December 8, 2010

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, S.W.
Washington, DC 20201

Attention: File Code OCIIO-9986-NC *(delivered electronically)*:

MAXIMUS Federal Services Inc. (MAXIMUS Federal) is pleased to respond to the Request for Information in connection with the Federal External Review Process under the Affordable Care Act. MAXIMUS Federal, a URAC accredited Independent Review Organization (IRO), has provided external appeals since 1989 and is the largest provider of government sponsored external review health care appeal programs in the United States. Our clients include the Centers for Medicare and Medicaid Services (CMS), the Unites States Office of Personnel Management (OPM), the Department of Defense (DoD), the Department of Veterans Affairs (VA) and more than 35 state regulatory agencies which follow the National Association of Insurance Commissioners (NAIC) Heath Carrier Uniform External Review Model Act (Model Act) or a derivation thereof. Since 1989, we have completed more than 800,000 health care appeals addressing issues of medical necessity, experimental/investigational services, benefit and coverage issues and correct coding and reimbursement and can speak confidently regarding IRO best practices and standards that the Departments of Health and Human Services and Labor will consider as they further evaluate and develop the Federal external review process.

For ease of reference, we replicate below those specific questions posed by the Departments and our corresponding responses.

Qualified Organizations and Staff

(1) What accreditation standards currently apply to IROs?

Accreditation by the Utilization Review Accreditation Commission (URAC) is the sole nationally recognized credential available for independent review organizations. Since June 1, 2000, MAXIMUS Federal has maintained full accreditation status as an IRO through a series of periodic URAC reviews and evaluations. In order to obtain accreditation from URAC, IROs

must establish that they meet or exceed URAC's IRO Standards by showing that they have formal policies and procedures in place addressing such independent review areas as confidentiality, conflicts of interest, staff training and development, reviewer credentialing, and quality assurance.

The specific URAC IRO accreditation process is based on a modular concept that is adaptable to the area of healthcare under review and encompasses a set of standards that are established for a particular health care function such as those appeal review functions performed by IROs. All URAC accredited entities must meet the set of 40 current Core Standards that cover multiple areas (including quality assurance, organization, policies and procedures, regulatory compliance, oversight of delegated functions, consumer protection, and clinical staff credentialing). Moreover, an accredited IRO also has to additionally meet a set of 17 Independent Review (IR) standards. The IR Standards include clinical staff requirements, organizational conflict of interest, credentialing, case processing, decision timeliness and expedited review standards.

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

Medical Reviewers

The MAXIMUS Federal credentialing program is extremely rigorous. Our standards surpass the combined requirements of National Committee for Quality Assurance (NCQA) and URAC. To serve on our panel, an Expert Medical Reviewer must be in active practice (defined as at least 24 hours of clinical practice a week) and meet the following minimum qualifications:

- Board certification in a recognized ABMS or ABOS practice area. A practitioner who is only board eligible with no board certifications will not be accepted to our panel;
- At least five years' experience as a practicing clinician;
- No unexplained or indefensible lapses in employment of three months or greater;
- Have an active and valid license with no history of any disciplinary actions;
- Have an active and valid DEA license; and
- No history of sanctions or disciplinary actions.

In addition, reviewers must also provide or comply with following:

- The most recent five-year malpractice history;
- Verification of hospital affiliation, privileges, and academic appointment;
- Multiple recommendations from respected colleagues and other Expert Reviewers; and
- Be credentialed by our Credentialing Committee.

MAXIMUS Federal initiates the credentialing process via an Expert Reviewer application form which requires candidates to provide the following information: Curriculum Vitae, American Medical Association (AMA) Profile, Medical License Verification, DEA Verification, Board Certification Verification, Work History Analysis, Malpractice Claim History and Disciplinary Action Review and Malpractice Insurance Coverage Verification, Hospital Affiliation, Privileges, and Academic Appointment Verification, and Recommendations. Once the

application and supporting documents have been returned to MAXIMUS Federal, the documents are subject to an initial screening process. During this process, the Director of Professional Relations reviews the application for completeness. If the application is not complete, a letter explaining the deficiency is sent. Expert Reviewer applications that have not been corrected and/or completed within 90 days are rejected. If the application is complete and all required documentation has been received, a referral is made to the AMA's Physician Profile Service. This profiling service offered by the AMA meets the primary source verification requirements set forth by the Joint Commission, NCQA, and URAC. Once completed, the profile is reviewed by both the Director of Professional Relations and the Medical Director, a file is established, and a letter of confirmation is sent to the reviewer applicant notifying him/her that the application is in process.

Once enlisted, Expert Reviewers are contractually required to inform us of any action taken by a licensing, certification or credentialing body to revoke or suspend the physician's license, certification or credentials (in whole or in part), or upon any action which is likely to lead to such revocation or suspension. The Expert Reviewers also agree to notify MAXIMUS Federal of any change in hospital affiliation(s) and insurance coverage, any move, prolonged absence, disability, or other event that would impair the Expert Reviewer's ability to comply with their MAXIMUS Federal or Department obligations.

MAXIMUS Federal recognizes that the practice of medicine is dynamic and that the licensure status of a physician may change at any time. Therefore, we include in our credentialing process the requirement that each physician be re-credentialed at a minimum of every three years. Every three years, current reviewers are expected to complete an application and verification process. The Committee reviews and discusses the application and determines the appointment status of the current reviewer. The appointment status for current reviewers includes: Permanent, Temporary/Provisional, Application Pended (need clarifying information), and Remove.

To further ensure that only appropriate reviewers are utilized, on a quarterly basis MAXIMUS Federal staff check all relevant Internet-based sources to verify that the Expert Reviewer's license is current and in good standing. As an added quality assurance safeguard, reviewers are contractually required to inform us of any action taken by a licensing, certifying or credentialing body to revoke or suspend the Expert Reviewer's license, certification or credentials (in whole or in part), or upon any action which is likely to lead to such revocation or suspension. The Expert Reviewers also agree to notify us of any change in hospital affiliation(s) and insurance coverage.

Medical reviewer credentialing is required and must comply with the URAC mandatory elements in contained in Core Standard # 30 (Clinical Staff Credentialing), Core Standard # 31 (Senior Clinical Staff Requirements) and Independent Review Standard # 4 (Reviewer Credentialing). All mandatory elements must be met in order to be eligible for maintain accreditation.

“Legal” Reviewers

In connection with the credentialing of legal reviewers, although URAC and NAIC do not mandate specialized qualifications for coverage and benefit reviewers at IROS, some states set forth such standards (e.g., Wisconsin) and MAXIMUS Federal applies its own internal

qualification standards to legal reviewers. Specifically, MAXIMUS Federal requires that the individual is a professional (JD or CPC designation) and trained in IRO standards. In addition, the reviewer must have three to five years experience reviewing insurance coverage and benefit or coding and reimbursement denials or comparable experience. There also is a formal ongoing training process and verification of credentials every two years.

It is important to note that term "Legal Reviewer" for those who complete coverage and benefit appeals excludes other professionals who are often necessary to complete coverage and benefit denials such as certified professional coders. In addition, existing state rescission external review programs require IROs to have access to health care actuaries.

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

MAXIMUS Federal's business philosophy is centered on the absolute need to maintain independence and integrity when performing independent reviews. We do not provide any services to or contract with any health plan and indemnity or disability insurer where it would create a conflict with a government program. Therefore, if a potential or actual conflict exists with a government program, we do not provide any review-related services or have any relationship with any health plan or health or disability insurer nor at any time in the future would we enter into any contractual agreements with any health plan or health or disability insurer for the provision of any similar services.

Compliance with the our conflict plan is independently verified not less than annually by means of an independent ISO registration, as part of URAC accreditation reviews, and by a separately agreed upon procedures audit. In summary, our policy and procedures preclude any ownership, financial interest, or significant familial relationship with any government agency client, with any provider, with any drug or device manufacturer, and with any party to an individual case.

To insure lack of conflict in an individual case, we submit both staff and consultants to a case specific conflict verification and attestation process. Additionally, prior to the assignment of a case to an expert reviewer, it is screened for material, professional, familial, or financial relationship with any of the following persons:

- the plan;
- any officer, director or management of the plan;
- the physician, the physician's medical group or the independent practice association proposing the service or treatment;
- the institution at which the service or treatment would be provided
- the development or manufacture of the principal drug, device, procedure or other therapy proposed for the covered person whose treatment is under review;
- the covered person; or
- National, state or local trade association of health benefits plans or health care providers.

Specifically, conflicts of interest checks occur at several points in the independent review process. When a new case is assigned to a MAXIMUS reviewer, a conflicts determination is made with respect to the enrollee and health plan. Upon receipt and review of the case file and

prior to assignment to the Expert Reviewer, the file is screened for any potential conflicts with providers involved in the case and/or manufacturers of any device or medication at issue in the case. During the case assignment process, the Project Manager determines if a selected Appeal Officer has any conflicts of interest with the given case. During the process of selection and assignment of an Expert Reviewer for a case, the Appeal Officer in consultation with the Director of Professional Relations, determines whether a specific Expert Reviewer has any known conflicts of interest regarding the pending review.

MAXIMUS Federal also researches all professional and financial affiliations our Expert Reviewers have with any health care institutions, health care providers, and managed care organizations. This allows us to determine prior to the assignment of a case whether an actual or apparent conflict of interest exists between the selected reviewer and the parties to the case. Further, each Expert Reviewer is contacted and the case file discussed as an additional means to avoid any conflicts of interest. After receipt of the case, Expert Reviewers are contractually obligated to review each case reviewed for potential or actual conflicts of interest and to notify MAXIMUS immediately if an actual or potential conflict exists so that the case may be promptly reassigned.

Per MAXIMUS internal standards, actual or potential conflicts include but are not limited to: (1) financial interest with the health plan; (2) provider relationship with the health plan or a delegated group; (3) relationship with the covered person/patient; or (4) relationship with a provider of a (disputed) drug or device.

As an added safeguard, MAXIMUS Appeal Officers review case files to identify potential conflict of interest prior to assigning the case. The Expert Reviewer is also contacted and the case file is discussed in order to further rule out actual or potential conflicts. In addition to screening for conflicts, MAXIMUS Federal screens Expert Reviewers and their reviews to ensure that Expert Reviewers are neutral, or display no general bias.

The importance of neutrality and objectivity is also stressed in Expert Reviewer orientation and training. MAXIMUS Appeal Officers screen all Expert Reviewer referrals for any signs of inappropriate or inflammatory language or any other indications of bias. If there appears to be any issue of objectivity or neutrality, the Expert Reviewer would be suspended from the MAXIMUS panel and subject to additional review by the Medical Director and Credentialing Committee. Finally, our Expert Reviewer Referral Form includes a certification regarding conflict of interest that the Expert Reviewer is required to complete as a part of his or her recommendation.

(4) What are IROs' current capacity for performing reviews? 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 issues, etc.)?

MAXIMUS Federal currently maintains a roster of more than 600 board certified, licensed expert reviewers. The reviewers are physicians and/or allied health care practitioners in active practice and there are at least three expert reviewers in each specialty and in almost every sub-specialty. Staffing and the time necessary for performing a review based on the type of claim

does not differ since we have cultivated and developed our extensive reviewer roster which allows us to address all types of independent review at all times. In the rare event that an appropriate specialist is not available or not on panel, MAXIMUS Federal maintains recruitment contacts and contracts at numerous academic medical centers throughout the country that provide us with recruitment services on an as-needed basis. Throughout our 20 year history we have never had to decline the processing of health care appeals because we did not have an appropriate reviewer available.
Staffing may differ based on the type of claim. For example, if a claim involves a dispute of correct coding, a certified professional coder may be necessary to assist in the completion of the review. Similarly, coverage and benefit issues may require and attorney and rescission cases may require the assistance of a health care actuary.

Time necessary for performing reviews may differ based on the type of claim and the requirements for the processing of claims. For example, some states require a panel of three reviewers to complete experimental and investigational review – processing these cases require more time than processing experimental and investigational cases that require only one reviewer to complete the case.

Infrastructure

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

MAXIMUS Federal uses an enhanced appeals case tracking system (ACTS) consisting of a distributed web-based application with a centralized relational database. The system is a complete case tracking intranet application that includes a self-service portal that can be made available over the internet to our state regulatory agency clients and other stakeholders, as appropriate. Please note that ACTS is fully compliant with federal and state privacy and security regulations.

ACTS contains a self-service portal facilitating a secure method to initiate cases and review case status via the internet, while ensuring the confidentiality and integrity of sensitive information. Health plans are able to securely upload documentation requested in support of a case. The self-service portal is more secure, less expensive, and timelier than overnight mail services. The system relies on the Java Enterprise Edition (JEE), with industry standard technologies including JSF, Spring, and Hibernate. The user interface uses AJAX components to provide enhanced user experience and to build a Rich Internet Application (RIA).

Imaging is also an integral part of ACTS. The use of scanned images enables secure, logged access to each case file record throughout the review lifecycle. All documents related to a case may be viewed electronically on the user's desktop at the push of a button.

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

Yes. MAXIMUS Federal complies with Section 508 Accessibility Standards in the development of all its web sites and web content and as applicable other forms of communication. Among the standards that we currently comply with under contract are the following:

- Section 508 of the Rehabilitations Act as amended by the Investment Act of 1998
- EIT accessibility standards (36 CFR Part 1194)
- Access Board 508 Standards
- FAR 39.2
- CMS/HHS standards defined at InfoTechGenInfo

We avoid approaches that cause significant barriers for users with disabilities, such as frames for page layout or image maps for navigation. As a standard best practice, MAXIMUS Federal builds forms that are laid out in a predictable manner and utilize accessibility features such as fieldsets and legends, labels, and customized keyboard shortcuts.
Other standard practices include providing text equivalents for any non-text elements and constructing data tables so that columns and rows are labeled and there is a logical relationship to the data when interpreted by an Assistive Technology (AT) device.

A common inconvenience that disabled web users experience is being forced to repetitively listen to links and other elements included in the top section of the page before being presented with the main content. Accessible sites built by MAXIMUS Federal include a link that provides users of screen readers the option to skip over these repetitive links and elements and go directly to the featured information.

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

MAXIMUS Federal provides a toll free 24-hour-a-day, 7-day a week telephone hotline service. The services are staffed with both administrative and professional personnel from 8:00 am to 5:00 pm EST, Monday through Friday, except federal holidays. At all times when the office is not staffed, the phone system automated attendant prompts callers, at their option, to leave a message which will be diverted to the IRO Project Manager's cell phone. The IRO Project Manager and an Appeal Officer(s) familiar with the client are available for emergency contact 24-hours a day, seven (7) days a week. In addition, a MAXIMUS Federal Services Medical Director or his/her designee is available 24-hours a day, seven (7) days a week for consultation with the Project Manager to address emergency appeals. Furthermore, the Project Manager has the discretionary authority to contact MAXIMUS Clinical Consultants after standard business hours.

MAXIMUS Federal currently has access to translation services in 27 different language for our federal and state IRO projects, with the ability to access different languages as necessary.

(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?

A successful contractor should have the ability to be operational upon the date of contract award. With more than 40 governmental external review projects currently operating simultaneously for such clients as CMS, DoD, TMA, OPM, the VA and over 35 state regulatory agencies, we are confident we can be fully operational upon contract award of any health care appeal contract.

MAXIMUS Federal currently serves the following Federal clients with similar independent medical review services:

- Centers for Medicare and Medicaid Services: Qualified Independent Contractor for Medicare Part C Program
- Centers for Medicare and Medicaid Services: Qualified Independent Contractor for Eastern and Western Region Medicare Part A Program
- Centers for Medicare and Medicaid Services: Qualified Independent Contractor for Southern Region Medicare Part B Program
- Centers for Medicare and Medicaid Services: Qualified Independent Contractor for Eastern and Western Region of Medicare Part D Program
- United States Office of Personnel Management: Medical and Dental Benefit Review Program.
- Department of Veterans Affairs NEBRASKA-WESTERN IOWA HEALTHCARE SYSTEM (VISN 23): Clinical Peer Review Contractor
- Department of Veterans Affairs HEALTHCARE SYSTEM OF OHIO (VISN 10): Clinical Peer Review Contractor
- Department of Veterans Affairs Rocky Mountain Network (VISN 19): Clinical Peer Review Contractor
- Department of Veterans Affairs MidSouth Healthcare Network (VISN 9): Clinical Peer Review and Credentialing and Privileging Auditing Contractor.
- Department of Defense TRICARE Management Activity: National Quality Monitoring Contractor
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In addition, we provide similar external review services for the following state clients:

- Alaska Department of Administration (2000)
- Arizona Department of Insurance (1998)
- California Department of Managed Health Care (2001)
- California Department of Insurance (2005)
- California Public Employee Retirement System (2005)
- Colorado Division of Insurance (2000)
- Connecticut Department of Insurance (2000)
- Florida Agency for Health Care Administration (2001)
- Georgia Department of Community Health (2008)
- Idaho Department of Insurance (2010)
- Illinois Department of Insurance (2010)

- Indiana Department of Insurance (1999)
- Kentucky Department of Insurance (2000)
- Maine Bureau of Insurance (2010)
- Maryland Insurance Administration (2000)
- Massachusetts Office of Patient Protection (2000)
- Massachusetts Board of Registration in Medicine (2000)
- Michigan Division of Insurance (1999)
- Minnesota Department of Health (2000)
- Minnesota Department of Commerce (2000)
- Minnesota Department of Human Services (2000)
- New Hampshire Insurance Department (2000)
- New Jersey Department Banking and Insurance (2007)
- Nevada Department of Insurance (2009)
- North Carolina Department of Insurance (2001)
- Ohio Department of Insurance (2000)
- Oklahoma Department of Health (2000)
- Pennsylvania Department of Health (2001)
- Rhode Island Department of Health (1994)
- South Carolina Department of Insurance (2001)
- Texas Department of Insurance (2010)
- Vermont Division of Health Care Administration (1999)
- Virginia Bureau of Insurance (2000)
- Virginia Department of Human Resource Management (2000)
- Washington Department of Health (2000)
- Wisconsin Department of Insurance (2001)
- Wyoming Department of Insurance (2010)

(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?

MAXIMUS Federal has conducted more than 750,000 independent medical reviews, health care appeals, clinical peer reviews, and provider reimbursement arbitrations for more than 40 government agencies, including DMHC, CDI, CalPERS, the Centers for Medicare & Medicaid Services (CMS), the Department of Defense (DoD) TRICARE Management Activity (TMA), the United States Office of Personnel Management (OPM), the Department of Veterans Affairs (VA) and over 35 state regulatory agencies. Additionally, we can offer the Departments the following resources upon contract award:

- More than 500 board-certified, licensed medical professional reviewers in active practice representing every ABMS and AOS specialty and subspecialty,
- 100 dual-degreed Appeal Officers comprised of over health care attorneys, advance practice nurses, pharmacists, medical coders and like professionals, and
- Proven independent workflows that meet the requirements of our 40 plus government clients and their respective state/federal rules and regulations, URAC, and the NAIC Model Act

Based on the foregoing we are confident, we have the necessary resources and experience to make this transition seamless. MAXIMUS Federal is the only IRO that can offer the Departments this combination of resources and expertise.

(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 State and/or local licensing requirements?

Through our numerous government external review projects, MAXIMUS Federal provides external review in all 50 states. Therefore, we are not limited to certain geographic areas. We provide external review nationwide and internationally.

As emphasized throughout this response, MAXIMUS Federal also has more than 35 state external review contracts, certifications, licensures or registrations. We are leading IRO in state-mandated external review, by a large margin. The next leading IRO has less than 20 such certifications.

MAXIMUS Federal also possesses the most stringent conflicts of interest (COI) policy in the IRO industry. Based upon our business philosophy and the absolute need to maintain our independence and integrity, we decided to not provide any services to or contract with any health or disability insurer or health plan where it would create a conflict with a government program. Therefore, if a potential or actual conflict exists with a government program, we do not provide any services (e.g., clinical review, technology assessment, consulting) or have any relationship with any health plan or health or disability insurer nor at any time in the future will we enter into any contractual agreements with any health plan or health or disability insurer for the provision of any similar services. We believe we are the only URAC accredited IRO to offer the Departments this level of COI measures.

(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?

MAXIMUS Federal has processed more than 1400 urgent and/or experimental and investigational (E/I) reviews in 2010. Other than the shorter time frames and the potential need for a three reviewer panel depending on the complexity of the case, we process these reviews using the same proven independent review workflow as we do for standard reviews. Therefore, we do not require a specialized contract for urgent care appeals or E/I cases. Further, our approach would not have any impact on coordination of these reviews.

(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.

Since we routinely provide both types of reviews in our 40 plus government contracts, including CMS QIC Parts A, C, and D, and can offer over 600 Medical Professional Reviewers and 300

Appeal Officers and Appeal Specialists including nurses, attorneys, certified coders and dual degreed professional (e.g., RN/JD) there is no substantive difference in our operating procedures and resources as it relates to the provision of medical necessity only reviews and combined medical necessity and coverage reviews. Although the staff and consultants assigned to a given case will be different depending on the type of case, our case processing procedures and work flows are similar for all case types.

Data Collection

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

MAXIMUS Federal operates a proprietary external appeals case tracking system (ACTS), which was developed and is maintained in support of our external appeal clients. This system facilitates both the timely reporting of review activity to clients on a routine and ad hoc basis, and internal monitoring of the processing of cases through the system.

ACTS is comprised of two modules. The first module is the Review Actions subsystem, which is the repository where discrete actions in the review process are captured to enable monitoring of case status and actions taken during the processing of a case. This module is directly populated by daily data entry from case reviewer activity logs. It results in routine reports that show case status, duration in that status and the overall timeliness of a given review.

The second module, the Reporting subsystem, involves a series of batch processes that draw upon data in the first module to produce both routine and ad hoc reports. Routine reports include a series of operational reports used by MAXIMUS Federal internally to manage the processing of cases and a series of reports required by clients. The reporting subsystem also facilitates ad hoc reporting both to meet operational requirements of our clients and to assist in the management of review activities at MAXIMUS Federal. This special reporting capability exists primarily by virtue of three elements:

- Skilled analysts with a thorough knowledge of the data contained in ACTS;
- Reliance on a fourth generation programming language with special capacity for statistical analysis and reporting; and
- Existence of auxiliary files which support the general reporting requirements of the program.

This combination of elements together with the fact that MAXIMUS Federal owns and operates our own data center, allows us to quickly respond to a wide variety of IRO requests from our clients. These requests range from profiles of review activities for specific health plans to general reports on the patterns of issues encountered in the conduct of external reviews.

The information captured in ACTS allows MAXIMUS Federal to provide reports which include the following information:

- External Review case decision data (affirm, reverse, partial reversal and dismiss) by type of health plan;

- External Review case decision data by type of dispute (inpatient hospital services, psychiatric services, skilled nursing facility services, durable medical equipment, pharmacy/prescriptions, dental services, chiropractic services, laboratory/imaging services, physician services, emergency/urgent care services, transportation, experimental/investigational denials, physical therapy/occupational therapy/speech therapy and other services);
- Percentage of overturns by basis of decision (coverage, medical necessity, mixed);
- The dispute category, diagnosis, cost of the disputed services (if provided by the health plan), health plan category, days to decision and decision for each case reviewed;
- Frequency of type of dispute; and
- Frequency of diagnosis.

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

MAXIMUS protects the privacy and confidentiality of patient information under its documented quality assurance program, and in accordance with all applicable state and federal laws and URAC IRO standards regarding the confidentiality of medical records.

A number of steps all contribute to the overall safeguarding of patient information. One measure is the requirement that all staff, reviewers and vendors sign confidentiality agreements acknowledging that information relating to the review is confidential and agreeing to prevent unauthorized disclosure of any kind. Staff and associates are not permitted to remove or take confidential information upon termination. All Expert Reviewer contracts include terms that require all information provided by MAXIMUS be kept strictly confidential and not be disclosed or re-disclosed to any person or party except those authorized by law.

Another security measure requires all staff to promptly conform to Federal Government user ID requests and associated security profile requirements. Employee system access is conditioned upon initial HIPAA and network security training delivered by an Instructional Design Team, completion of any security training required by the client, and the successful completion of all required training is tracked through a learning management system. Similarly, subcontractors and independent contractors are required to complete system security training prior to assignment and accessing project systems.

Building and office security are additional security measures taken. Physical access to the IRO department during working hours is via a secure and locked reception area, which is designed to also accommodate mail and case file delivery. Vendors and unauthorized personnel are not permitted past this area. The remainder of the facility is segregated into zones, such as the mailroom/operations area, computer equipment room, records room, and work team areas. During non-business hours, access to the entire building is by smart card access and an authorized access code. MAXIMUS also utilizes recording security cameras which record all movement that occurs at facility entrances and intrusion detection on all first floor windows.

MAXIMUS recognizes that the review file contains protected health information that can be used to steal one's ID, and because public news accounts of lost or stolen PHI are becoming

more frequent, IRO staff observe stringent case security. Case file and PHI protections are fully compliant with the Privacy Act and HIPAA. Files and supplementary material are logged, tracked, and retained in a secure records room area. In addition, all workstations include locking files that are used to secure material when staff members are not present. Drafts of obsolete records are deposited in secure bins, prior to destruction by certified vendors.

MAXIMUS also maintains ISO controlled procedures covering the records management process, and such procedures are subject to periodic verification by trained ISO auditors.
We have an on-site secure medical records room with careful tracking of all physical case files. Case file documents that are currently in use are required to be at Appeal Officers' desks in locked compartments after hours. Completed reviews are routinely indexed and filed with a nationally recognized vendor for secure storage that employs a strict and complex set of security measures to limit access to files retained in its facility, including a 24-hour fire and security monitor, climate control, halon protected vaults, computerized inventory tracking, disaster recovery, and contingency planning.

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?

MAXIMUS Federal continually evaluates its operations and seeks to detect and correct potential errors at the earliest stage possible. We achieve this by conducting regular internal audits, reviewing COGNOS data on a routine basis as well as through retrospective quality reviews of appeal decisions.

Our internal audit program is managed by a Quality Assurance Director and our pool of ISO 9001:2008 trained internal auditors are fully qualified to conduct audits on any project. An audit schedule prepared each year ensures all processes within the Quality Management System are audited at least once every 12 months. Additional special audits are conducted to address any special concerns that our clients may request.

Numerous COGNOS reports are generated, many of which are reviewed on a daily basis. These reports can be supplemented as needed with Siebel queries. SAS is utilized when necessary to performed detailed statistical analysis. These reports are used by management and the Quality Assurance team to ensure MAXIMUS Federal is meeting client requirements and that consumers are using the external review process in a timely manner. An example of a report that is run on a routine basis to insure timelines in case processing includes a daily unassigned case report that shows all cases pending assignment to an adjudicator for review.

Case reviews include an analysis not only of the reviews completed by adjudicators but also the quality of systems data entered data as well as the medical necessity reviews completed by our panel of physicians. The results of the retrospective quality reviews are recorded and measured

to identify trends or weaknesses in the process. Training issues and cases that may require a corrected letter can also be flagged via retrospective quality reviews.

Evaluations oftentimes result in quality improvement initiatives. For example, MAXIMUS Federal has enhanced its quality reporting by measuring and reporting a "simple" error rate, as well as a "correct decision" rate. Specifically, the "simple" error rate is a measurement, on an individual staff basis, of the presence of any deficiency within the case, even if that deficiency did not lead to an incorrect decision. Another example involves coordination between the Quality Assurance Manager and the reporting team to obtain and review measurements of process conformity. Resulting data reports on case status facilitates identification of cases that may be at risk of being untimely, and complementary weekly timeliness trend reports display the project's performance over time.

The theme of continuous improvement plays an important role in our evaluation process. In this regard, MAXIMUS Federal maintains a corrective and preventive action program. Corrective actions address any verified nonconformity, while preventive actions tackle issues where the potential for nonconformity exists. Either may be found through the course of auditing, data analysis, or customer feedback. These are recorded on an approved Corrective Action Request (CAR) or Preventive Action Request (PAR) form. Appropriate action is taken to resolve the immediate issue, and an independent investigation by the Quality Assurance Manager is conducted to define the cause. Managers and the Project Director are required to sign off on a completed CAR or PAR.

Management Review is the final key element of the IRO continual improvement program. A committee of managers and supervisors meets regularly to review the performance of the quality management system. This committee reviews key performance indicators, results of monitoring and measuring activities, internal audit reports, corrective actions, and preventive actions. It is the committee's responsibility to provide recommendations for improvement actions, authorize proposed improvement activities, and ensure that adequate resources are provided to maintain an efficient quality management system.

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

MAXIMUS Federal's Quality Assurance program is the foundation on which we assess those specific requirements that should align with performance goals. The objectives of the MAXIMUS Federal QA Program establishes goals and expectations throughout our IRO review processes, and these also constitute those overarching performance goals that we would deem the most appropriate:

- Timeliness of all provided services and related actions;
- Accuracy in all work performed;
- Conflict-free and impartial performance of all required tasks; and
- Expertise of staff to complete assigned activities.

Applying these performance goals then to the specific measurements that will be applicable to IROs in the external review context, the Departments will want to evaluate the following:

- the IRO's appropriate use of legal experts to make coverage determinations and the use of expert medical reviewers to make medical necessity, experimental treatment and investigational technique case determinations;
- whether the IRO efficiently tracks the requirement that plans must provide the IRO, within five business days of a claim's assignment, all documents and information that the plan considered in making the adverse determination or decision on appeal;
- the extent to which the IRO properly considered relevant materials outside of the plan's claim file;
- IRO timeliness in issuing written notice of a decision within 45 days of receipt of the external review request;
- accuracy and comprehensiveness of the content contained in the IRO's written decision letter, including recitation of required content under regulations and agency guidance (i.e. statement that the IRO's decision is binding, contact information for consumer assistance or ombudsman office);
- timeliness of IRO notice of final external expedited review decision, including:
  - as expeditiously as the claimant's medical condition requires but no later than 72 hours after receiving the request for expedited review;
  - if notice of final decision is not in writing, provide the claimant and plan written confirmation of the decision no later than 48 hours after providing verbal notice of final decision.

MAXIMUS Federal's QA program constantly monitors similar performance goals such as these in our existing health care appeal programs, via many of the following initiatives:

Existing Comprehensive ISO 9001:2008 Certified Quality Assurance Program, Certified by Independent Registrar
▪ Discrete measurement of contract requirements (for example, timeliness, accuracy, administrative tasks)
▪ Trained/certified ISO internal auditors with significant QA and auditing experience
▪ Internal audits conducted regularly to ensure workflow processes meet quality standards
▪ Subcontractor performance monitored through regular periodic reviews
▪ Robust performance measures applied to all key processes to ensure timeliness, consistency and customer satisfaction
▪ Continuous improvement process via Quality Council and preventive/corrective action planning and evaluation
▪ Multi-level quality reviews of appeal decisions: o Correct data entry o Correct appeal issue analysis and help ensure correct, consistent decisions
▪ Quality reviews of medical reviewer decisions o Correct application of rules, regulations, and policies o Appropriate writing style o Evidence-based/peer defensible decisions
▪ Measurement of "simple error rate" (i.e. any error such as inaccurate reference vs. measurement of decision accuracy only)

Thank you for allowing MAXIMUS Federal to submit this response to your request for information. If you have any questions or require additional information please do not hesitate to contact me at thomasnaughton@maximus.com or 703.251.8545.

Sincerely,

Thomas Naughton, JD, LLM
Vice President, Operations
MAXIMUS Federal Services, Inc.