

Overview

Risk management is the process involving the identification, investigation, analysis, evaluation and prevention of problems, including quality of care issues, affecting the provision of medical care. The goal of the Risk management function is to provide the most advantageous method for correcting, reducing or eliminating identifiable risks. Risk management relies on the Incident Reporting system to identify incidents leading to risk that occur throughout the health care delivery system.

Medical Practice Risk Management

The following protocols are recommendations regarding medical practice risk management. Providers should assign a designated risk manager for his or her office and develop their own risk management policies and procedures to assist in reducing medical practice risks.

Staff Training

The provider's designated risk manager should train all new employees at their initial orientation and at least one hour annually thereafter. The provider's support staff is a reflection of the provider's practice and is important in ensuring patient satisfaction. Support staff should be instructed to be courteous and respectful to all patients.

Risk Management Definitions

Adverse or untoward incident – an event over which health care personnel could exercise control, including:

- An unexpected occurrence during a health care encounter involving member death or serious physical/psychological injury or subsequent illness, including loss of limb or function, not related to the natural course of the member's illness or underlying condition.
- Any process variation for which a recurrence carries a significant chance of a serious adverse outcome.

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- Events such as breeches in medical care, administrative procedures or others, resulting in a negative impact on a member, even where death or loss of limb or function does not occur.
- An event over which health care personnel could exercise control and:
 - Is associated in whole or part with medical intervention (actions of any health care facility or personnel of the facility in the provision of health care) rather than the condition for which such intervention occurred;
 - Is not consistent with or expected to be a consequence of such medical intervention;
 - Occurs as a result of medical intervention to which the patient has not given his or her informed consent;
 - Occurs as the result of any other action or lack thereof on the part of the facility or personnel;
 - Results in a surgical procedure being performed on the wrong patient;
 - Results in a surgical procedure unrelated to the patient's diagnosis or medical needs being performed on any patient including the surgical repair of injuries or damage resulting from the planned surgical procedure, wrong site or wrong procedure surgeries, and procedures to remove foreign objects remaining from surgical procedures; and
 - Causes injury to a patient as defined below.

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Injury – for the purposes of reporting is any of the following outcomes when caused by an adverse incident:

- Death;
- Brain damage;
- Spinal damage;
- Permanent disfigurement;
- Fracture or dislocation of bones or joints;
- Any condition requiring definitive or specialized medical attention which is not consistent with the routine management of the patient's case or patient's preexisting physical condition;
- Any condition requiring surgical intervention or control;
- Any condition resulting in transfer of the patient, within or outside the facility, to a unit providing a more acute level of care;
- Any condition that extends the patient's length of stay; and
- Any condition that results in a limitation of neurological, physical or sensory function which continues after discharge from the facility.

Reporting Unusual Incidents on Provider Premises

Unusual incidents that occur on provider premises should be reported to the designated Risk Manager at that location. The following are examples:

In the event of an incident/injury to a member or visitor at a Plan-participating provider:

- Report occurrence to office administrator or

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risk management contact person in their office immediately.

- If injury has occurred, obtain immediate medical assistance for visitor by a physician or offer ambulance transportation to nearest contracted Emergency Room.
- Medical record will be completed and documented in compliance with the Plan's medical record keeping guidelines for any other member.

In the event a patient or visitor becomes abusive (physically or verbally) at a Plan provider premises:

- Report occurrence to office administrator or risk management contact person in their office immediately. Attempt to calm the patient or visitor (do not argue or disagree with the abusive individual).
- Notify the police if the patient/visitor is physically threatening.
- Remove other patients or visitors from the immediate area.
- Do not attempt to restrain abusive individual unless another person is in danger. If restraint must be used, every effort must be made to keep the abusive person from physical harm (it is recommended that two individuals be present to assist an abusive individual).
- In the event the abusive individual is a member, the attending physician should also be notified immediately.
- The participating provider's office notifies the Plan's Customer Service department of the incident, if appropriate.

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Other incidences required to be communicated to the Plan include:

- A slip or fall by a patient or family member;
- Medication error or reaction requiring treatment;
- Abusive Plan member who is a patient or their relative;
- A theft or loss from the provider's office;
- Malfunction or damage of equipment during treatment;
- Accusations of malpractice by a patient or family member; and
- Non-compliance with potential to be life-threatening.

An Incident Report form, included in the **Forms** section of this manual, should be used to report all incidents to the Plan's risk manager.

Further reporting to the Plan's insurance carrier and governmental agencies, as appropriate, shall be arranged within the prescribed time frames by the Plan's risk manager.

Exposures to Blood

Health care workers are at risk for occupational exposure to bloodborne pathogens, including hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV). Exposures occur through needle sticks or cuts from other sharp instruments contaminated with an infected patient's blood or through contact of the eye, nose, mouth or skin with an infected patient's blood.

Important factors that may determine the overall risk for occupational transmission of a bloodborne pathogen include: the number of infected individuals

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in the patient population, the chance of becoming infected after a single blood contact from an infected patient, and the type and number of blood contacts.

Most exposures do not result in infection. After a specific exposure, the risk of infection may vary based on factors such as these:

- The pathogen involved;
- The type of exposure;
- The amount of blood involved in the exposure; and
- The amount of virus in the patient's blood at the time of exposure.

Physicians should have a system in place for reporting exposures in order to quickly evaluate the risk of infection, to inform patients about treatments available to prevent infection, to monitor patients for side effects and to determine if infection occurs. This may involve blood tests of the patient exposed and the source patient, offering appropriate post-exposure treatment.

To Prevent Occupational Exposures

Many needle sticks and other cuts can be prevented by using safer techniques (e.g., not recapping needles by hand, disposing of used needles in appropriate containers and using medical devices with safety features designed to prevent injuries). Many exposures to the eyes, nose, mouth or skin can be prevented by using appropriate barriers (e.g., gloves, eye and face protection, gowns) when contact with blood is expected.

If An Exposure Occurs

Scientific evidence does not show that using antiseptics or squeezing the wound will reduce the risk of transmission of a bloodborne pathogen. Using

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a caustic agent such as bleach is not recommended. Immediately following an exposure to blood:

- Wash needle sticks and cuts with soap and water;
- Flush splashes to the nose, mouth or skin with water; and
- Irrigate eyes with clean water, saline or sterile irrigants.

Following Any Blood Exposure

- Report the exposure to the department (e.g., occupational health, infection control) responsible for managing exposures. Prompt reporting is essential because, in some cases, post-exposure treatment may be recommended and it should be started as soon as possible.
- Discuss the possible risks of acquiring HBV, HCV and HIV and the need for post-exposure treatment with the provider managing the exposure. All persons should have received the hepatitis B vaccine, which is extremely safe and effective in preventing HBV infection.

Other Sources of Information

- ***HBV and HCV***

For additional information about hepatitis B and hepatitis C, call the Hepatitis Information line at (888) 4-HEPCDC (888-443-7232) or visit CDC's hepatitis Web site at: www.cdc.gov/ncidod/diseases/hepatitis/index.htm

Anyone believing they have had a reaction or adverse event should report it to his or her

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health care provider. The Vaccine Adverse Event Reporting System at (800) 822-7967 receives reports from health care providers and others about vaccine side effects.

- **HIV**

Information specialists who staff the CDC National AIDS Hotline at (800) 342-2437 can answer questions, provide information on HIV infection and AIDS and direct people to local resources. The HIV/AIDS Treatment Information Service (800-448-0440) can also be contacted for information on the clinical treatment of HIV/AIDS.

For free copies of printed material on HIV infection and AIDS, please call or write the:

**CDC National Prevention Information
Network** P.O. Box 6003
Rockville, MD 20849-6003
Telephone: (800) 458-5231
Web site: www.cdcnpin.org

Additional information about occupational exposures to bloodborne pathogens:

CDC's Hospital Infections Programs Web site at
www.cdc.gov/ncidod/dhqp/index.html

CDC's National Institute of Occupational Safety and Health Web site at
www.cdc.gov/niosh or call (800) 35-NIOSH
(800-356-4674)

Universal precautions are intended to supplement rather than replace recommendations for routine infection control, such as hand washing and using gloves to prevent gross microbial contamination of hands. Because specifying the types of barriers needed for every possible clinical situation is impractical, some judgment must be exercised.

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Universal Precautions for Infection Control

The risk of nosocomial transmission of HIV, HBV and other bloodborne pathogens can be minimized if health care workers use the following general guidelines:

- Take care to prevent injuries when using needles, scalpels and other sharp instruments or devices, when handling sharp instruments after procedures, when cleaning used instruments and when disposing of used needles;
- Do not recap used needles by hand;
- Do not remove used needles from disposable syringes by hand;
- Do not bend, break or otherwise manipulate used needles by hand;
- Place used disposable syringes, needles, scalpel blades and other sharp items in puncture-resistant containers for disposal;
- Locate the puncture-resistant containers as close to the use area as is practical;
- Use protective barriers to prevent exposure to blood, body fluids containing visible blood and other fluids to which universal precautions apply. The type of protective barrier(s) should be appropriate for the procedure being performed and the type of exposure anticipated; and
- Immediately and thoroughly wash hands and other skin surfaces that are contaminated with blood, body fluids containing visible blood or other body fluids for which universal precautions apply.

Glove Use for Phlebotomy

Gloves should reduce the incidence of blood

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contamination of hands during phlebotomy (drawing blood samples), but they cannot prevent penetrating injuries caused by needles or other sharp instruments.

The likelihood of hand contamination with blood containing HIV, HBV or other bloodborne pathogens during phlebotomy depends on several factors:

- The skill and technique of the health care worker;
- The frequency with which the health care worker performs the procedure (other factors being equal, the cumulative risk of blood exposure is higher for a health care worker who performs more procedures);
- Whether the procedure occurs in a routine or emergency situation (where blood contact may be more likely);
- The prevalence of infection with bloodborne pathogens in the patient population.

The likelihood of infection after skin exposure to blood containing HIV or HBV will depend on the concentration of virus (viral concentration is much higher for hepatitis B than for HIV), the duration of contact, the presence of skin lesions on the hands of the health care worker and for HBV the immune status of the health care worker.

Although not accurately quantified, the risk of HIV infection following intact skin contact with infective blood is certainly much less than the 0.5 percent risk following percutaneous needlestick exposures.

In universal precautions, all blood is assumed to be potentially infective for bloodborne pathogens, but in certain settings (e.g., volunteer blood-donation centers) the prevalence of infection with some bloodborne pathogens (e.g., HIV, HBV) is known to be very low. Some institutions have relaxed

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recommendations for using gloves for phlebotomy procedures by skilled phlebotomists in settings where the prevalence of bloodborne pathogens is known to be very low.

Institutions with a judgment that routine gloving for all phlebotomies is not necessary should periodically reevaluate their policy. Gloves should always be available to health care workers who wish to use them for phlebotomy.

In addition, the following general guidelines apply:

- Use gloves for performing phlebotomy when the health care worker has cuts, scratches or other breaks in his or her skin;
- Use gloves in situations where the health care worker judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative patient;
- Use gloves for performing finger and/or heel sticks on infants and children; and
- Use gloves when persons are receiving training in phlebotomy.

Selection of Gloves

The Center for Devices and Radiological Health, FDA, has responsibility for regulating the medical glove industry. Medical gloves include those marketed as sterile surgical or non-sterile examination gloves made of vinyl or latex. General purpose utility (rubber) gloves are also used in the health care setting, but they are not regulated by FDA since they are not promoted for medical use. There are no reported differences in barrier effectiveness between intact latex and intact vinyl used to manufacture gloves. Thus, the type of gloves selected should be appropriate for the task being performed.

The following general guidelines are recommended:

- Use sterile gloves for procedures involving contact with normally sterile areas of the body;
- Use examination gloves for procedures involving contact with mucous membranes, unless otherwise indicated, and for other patient care or diagnostic procedures that do not require the use of sterile gloves;
- Change gloves between patient contacts;
- Do not wash or disinfect surgical or examination gloves for reuse. Washing with surfactants may cause "wicking," i.e., the enhanced penetration of liquids through undetected holes in the glove. Disinfecting agents may cause deterioration; and
- Use general-purpose utility gloves (e.g., rubber household gloves) for housekeeping chores involving potential blood contact and for instrument cleaning and decontamination procedures. Utility gloves may be decontaminated and reused but should be discarded if they are peeling, cracked or discolored, or if they have punctures, tears or other evidence of deterioration.

Waste Management

- 1) Universal precautions are not intended to change waste management programs previously recommended by CDC for health care settings. Policies for defining, collecting, storing, decontaminating and disposing of infective waste are generally determined by institutions in accordance with state and local regulations.
- 2) Information regarding waste management

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regulations in health care settings may be obtained from state or local health departments or agencies responsible for waste management.

Article II. From the Department of Health and Human Services and Centers for Disease Control (CDC) Web site: <http://www.cdc.gov>

Fraud and Abuse

The Plan is committed to the prevention, detection and reporting of health care fraud and abuse according to applicable federal and state statutory, regulatory and contractual requirements. The Plan has developed an aggressive, proactive fraud and abuse program designed to collect, analyze and evaluate data in order to identify suspected fraud and abuse. Effective detection tools have been developed to identify patterns of health care service use, including over utilization, unbundling, up-coding, misuse of modifiers and other common schemes.

Federal and state regulatory agencies, law enforcement, and the Plan vigorously investigate incidents of suspected fraud and abuse. Service providers are cautioned that unbundling, fragmenting, up-coding, and other activities designed to manipulate codes contained in the International Classification of Diseases (ICD), Physicians' Current Procedural Terminology (CPT), the Healthcare Common Procedure Coding System (HCPCS), and/or Universal Billing Revenue Coding Manual as a means of increasing reimbursement, may be considered an improper billing practice and may be a misrepresentation of the services actually rendered.

In addition, providers are reminded that medical records and other documentation must be legible and support the level of care and service indicated on claims. Providers engaged in fraud and abuse may be subject to disciplinary and corrective actions, including but not limited to, warnings, monitoring,

administrative sanctions, suspension or termination as an authorized provider, loss of licensure, and/or civil and/or criminal prosecution, fines and other penalties.

To report suspected fraud and abuse, please refer to the **Quick Reference Guide** of this manual and call our confidential Trust Program hotline.

Fraud and Abuse Definitions

Fraud – Any type of intentional deception or misrepresentation made by an entity or person with the knowledge that the deception could result in some unauthorized benefit to the entity, himself, or some other person. It includes any act that constitutes fraud under applicable federal or state law.

Some examples of fraud include, but are not limited to the following:

- Falsifying any medical record, note, diagnostic test result, report, claim, or any financial, administrative or clinical documents used to validate services.
- Billing for services, supplies, or equipment not actually furnished to any health plan member.
- Providing false and intentionally misleading information regarding health plan coverage, limitations, and exclusions to any health plan member.
- Misrepresentation of any date of service, frequency, duration, or description of any service, or the identity of the recipient of such services, or the identity of the service provider.
- Billing for non-covered or non-chargeable services, supplies, or equipment disguised as any covered or chargeable service.

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- Duplicate billings (e.g., billing more than once for the same service, multiple providers billing for the same service for the same member on the same day, billing the health plan and the member for the same services, or submitting claims to both the health plan and other third parties without making full disclosure of relevant facts to all parties).
- Providing payment or other inducement to any health plan member in exchange for the use of their identification card or other member information with or without the permission of the health plan member for the purpose of obtaining wrongful payment.
- Receipt or offering of any unlawful kickback, gratuity, or other inducement made with the intent to increase referrals.
- Reciprocal billing (e.g., billing or claiming services furnished by another provider or furnished by the billing provider in a capacity other than claimed).
- Practicing medicine or other health care without a valid license, or with an expired or revoked license, or without proper credentials, or while excluded from participation in any Federal or State health care program.
- Any agreement or other arrangement between a provider and a health plan member that results in claims for unnecessary costs or charges to the health plan (e.g., providing health care services, supplies, or equipment to an ineligible person that is in possession of a health plan member's identification card, or any fraudulent scheme involving the use of member information to submit false claims).
- Any other intentional misrepresentation of a material fact regarding the provision of health

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care services for the purpose of obtaining wrongful payment.

Abuse – Practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicare program, or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards or contractual obligations for health care.

Abuse also includes member practices that result in unnecessary cost to the Medicare Advantage program or the health plan, contractor, subcontractor, or provider. It should be noted that Medicare Advantage funds paid to a health plan and subsequently used to pay for goods and services provided by contractors, subcontractors and providers at all levels are always considered Medicare Advantage Program funds, and may not be used for purposes other than intended.

Some examples of health care abuse include, but are not limited to the following:

- Unauthorized waiver or reduction of applicable member co-payment or deductible.
- Billing for services, supplies or equipment in any amount in excess of the applicable Federal and/or State fee schedules, negotiated or contract rate.
- Direct or balance billing of health plan members where prohibited.
- Billing for services that are not medically necessary, or if medically necessary, not to the extent actually provided.
- Providing health care services of an inferior quality (i.e., services that do not meet generally accepted standards of care), or in an inappropriate setting, or at a level of care

that is in excess to medical necessity.

- Failure to fully document services according to generally accepted standards (i.e., records must be legible, clearly document the services provided, etc.) and maintain adequate clinical, financial, and other records substantiating claims.

Special Investigations Unit

A corporate Special Investigations Unit (SIU) has been established according to federal and state statutory, regulatory and contractual requirements and includes management, investigators, analysts, medical coding auditors and claim review specialists. SIU capabilities include pre-payment and retrospective reviews, provider profiling models, performance metrics, data mining, analysis and reporting, and specialized business partner arrangements to augment in-house resources. The mission of the corporate SIU is outlined below:

- Comply with applicable federal and state statutory, regulatory, and contractual requirements regarding fraud, waste, and abuse;
- Effectively detect, investigate and report suspected fraud, waste, and abuse;
- Identify and recover overpayments caused by error, fraud, waste, or abuse;
- Assist in the development of anti-fraud plans, policies and procedures, and fraud and abuse awareness, education and training materials;
- Assist in conducting education and training for associates, providers, members, first-tier, delegated and related entities on fraud and abuse awareness and other related topics according to established training schedules; and

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- Assist in conducting vulnerability assessments, auditing and monitoring activities of first-tier, delegated and related entities.

Education and Training

The Provider Relations department is responsible for distributing provider manuals and other information, as well as conducting provider education and training. Providers may contact the Provider Relations department to arrange education and training, or answer questions regarding health plan benefits, coverage, limitations and exclusions, policies and procedures, provider rates and contracting issues, claims, fraud and abuse awareness, and other information.

Inspection of Records

Providers are required to make all administrative, clinical and financial records and service delivery sites open to the Plan, the Centers for Medicare and Medicaid Services (CMS), the Health and Human Services Office of the Inspector General (HHS-OIG), the General Accounting Office (GAO), State Auditor's Office, Office of the Attorney General, Comptroller General, or their designees. The Plan, CM, HHS-OIG, GAO, the State Auditor's Office, the Office of the Attorney General, the Comptroller General and/or their designees have the right to examine and make copies, excerpts or transcripts from all records, contact and conduct private interviews with provider clients and employees, and do on-site reviews of all matters relating to service delivery.

Release of Records

Providers will release medical records of members, as may be authorized by the member, or as may be directed by the Plan, appropriate agencies of the state, or the United States Government. Release of medical records will be consistent with applicable federal and state statutory, regulatory and contractual requirements regarding confidentiality.



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WellCare Health Plans, Inc. (WellCare) is the parent company to the following existing and applicant subsidiaries: WellCare of Florida, Inc., HealthEase of Florida, Inc., WellCare of New York, Inc., WellCare of Connecticut, Inc., WellCare of Louisiana, Inc., WellCare of Georgia, Inc., WellCare of Ohio, Inc., WellCare of Texas, Inc., WellCare Health Plans of New Jersey, Inc., Harmony Behavioral Health, Inc., Harmony Health Plan of Illinois, Inc., Harmony Health Plan of Indiana, Inc., WellCare Prescription Insurance, Inc., WellCare Health Insurance of Arizona, Inc., WellCare Health Insurance of Illinois, Inc., and WellCare Health Insurance of New York, Inc.