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Introduction

IntegriGuard, LLC, a wholly owned subsidiary of HMS Holdings Corp., is an ISO-certified and URAC-accredited organization devoted to the prevention and detection of fraud, waste, and abuse in federal healthcare systems. Over the past 10 years, IntegriGuard has delivered effective program integrity and payment accuracy solutions to the federal government. Our extensive experience encompasses audit, compliance & education, data & analysis, eligibility verification, medical review, and investigation.

Since 2002, IntegriGuard has served the Centers for Medicare & Medicaid Services (CMS) as a Program Safeguard Contractor (PSC), both as a prime contractor, and as a subcontractor to other PSCs. As such, IntegriGuard is recognized as having the expertise and capabilities to perform program integrity work to protect the Medicare Trust Fund under the Medicare Integrity Program. IntegriGuard has conducted medical review, proactive data analysis, cost report audits, investigation of potential fraud cases for referral, and outreach and education in the Medicare program. IntegriGuard's work as a PSC has involved reviewing, investigating, and auditing claims, medical records, and cost reports for a variety of provider types including, hospitals, Skilled Nursing Facilities, Outpatient Therapy Clinics, CMHCs, Comprehensive Outpatient Rehabilitation Facilities, Rural Health Clinics, DME, and physician offices.



In March 2010, IntegriGuard received the prestigious Inspector General's Integrity Award for helping the Office of the Inspector General (OIG) protect the integrity of federal funds originating from the U.S. Department of Health and Human Services.

IntegriGuard's Medical Review team uses established plan coverage policies, American Medical Association (AMA) coding rules, and evidence-based research to conduct medical review of claims. Reviews are completed using the applicable coding information and coverage policy for the dates services were rendered. IntegriGuard's network of more than 500 physician reviewers with 65 surgical, non-surgical, behavioral health, and allied health specialties provide expert peer review analysis. Physician reviewers are all board certified by the American Board of Medical Specialties (ABMS) or the American Osteopathic Association (AOA) and hold current, unrestricted licenses to practice healthcare, within the scope of their licensure, in the United States.

A stringent quality monitoring program is applied to IntegriGuard's medical reviews to ensure accurate and consistent review results.

Exhibit 1 provides further detail of IntegriGuard's medical review offerings.

Exhibit 1 ▶ *IntegriGuard offers a rich array of medical review services.*

Core Competency	Description	Relevance to RFI
Independent Medical Review	Conduct review of medical claims for validation of services rendered, medical necessity of services, and correct coding.	Purpose and Objectives; Qualified Organizations and Staff: Question 4; Infrastructure: Question 12
Medical Coverage Policy Development	Create, review, and revise policies that describe specific medical benefit coverage.	Infrastructure: Question 12
Provider Education	Provide structured education to providers regarding specific benefit coverage requirements.	Qualified Organizations and Staff: Question 4 Infrastructure: Question 11
Claims Coding Validation	Verify correct coding of claims that do not require a medical necessity review.	Qualified Organizations and Staff: Question 4
Review Determinations	Provide a clear decision regarding payment of service, rationale for decision supporting coverage policy, and/or state/federal regulations.	Qualified Organizations and Staff: Question 4; Infrastructure: Question 12
Customer Satisfaction	Provide customer satisfaction survey to ensure excellence in service provision.	Evaluation: Question 13

State IRO Knowledge and Experience

Additionally, IntegriGuard is able to leverage the experience of our sister company, Permedion, to fully understand the state external review process.

Permedion, Inc. was founded by a group of physicians in 1974 as a not-for-profit Ohio corporation providing medical peer review and quality assurance services in the state. Effective October 5, 2007, Permedion became a wholly owned subsidiary of HMS. HMS was also founded in 1974, and provides expertise in Medicaid program policy, data, program analysis, data analytics, and recovery. Permedion's organizational experience extends to performing rigorous review of medical billing issues and correct coding issues. The company has performed extensive peer review for state licensing boards in

medicine and dentistry, culminating in Corrective Action Plans and, in rare cases, recommendations to revoke rights of participation.

Permedion has been providing external review services since 2000, and currently serves as IRO to 12 states, as listed in Exhibit 2.

Exhibit 2 ▶ *Permedion has been certified by 12 states to conduct external reviews on behalf of the state.*

State	Agency	Period of Performance
Arizona	Department of Insurance	March 2001 - present
Colorado	Division of Insurance	July 2000 - present
Connecticut	Department of Insurance	January 2008 - present
Georgia	Department of Community Health	June 2008 - present
Indiana	Department of Insurance	February 2001 - present
Michigan	Department of Energy, Labor & Economic Growth, Office of Financial and Insurance Services	January 2001 - present
New Jersey	Department of Banking & Insurance	September 2006 – present
Ohio	Department of Insurance	May 2000 – present
Oregon	Insurance Division	July 2002 - present
Pennsylvania	Department of Health	October 2004 – present
Washington	Department of Health	June 2001 – present
Wisconsin	Office of the Commissioner of Insurance	July 2001 - present

In New Jersey, Permedion-HMS is considered a "Safety Net" vendor, coming behind the Department and primary utilization review vendor to identify and target remaining claims not initially identified with potential errors. Since January 2008, Permedion has identified more than \$1.6 million in overpayments.

Permedion's performance in Ohio in SFY 2008 and 2009 includes over \$1.3 million in identified savings for ODRC in the prior authorization program and over \$16 million identified in overcharges (based on billed charges) to ODRC in the retrospective review program.

Qualified Organizations and Staff

1. What accreditation standards currently apply to IROs?

IntegriGuard is accredited under the URAC Independent Review Organization (IRO) standards. These standards include 35 core standards and 17 IRO-specific standards. URAC is an independent, nonprofit healthcare accrediting organization dedicated to promoting healthcare quality. URAC offers accreditation programs assessing health plan operations, including but not limited to, network operations, healthcare practitioner credentialing systems, and medical management functions (such as utilization management, case management, disease management, and health call center services).

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

IntegriGuard follows URAC credentialing standards for medical reviewers. We verify board certifications, specialties, licensing, education, and training. We also review the reviewer's history of sanctions and/or disciplinary actions, and check the OIG and HHS exclusions databases. We screen each reviewer candidate according to these standards prior to offering employment or a contract, and repeat the process every two years to re-credential each active reviewer. We do not credential any reviewer who has a history of sanctions, disciplinary actions, or exclusion.

When a reviewer candidate has been favorably screened, our Credentialing Committee makes the final determination to approve the reviewer. IntegriGuard's Credentialing Committee meets quarterly and on an as-needed basis to extend credentials to new reviewer candidates, or to re-credential current active reviewers.

Our credentialing standards for legal reviewers include similar components to the medical standards. We verify bar registration and licensure, education, and professional history. We check the OIG and HHS exclusions databases, and screen out any candidate with a history of disbarment or malpractice.

Credentialing is required for medical and legal reviewers. We also conduct background checks and require each reviewer to complete conflict of interest disclosures and financial disclosures to ensure impartial reviews.

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

IntegriGuard has policies and procedures in place to ensure confidentiality and neutrality of reviewers. Our federal work requires annual compliance training and completion of non-disclosure and conflict of interest forms.

Our conflict of interest policies include:

- ▶ Employees must complete and sign a conflict of interest attestation annually.

- ▶ Our credentialing process requires reviewers to disclose any affiliations that would pose a conflict of interest in conducting an independent medical review.
- ▶ The agreement signed by medical reviewers on our panel obligates the reviewer to disclose a potential conflict of interest.
- ▶ During training, all medical reviewers receive an overview of the importance of identifying conflicts of interest in a timely manner to IntegriGuard.
- ▶ Upon receipt of a case, complete organizational screening for conflict of interest, defined as: A material professional, familial, or other affiliation with any of the following:
 - The referring entity
 - Health plan or any officer, director, or management employee of the health plan
 - The providing physician or the providing physician's medical group
 - Enrollee(s) and / or patient(s)
 - Facility at which the service was/would be provided
 - Developer or manufacturer of the principle drug, device, procedure, or other therapy recommended for the consumer
- ▶ Screen reviewers for affiliations as part of the case selection process.
- ▶ Medical reviewers are required to sign a disclosure for every submitted review verifying no conflict of interest.
- ▶ If a real or apparent conflict of interest arises with a selected clinical reviewer, the case is re-assigned.

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 \(e.g., medical necessity, experimental/investigational treatment, coverage issues, etc.\)?](#)

IntegriGuard's network of reviewers is able to perform thousands of reviews each month. Staffing and time per review differ based on the type and complexity of the claim, as well as length of stay. For example, it is possible to complete over 25 simple office visit claims per day. More complex claims, such as inpatient stays of 30 days or more, require much more time. A reviewer may only be able to complete one to four of this type of claim per day.

Our current staffing model is based on knowledge and specialty of reviewer matched to the claim that is to be reviewed. The standards for reviews are:

- ▶ Medical Necessity: 25-30 per day, per reviewer (600 per month)
- ▶ Experimental/Investigational Treatment: 25 per day, per reviewer (500 per month)
- ▶ Coverage Determinations: 30-40 per day, per reviewer (800 per month)

Infrastructure

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

IntegriGuard's secure proprietary case management tracking system, Medical Review System Database (MRS), has monitoring and reporting capabilities as well as the ability to capture information regarding medical case review.

MRS tracks data and meta-data concerning the review of medical records and accompanying documentation that justify clinical care. MRS also tracks information/documentation submitted by providers to justify reimbursement for Durable Medical Equipment.

The current system tracks five major activities:

- ▶ Requesting information from the providers of equipment and services
- ▶ Logging the receipt of the requested information
- ▶ Status of the review of the provided information
- ▶ Results and rationale for the reviewer's determination
- ▶ Results of the internal Quality Assurance (QA) process

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

MRS is a secure system, and currently operates as a pc-based application. Permedion currently maintains a secure web area using Base 10 from Bridgeline Digital, Inc. The secure web area serves as a repository for all project reports and letters sent to providers. It provides a 508-compliant, 24/7 secure communications mechanism and the ability to easily designate which web items are accessible to which individual user. Permissions can easily be customized based on an individual's need to know. IntegriGuard is able to adapt the Base 10 product for use with our tracking, analytical, and reporting functions.

We make continuous improvements to all of our hardware and software systems to assure continued compliance with federal regulations, and to maximize the efficacy and efficiency of our staff as well as the quality of our deliverables and services.

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)?

IntegriGuard currently provides individual points of contact to our customers. When larger-scale technical support is needed, we are able to provide a 24-hour hotline with translation services.

Our telephone system offers a range of call monitoring, routing and reporting capabilities, allowing us to provide statistics to meet contractual performance objectives. We understand the importance of timely service and quality systems, and our comprehensive reports include information that validates our ability to meet project standards, while providing a model for continuous quality improvement.

Our telephone solution also offers an interactive voice response (IVR) system that serves as the first point of contact for incoming calls. It provides callers with access to automated information using a menu format. Our IVR has capabilities like that of a computer, from looking up timetables to moving calls around an automatic call distributor (ACD). It offers skills-based routing, connecting clients and providers with the staff who can best help them. If there is a backup in queue calls, callers are redistributed to other available queues, ensuring service quality and efficiency.

We use AT&T Language Line services to support callers who need assistance in a language other than English or Spanish. We also use the language line to provide overflow capacity for Spanish-speaking callers. When a customer calls who is not English or Spanish speaking, staff place the caller on hold, dial the language line, select the language, and wait on the line for an interpreter to provide the necessary translation. The Customer Service Coordinator, customer, and interpreter then enter a conference call.

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 minimum of 90 days after the date of contract award would be reasonable to become fully operational. IntegriGuard would require the following resources during the transition period:

- ▶ Project management
- ▶ Administrative support
- ▶ IT support
- ▶ Applications development
- ▶ Trainer support
- ▶ Systems Security Officer
- ▶ Physician subject matter experts
- ▶ Communications support
- ▶ Data analysis support
- ▶ Workstation equipment
- ▶ Server and connectivity equipment
- ▶ Shredding and off-site storage vendor agreements as needed

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?

The foundation for a successful transition is a carefully considered project plan, to include the following components:

- ▶ Identification of all stakeholders
- ▶ Identification of transition milestones
- ▶ Kick-Off Meeting
- ▶ Identification of scope of transition and outgoing workload
- ▶ Discussions to communicate DOL/HHS risks, needs, and requirements
- ▶ Solutioning meetings with technical stakeholders involved in transitioning the work
- ▶ Installation and testing of hardware and software
- ▶ Connectivity with government systems
- ▶ System enhancements, developing, and testing
- ▶ Security protocols
- ▶ Training
- ▶ Communications strategy
- ▶ Education/outreach plan to redirect consumers to new resources
- ▶ Phase-in schedule to minimize interruption of operations
- ▶ Detailed go-live plan with clear criteria for customer acceptance

- ▶ Transfer of files
- ▶ Contingency planning
- ▶ Reporting

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?

IntegriGuard currently performs federal reviews nationally. Permedion currently serves as a Certified IRO to 13 individual states, and is able to operate in any state. IROs that currently serve local areas are able to serve multiple states simultaneously. Some states require same-state licensing to perform review work.

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?

HHS and/or DOL should take into consideration the special circumstances and complexity of each individual review. Urgent care appeals would not necessarily require more time to review, but the contractor would have to select reviewers with the appropriate knowledge base to properly review urgent care claims. Experimental and investigational treatments generally are more complex reviews, requiring additional research for each element, and/or legal interpretations. In these situations, the review would take more time per review.

This type of approach should not make a significant impact on coordination, if the specialized contractor's scope is clearly defined and communicated.

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.

Appeals that involve only medical necessity require a physician reviewer of an appropriate specialty. The peer-matched physician reviewer would look at all medical records associated with the appeal, apply medical guidelines and criteria to the review, and decide to agree or disagree with the original determination. Appeals that involve both medical necessity and coverage questions require the addition of a legal reviewer and research into National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs). A physician reviewer would conduct the medical necessity component of the review, and a legal reviewer would review the policy and associated statutes as they relate to the diagnoses in the medical records. Legal and medical reviewers should work in conjunction with one another to make a final determination.

Data Collection

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

IntegriGuard collects the following data for tracking and analyzing appeals:

- ▶ Approval vs. denial percentages (reviewers' approval scores)

- ▶ Physician reports
- ▶ Type of reviews
- ▶ Denial percentage as a whole
- ▶ Number and frequency of overturned appeals
- ▶ Reviewer productivity: number of reviews per person per day
- ▶ Education documentation: highest occurrence of denial/approval codes per provider
- ▶ Trending of specific ICD-9 or HCPCS codes by provider or supplier

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

IntegriGuard currently adheres to the CMS Business Partners Systems Security Manual (BPSSM), where the security policies, procedures, and systems undergo annual risk assessment audits. The security of confidential information is maintained through personnel, facility, network, media, and data security policies and procedures. More specifically:

Personnel Security

IntegriGuard performs thorough employment reference checks and background checks of each prospective employee, and conducts background re-investigations every five years. All IntegriGuard employees receive initial and yearly role-based security training, which includes education in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and security policies and procedures. Employees also sign confidentiality statements each year.

Facility Security

IntegriGuard's facilities are secured with electronic door locks, motion detectors, glass-break detectors, and physical intrusion detection systems, which are monitored around the clock. Only IntegriGuard employees, contractors, and authorized visitors are given facility access cards. Each office maintains a guest and visitor log for pre-approved vendor and maintenance personnel. Authorized employees follow opening and closing procedures to maintain security in each office. Server rooms and file rooms are secured with floor-to-deck walls and electronic locks. Doors remain closed and locked at all times, and only authorized personnel have access cards for these rooms. Server rooms are equipped with a master power shutoff switch for electrical power to the server room.

Network Security

To maintain infrastructure integrity, the secure IntegriGuard Private Network (IPN) is protected by automated virus, spyware, worm, and malware detection and removal. An independent reviewer conducts an annual information security risk assessment on the IPN. Each workstation is set up in accordance with configuration management policies and procedures, and uses a password-protected screen saver, which activates after 15 minutes of computer inactivity. Employees comply with a password policy with strict parameters, including a forced change every 45 days.

Media and Data Security

IntegriGuard follows a need-to-know policy for all media and data. Browsing of files and folders in storage rooms is prohibited. Sensitive information is logged in and out, and is not left unattended. All media containing protected information is stored in secure file rooms or secure file cabinets.

Employees follow mailroom procedures to track incoming and outgoing media, and facsimile logging and monitoring. Established procedures are followed to monitor and log the shredding of sensitive material. All cabinets, desk drawers, and containers must be locked. Area Security Officers conduct daily security checks to ensure compliance.

Data Backup

IntegriGuard uses Symantec backup Exec v.12d for data backup.

Weekly backups are done on Friday afternoon; differential backups are done Monday through Thursday. Backup tapes are LTO3, and the backup unit is a Dell TL series TL4000 4U tape library using LTO3 technology with 2 drives. The weekly backup set is picked up every Friday morning by Iron Mountain for secure off-site storage. Archived backups are done bi-annually. Shadow copy services are done three times daily on file server. Shadow copy services are set for 30 day retention.

All servers' standard Operating System partitions are three physical disks in a RAID 5 array. All external storage connected to all servers (via SCSI to PowerVault 220s) are configured in a RAID 5 array with an extra drive designated as a Global Hot Spare. All production servers have redundant power supplies. All servers are monitored by Dell System Administrator and any warning or error messages are emailed to the IT Staff as well as audible beeps from the hardware. All servers have multiple memory sticks. Three weeks (generations) of backups are available off-site at any given time.

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?

IntegriGuard performs semi-annual internal audits of our processes, policies, and procedures. We evaluate the effectiveness of our operations in meeting or exceeding our customers' requirements for the quality, performance, timeliness, and cost of our external review services. The results of our internal audits have recently informed process improvements in the following areas:

- ▶ Secure file storage procedures
- ▶ Chain-of-custody documentation
- ▶ Complex medical review templates

These process improvements helped to strengthen our security program, ensure confidentiality, streamline our medical review process, and ensure more consistent and precise documentation of complex medical review determinations.

IntegriGuard sends satisfaction surveys to each of our clients annually. We analyze these survey results and the ratings and comments on our evaluations within the NIH Contractor Performance System, and target areas for improvement based on this feedback. We recently responded to customer feedback by combining data analysis with our complex medical review, providing stronger end results.

IntegriGuard has established a Continuous Process Improvement initiative that provides all staff the mechanism to identify and suggest opportunities for improvement. This process encourages staff to communicate workflow refinement, innovation, and troubleshooting to their supervisors. Continuous process improvements suggested by staff are evaluated for benefit to the company, and employees are recognized for implemented changes. We then monitor implemented opportunities for improvement, to determine if the changes had the desired results, and if revisions are needed.

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

Timeliness and accuracy are the most appropriate performance goals for IROs.