only to the extent necessary to ensure performance under a contract. The IROs must maintain case files, including all records, correspondence, reference materials and documents pertaining to the review, for at least five (5) years, or for three (3) years after final payment under the contract, whichever is later. Unauthorized individuals do not have access to any materials furnished by the DMHC to the IROs.

The methods and procedures employed by the IROs for the security of the DMHC's data and information may not be changed unless the DMHC has given its prior approval in writing.

Moreover, no information obtained by the IROs, their staff, contractors or subcontractors may be used for marketing, solicitation or other commercial purpose.

Moreover, the DMHC reserves the right to conduct a thorough background investigation of the IROs, their agents, subcontractors and individual employees who will have access to medical information as part of their duties under a contract; and the DMHC reserves the right to disapprove any individual from performing under the scope of such a contract. This background investigation includes fingerprinting and a California Department of Justice criminal record check.

In addition, MAXIMUS Federal employs a full time Compliance Officer to analyze and ensure corporate compliance of applicable confidentiality and privacy laws, statutes, and regulations including DMHC's confidentiality requirements described above. Additionally, MAXIMUS Federal requires that all staff, reviewers, and vendors sign Confidentiality Agreements acknowledging that information relating to clinical review is confidential and agreeing to prevent unauthorized disclosure of any kind. Moreover, all staff members are required to conform to Federal Government user ID requests and associated security profile requirements. Employee system access is conditioned upon initial HIPAA and internal network security training and completion of any security training required by clients. Successful completion of all required training is tracked through MAXIMUS Federal's learning management system.

Evaluation

[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?

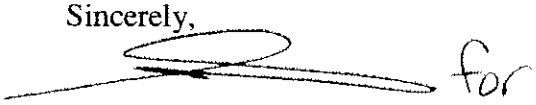
California law does not require IROs to conduct evaluations.

[16] What specific requirements should be applied to IROs to evaluate progress toward performance goals? What performance goals are the most appropriate?

Timely completion of reviews is an appropriate performance goal. The DMHC requires MAXIMUS Federal to complete standard reviews within 21 calendar days following receipt of medical records. An expedited Health & Safety Code § 1370.4 experimental or investigational review must be completed within seven (7) days. Finally, all other expedited reviews must be completed within three (3) days. MAXIMUS Federal is required to notify the DMHC immediately by email, fax, or phone when circumstances occur that will prevent completing a timely review.

If you should have any further questions, please contact me at (213) 620-2311 or emackani@dmhc.ca.gov.

Sincerely,



Elhahm Mackani
Staff Counsel
Office of Legal Services
EM:em