



Policy and Procedure Manual

Cork Medical

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Governing Body & Legal Authority

Effective Date: 01/01/2012

Revisions: 03/31/2015, 02/29/2016, 6/7/2018

Review: 04/25/2019

CHAP: C1.2

Summary:

Cork Medical, LLC. has the structure and functional mechanisms necessary to support and accomplish its stated mission.

Policy:

Cork Medical has the legal authority to operate and is in compliance with Local, state and federal regulations. The governance structure is defined in legal documents. The governing body assumes full legal authority, responsibility, and accountability for organizational performance; appoints a qualified administrator and designates advisory group membership as applicable. The governing body is made up of individuals with relevant expertise, business acumen, and professional relationships specific to the stated mission of the organization. Governing body members are oriented to the organization and are knowledgeable and responsive to key issues affecting the organization.

Governing Body Responsibilities Include:

1. Establishing policies consistent with organizational mission
2. Approving new and/or revised policies and procedures as indicated and necessary
3. Holding management accountable for the fiscal solvency of the organization and adequacy of financial resources
4. Approving budgets and capital expenditures
5. Selecting and evaluating the chief administrator
6. Evaluating organizational performance
7. Developing and approving strategic plan
8. Reviewing legal and business documents considering real or potential changes to the organization on a periodic basis at least every 36 months.
 - a. Articles of incorporation
 - b. Bylaws
 - c. Legal agreements

Annually, the members of the governing body and executive staff provide written disclosure of all professional or personal relationships or interests, direct or indirect that might present a conflict of interest. Statements are on file in corporate office.

Governing body retains accurate, complete, and signed minutes of all official meetings and are distributed in accordance with organizational policy and retained for five (5) years.

Conflict of Interest and Disclosure

Effective Date: 01/01/2012

Revisions: 05/15/2015

Review: 11/30/2018, 07/25/2019

Summary:

Cork Medical employees, including all members of the Board of Directors, shall adopt a high ethical standard of conduct in performance of duties.

Policy:

Cork Medical, LLC. employees will observe laws and regulations governing business transactions, compete fairly with others, and use Company funds only for ethical, legitimate purposes.

Employees of the Company must avoid incurring any financial or personal obligations that may affect (or appear to affect) their judgment in dealing, on Cork Medical's behalf, with other companies or individuals.

Select areas of concern include:

1. Holding an interest, directly or indirectly, in a firm that is in competition with Cork Medical, LLC. or a firm with which Cork Medical, LLC. does business.
2. Receiving gain from any purchase or decision made by Cork Medical, LLC.
3. Accepting favors, financial or otherwise, from an outside person or organization that may affect the employee's judgment in making decisions related to Cork Medical, LLC.
4. Using information to which an employee has access by reason of his or her position by disclosing such information to competitors (e.g., financial information, technical information, or trade secrets) or using such information for his or her own benefit.
5. Offering consulting services or serving as an employee of another organization.

President

Effective Date: 01/01/2012

Revisions: 03/31/2015

Review: 11/30/2018, 01/06/2020

CHAP: C1.4

Summary:

The President of Cork Medical, LLC. will be responsible for overall operations and services of the Company. The President will operate the company in accordance with all applicable federal, state, and local laws and regulations. The President will also adhere to Medicare Supplier Standards in the operation of the Company.

Policy:

The President's job description will clearly define his or her authority, duties, responsibilities, and accountabilities. The President will be qualified for the position as outlined in the job description and any applicable federal or state laws. A copy of the President's application and/or resume will be placed in his or her personnel file as proof that he or she meets the minimum education and experience requirements for the position.

In the temporary absence of the President, the Chief Executive Officer will assume the duties of the President and will be responsible for the operation of Cork Medical. All employees shall give the Chief Executive Officer their best cooperation in providing services to company patients.

Mission Statement

Effective Date: 01/01/2012

Revisions: 06/22/2016

Review: 05/03/2018, 11/19/2019

Mission Statement:

Cork Medical's mission is to improve lives through innovative wound care products.

Company Goals

Effective Date: 01/01/2012
Revisions: 02/29/2016, 02/23/2018
Reviewed: 04/25/2019

Policy:

Cork Medical, LLC. has a vision, a mission and core values that are the building blocks used to guide the strategic planning process, which is then used to set Company Goals. In addition to this, Cork Medical is constantly analyzing the environment. Using this information, Cork Medical develops strategies and objectives for the Company during its quarterly executive meetings. During these meetings, the Executive Team discusses the following key areas of the business:

- Sales
- Operations
- Compliance/Risk
- Customer Service
- Financial
- Clinical
- Human Resources

The objective of these meetings is to set strategic objectives for the next quarter that will align with the company's mission and vision and allow the Company to achieve its long-term goals while maintaining a level of success in the short term as well. The objectives are prioritized, and action plans are set. Each item has an executive sponsor who is ultimately responsible to ensure the objective moves forward.

Every quarter, the Executive Team will review the objectives set from the previous quarter to ensure they have been completed. If not completed, a new deadline is set. The goal is to have a system of accountability in place where the company can set objectives, hold the company accountable for reaching the objectives and continue to meet Company goals.

Compliance with Federal, State and Local Laws

Effective Date: 01/01/2012
Revisions: 02/24/2015, 11/30/2018
Review: 07/25/2019

Summary:

Cork Medical operations will be in compliance with all applicable federal, state, and local laws and regulations.

Policy:

Each location will take appropriate action on reports and recommendations of authorized planning, regulatory, and inspection agencies. Each location will comply with fire protection regulations and will secure a fire inspection certificate when required.

Documentation will be kept regarding registration, licensure, and inspection activities. These records will be filed and maintained for at least 3 years.

All rules, regulations, and laws that require posting by federal and state mandate will be posted for easy review by all personnel. All licenses, permits, and accreditation documents will be posted for easy review by the general public.

Reporting of Outcomes

Effective Date: 01/01/2012
Revisions: 02/29/2016, 06/08/2018
Review: 10/16/2019

Policy:

It is the policy of Cork Medical to inform key stake holders of outcomes that affect regulatory compliance or licensure for the company.

Procedure:

The Board of Directors is to be informed within 24 hours of any outcomes from reviews and/or audits that could affect regulatory compliance or licensure of the Company.

Regulatory agencies will be informed as required by statute of any outcomes from reviews and/or audits that could affect regulatory compliance or licensure of the Company.

The company's accrediting body will receive a notice as required, of the occurrence of any of the following:

1. Company license(s) suspension
2. Company license(s) probation
3. Conditions or restrictions placed on any company license(s)
4. Changes in company structure
5. Changes in company locations
6. Civil penalties against the company or offices of ten thousand dollars (\$10,000.00) or more
7. Third-party recovery of insurance payments of ten thousand dollars (\$10,000.00) or more

Service Description

Effective Date: 01/01/2012
Revisions: 04/08/2015, 02/21/2018, 11/19/2019

Summary:

Cork Medical offers a variety of services, all of which are geared toward making life better for our patients and our referral services. We are committed to offering superior service in all aspects of the business.

Policy:

Cork Medical provides the following equipment:

- Negative Pressure Wound Therapy
- Hospital Beds
- Non-Powered Pressure Reducing Support Surfaces
- Powered Pressure Reducing Support Surfaces
- Trapeze Bars
- Patient Lifts
- Cushions
- Overlays
- Wound Dressings

The company guides patients through the unique requirements of each insurance plan. The cost and patient responsibility portion are communicated to the patient in advance of supplying equipment.

Patient Rights and Responsibilities

Effective Date: 01/01/2012
Revisions: 02/29/2016, 11/30/2018
Review: 04/25/2019

Cork Medical will provide a copy of the Patient Bill of Rights and Responsibilities to each patient upon admission. The Patient Bill of Rights and Responsibilities shall be discussed with the patient and/or the patient's family and/or other responsible party, with documentation of receipt and understanding of the information. Copies of the Patient Bill of Rights and Responsibilities will be made available to anyone requesting a copy.

The Patient Bill of Rights and Responsibilities shall address, at a minimum, the following:

1. Receive reasonable coordination and continuity of services from the referring agency for home medical equipment services
2. Receive a timely response from Cork Medical when homecare services or care are needed or requested
3. Be fully informed in advance about service or care to be provided, and any modifications to the Plan of Service or the Plan of Care
4. Participate in the development and periodic revision of the Plan of Service or the Plan of Care
5. Informed consent and refusal of services, care or treatment after the consequences of refusing services, care or treatment are fully presented
6. Be informed in advance of the charges, including payment for service or care expected from third parties and any charges for which the patient will be responsible
7. Have one's property and person treated with respect, consideration, and recognition of patient dignity and individuality
8. Be able to identify visiting staff members through proper identification
9. Voice grievances or complaints or recommend changes in policy, staff or service or care without restraint, interference, coercion, discrimination, or reprisal
10. Choose a health care provider
11. Confidentiality and privacy of all information contained in the patient record and of Protected Health Information
12. Receive appropriate service or care without discrimination in accordance with physician orders
13. Be informed of any financial benefits when referred to an organization
14. Be fully informed of one's responsibilities
15. Be informed of provider service or care limitations
16. Be informed of patient rights under state law to formulate advance care directives
17. Be informed of anticipated outcomes of service or care and of any barriers in outcome achievement

When the patient is unable to make medical or other decisions, the family should be consulted for direction. Cork Medical will respect the patients' rights and responsibilities.

All staff members will understand and be able to discuss the Patient Bill of Rights and Responsibilities with the patient and caregiver(s). Each staff member will receive training during orientation and attend an annual in-service education class on the Patient Bill of Rights and Responsibilities.

The patient and caregiver(s) will also receive a copy of the DMEPOS Supplier Standards, which is included in the Patient Handouts forms.

Patient Complaints and Concerns Policy

Effective Date: 01/01/2012

Revision Date: 02/03/2016,

06/11/2018

Review: 07/25/2019

Summary:

This policy is designed to assist employees and patients through the patient complaint process. All Cork Medical patients are important and deserve a forum to express their thoughts, concerns, and complaints.

Policy:

Complaints are defined as:

- Complaint: A legal or safety matter.
 - Example:
 - Newly delivered equipment causes injury due to improper assembly
 - Patient receives EOB for item billed but not received
 - Property damage accidents
 - Letters from Federal or State Agencies of a legal matter

Cork Medical addresses patient complaints as follows; acknowledge receipt within 5 days from receipt, and a written response detailing the results of its investigation will be provided to the complainant within 14 days.

Patient Concerns are defined as:

- Concern/Issue: All other matters of concern to a patient

Cork Medical addresses patient concerns with expediency. Concerns are documented in sales pilot notes and referred to manager for resolution.

Patients have the right to lodge a complaint/concern without concern for reprisal, discrimination, or unreasonable interruption of service.

Procedure:**Complaints:**

- The employee taking the patient call will document the call in Sales Pilot
- Complaint will be forwarded to the Department/Branch Manager, and Customer Service Team Manager. A copy is retained on file at local office.
- Customer Service Team will update the Complaint log tracker to ensure timely resolution and assist as needed.
- Customer Service Team will notify Compliance Department of patient complaint.
- Customer Service Team will work with department Manager to develop an appropriate response to the complaint.
- Compliance Officer will draft response letter and ensure timely delivery.
- Customer Service Team will update status and provide an update to Compliance
- Complaints regarding specific employees will also be reported to HR.
- Additional complaints received after the response letter has been drafted and sent will go directly to the Compliance Office and another complaint ticket will be started following the response protocol.

Concerns:

- Concerns notes will be assigned a task in Sales Pilot and the appropriate Manager notified.
- Concerns unable to be resolved timely will be forwarded to Customer Service Team for review.

Confidentiality of Personal Health Information

Effective Date: 01/01/2012

Revisions: 01/27/2015

Review: 11/30/2018, 10/16/2019

Summary:

All Personal Health Information (PHI) shall be treated confidentially.

Policy:

PHI is defined as personal information that identifies or could be used to identify an individual. PHI includes but is not limited to:

- Full Name
- Date of Birth
- Social Security Number
- Insurance Number
- Medical Diagnosis
- Any partial combination of the above

Patient information will not be displayed in areas accessible to the public or unauthorized personnel. Any non-employee having access to records is required to have a signed Confidentiality Agreement on file. Employees will discuss patient-related information with Company personnel only on a need-to-know basis.

Each employee receives training in confidentiality of patient information during orientation and annually. In addition, the following documents confirming confidentiality of PHI is kept on file for each employee:

- HIPAA acknowledgment form
- Confidentiality and Non-Solicitation agreement (for non-sales personnel)
- Non-Compete agreement (for sales personnel)

Each patient is provided a written copy of the Patient Bill of Rights and Responsibilities and HIPAA/Privacy Policy as included in the Patient Handbook during initial set up.

Advance Care Directives

Effective Date: 01/01/2012
Revisions: 01/25/2015, 11/30/2018
Review: 11/19/2019

(Medicare Client Right – The patient has the right to be informed of his/her right under state law to formulate advanced care directives)

Summary:

The patient has the right to be informed of his/her right under state law to formulate advanced care directives

Policy:

The patient has the right to accept or refuse medical services and the right to formulate advance care directives. Patient service or care is not prohibited based on whether or not the individual has an advance directive.

Procedure:

Upon Delivery patients are provided a patient handbook with information on the Patient Bill of Rights and Responsibilities, which includes information on Advance Directives, as part of his or her initial set-up paperwork.

Unstable Health Conditions

Effective Date: 8/13/2018

Review: 04/25/2019

Summary:

To distinctly define our services as a durable medical equipment provider and ensure that any display or concern regarding a patient's medical instability is reported to the appropriate family members and medical staff.

Policy:

Upon discovering that a client's medical condition has become unstable or unpredictable, our agency will notify the following:

1. Emergency personnel (911)
2. Compliance Officer
3. Remain with patient until help arrives

Procedure:

1. Upon notice of any unusual behavior, unresponsiveness, loss of consciousness, severe agitation, severe injury, severe bleeding, and our staff will contact emergency personnel and the compliance officer immediately to report the observation.
2. Cork Medical personnel will remain with patient until help arrives.
3. Upon receiving a report of unstable health condition, the compliance officer will immediately contact the patient's family, including caregiver, of these observations.
4. The Compliance Officer will complete an incident report of these events and store in the patient's file.

Patient Abuse or Neglect

Effective Date: 01/01/2012
Revisions: 02/29/2016, 11/30/2018
Review: 07/25/2019

Summary:

It is the policy of Cork Medical to report suspected abuse, neglect, exploitation or death due to maltreatment of any patient receiving our services.

Policy:

Any abuse or suspected abuse to a patient must be reported within 1 business day to the Compliance Officer. The Compliance Officer is required to report suspected abuse or neglect to the appropriate state Department of Health and the Department of Human Services.

Procedure:

Any abuse or suspected abuse to a patient must be reported within 1 business day to the Compliance Officer. The Compliance Officer is required to report suspected abuse or neglect to the appropriate state Department of Health and the Department of Human Services.

Abuse and/or neglect include, but are not limited to, the following:

- Malnutrition
- Bruises, welts, abrasions
- Puncture wound
- Laceration
- Burn
- Dislocation, fracture
- Hitting and slapping
- Sexual abuse, assault, exploitation
- Verbal assault, humiliation, threat
- Money misuse and/or theft
- Property misuse and/or theft
- Failure to provide physical, emotional, or medical care
- Unacceptable environment
- Inadequate supervision

Ethics

Effective Date: 01/01/2012

Revisions: 02/29/2016

Review: 11/30/2018, 10/16/2019

Summary:

Cork Medical provides a vehicle and processes that considers, addresses, and resolves conflicts and ethical issues associated with patients, caregivers, staff, physicians, referral sources and other healthcare partners. The company identifies ethical issues and educates its personnel about ethical aspects of care or service.

At orientation, annually and as needed, Cork Medical employees are informed of the process for identifying and resolving ethical and/or compliance issues. Information includes but is not limited to:

- The definition and examples of ethical issues within the Company
- The resources to be utilized when potential issues arise which include the contact information for the Compliance Officer and the Executive Team members
- Regular updates on industry changes and requirements
- Refresher training on various topics of Compliance and Ethics related to patient care and the industry

By authority of the Executive Team, the Compliance Officer is charged with managing, investigating, and resolving violations with respect to ethical issues associated with patient care or service. The Compliance Officer uses the Compliance Committee as the vehicle in which to discuss and vet compliance and ethical policies.

Code of Conduct

Effective Date: 01/01/2012

Revisions: 09/29/2015

Reviewed: 05/10/2018, 11/19/2019

1. Provide patients and co-workers with respect and personal dignity
2. Not discriminate on the basis of age, sex, race, creed, color, national origin or disability
3. Consistently strive to provide quality services with the highest professional standards possible
4. Take appropriate precautions necessary to ensure the safety of employees and patients
5. Abide by federal, state, and local laws, statutes, regulations, and ordinances, including full compliance with all federal health care program requirements and company policies and procedures
6. Prepare and submit accurate claims consistent with federal health care program requirements
7. Conduct business ethically to prevent fraud or abuse of federal, state, or private payer health care programs
8. Report suspected violations of any federal health care program requirements or company policies and procedures to the Compliance Officer
9. All individuals have the right to use the Disclosure Program. Cork Medical is committed to non-retaliation and to maintain, as appropriate, confidentiality and anonymity with respect to disclosures.

Cultural Beliefs

Effective Date: 01/01/2012

Revisions: 01/26/2015

Reviewed: 11/27/2018, 04/25/2019

Summary:

Cork Medical recognizes that cultural backgrounds and religious beliefs may impact a patient's lifestyle and his or her view of healthcare.

Policy:

During the patient's initial assessment, Cork Medical employees may identify differences and make efforts to understand how the patient's cultural beliefs impact their perception of their illness. Employees will conduct themselves with respect for each patient's cultural background and religious beliefs, to the greatest degree that is practical and safe.

Communication Methods

Effective Date: 01/01/2012

Revisions: 01/25/2015

Review: 11/30/2018, 7/25/2019

Summary:

Cork Medical provides clear communication, in the client's language, of the safe, appropriate and intended use of the equipment.

Policy:

Cork Medical employees communicate with each patient in a language or form that the patient can understand. When a communication barrier exists, the employee will use special methods, devices, interpreters and other communication aids to ensure the interaction is clear and concise.

Compliance Program

Effective Date: 01/01/2012

Revisions: 09/24/2015, 02/27/2018, 07/25/2019

Compliance Program Overview:

Cork Medical recognizes that an effective Compliance Program begins with the Compliance Officer and the Compliance Committee and is exhibited throughout the structure of the Company. Both are responsible for the oversight of the Company Compliance Program. The Compliance Committee members must possess sound working knowledge of the Company's internal processes in order to effectively manage the Compliance Program.

- I. Compliance Committee
- II. Roles and Responsibilities of Compliance Officer
- III. Code of Conduct
- IV. Disclosure Program
- V. Overpayment Policy
- VI. Risk Assessment
- VII. Audits and Monitoring
- VIII. Education

I. Compliance Committee

The Compliance Committee consists of Directors and Managers assigned by the President and meets on a quarterly basis. The Compliance Officer chairs each meeting and is responsible for the meeting agenda and minutes.

The role of the Compliance Committee is to assist in the analysis of the Company's areas of risk and assist in the oversight of compliance guidelines and implemented changes. The Compliance Committee recognizes that the Company is not indifferent to the law and has considered the following factors in the Compliance Program:

- a. Implementing compliance rules and procedures that are reasonably capable of reducing the prospect of wrongdoing.
- b. The assignment of high-level personnel to oversee the compliance effort.
- c. The use of due care to prevent the delegation of substantial discretionary authority to individuals whom the Company knew or should have known had a propensity to engage in illegal activities.
- d. The effective communication of the standards and procedures of the program to all employees.
- e. Taking reasonable steps to achieve compliance with the standards by monitoring and auditing systems reasonably calculated to detect criminal conduct and the establishment of a reporting system so that irregularities and items of concern can be properly reported.
- f. Consistent enforcement of the standards through appropriate disciplinary mechanisms, including discipline of individuals responsible for any improper conduct or wrongdoing.
- g. Taking all reasonable steps to respond appropriately to any detected offenses and to prevent further similar offenses, including any necessary modifications to the Compliance Program to prevent and detect violations of law.

II. Roles and Responsibilities of Compliance Officer

The Compliance Officer is responsible for ensuring knowledge and compliance through company policies and procedures. All standards and procedures of the Compliance Program shall be communicated to all employees, contractors and agents.

- a. Review matters relating to education, training and communication in connection with the Compliance Program.
- b. Ensure that the Company's policies and procedures and quality standards are properly disseminated, understood, and followed.
- c. Conduct compliance training for all new hires.
- d. Investigates, resolves and reports any compliance issues, patient complaints, or disclosures.
- e. Report to the Compliance Committee the results of all investigations and audits. If a criminal offense is found, the Company shall notify the appropriate law enforcement agency within a reasonable amount of time after becoming aware.
- f. Conduct Compliance Committee meetings quarterly.
- g. Make on-site visits to each Cork Medical location at least annually.
- h. Assist any employee who needs clarification of any issues within the Company and/or help with problems or concerns related to the Compliance Program.
- i. Ensure that each employee understands that he or she has an affirmative duty to report any violation of the Code of Conduct promptly.
- j. Periodically review and revise the Compliance Program to address new laws and regulations. The Compliance Program shall be systematically reviewed with each employee at least annually.

III. Code of Conduct

- Provide patients and co-workers with respect and personal dignity
- Not discriminate on the basis of age, sex, race, creed, color, national origin or disability
- Consistently strive to provide quality services with the highest professional standards possible
- Take appropriate precautions necessary to ensure the safety of employees and patients
- Abide by federal, state, and local laws, statutes, regulations, and ordinances, including full compliance with all federal health care program requirements and company policies and procedures
- Prepare and submit accurate claims consistent with federal health care program requirements
- Conduct business ethically to prevent fraud or abuse of federal, state, or private payer health care programs
- Report suspected violations of any federal health care program requirements or company policies and procedures to the Compliance Officer
- All individuals have the right to use the Disclosure Program. Cork Medical is committed to non-retaliation and to maintain, as appropriate, confidentiality and anonymity with respect to disclosures.

IV. Disclosure Program

The Disclosure Program is a way for individuals to disclose any issues or questions associated with Cork Medical's business practices. By visiting www.corkmedical.com and selecting the Contact tab, then selecting the Compliance Inquiry tab, individuals can submit issues or questions directly to the Compliance Officer. The individual may select to include or exclude their personal information. Only the message is a required field in the form and all other information is optional. By submitting it through this mechanism, an email is sent to the Compliance Officer. In addition, the individual may select to include or exclude their personal information.

Internal disclosures made in person or another manner other than the online Compliance Inquiry is documented by the Compliance Officer.

Upon receipt of disclosure, the Compliance Officer shall gather all relevant information and make a good faith inquiry into the allegations set forth in the disclosure. All disclosures, substantiated and unsubstantiated, shall be logged in a disclosure log within 48 hours of receipt.

Individuals reporting compliance concerns shall do so without concern for retribution or retaliation.

V. Overpayment Policy

Cork Medical's overpayment policy defines and identifies how to quantify, address, and issue repayments from the Billing and Accounting departments.

Summary:

Cork Medical's overpayment policy defines and identifies how to quantify, address, and issue repayments from the Billing and Accounting departments.

Policy

Overpayment

1. An overpayment is the amount of money Cork Medical has received in excess of the amount due and payable under any Federal health care program requirements.
 - a. Examples include billing for services not provided, duplicate payment, claims for non-covered services billed as covered services, breaches of the Assignment of Benefits Agreement, routine waiver of coinsurance and/or deductibles, receiving or giving kickbacks

Substantial Overpayment

2. \$1,000.00 over/above any line item allowable for the equipment and/or
3. Multiple small claims from a single payor, within a 30-day period, who together total up to \$100,000.00
4. Overpayments having the same root cause totaling \$100,000.00 or more outside the normal course of business, within a 1-year period. Once an overpayment has been identified, Cork Medical will submit an internal refund request within 5 business days.
5. Cork Medical processes refunds on a weekly basis.
6. Overpayments will be processed and a refund will be issued no later than 30 days.

VI. Risk Assessment

Yearly the President and CEO will meet to discuss risk within the company. If the President or CEO is not on the compliance committee, the compliance committee will be invited to the meeting. After meeting, the President will present the risk to the Executive Team to confirm risk assessment. Once yearly risk is assessed, the President will meet with the Compliance Officer or other members that will be driving compliance and discuss the topics for the yearly risk assessment.

Once the priorities are set, a plan of action will be created with the following approach:

1. Educate
2. Audit
3. Respond

Educate: Create training modules to cover areas of risk for the Company. These trainings will be refined and given to the required employees.

Audit: The Compliance Officer or other members of the Compliance Committee will audit these risk items throughout the year to ensure the education is impacting the results. Audits include reviewing the Reverse Quality Program, Site Visits, and documentation audits.

Respond: Based on the audit results, Cork Medical will respond to any issues and determine if we need to further educate, modify the education materials and approach or make any other necessary changes that will allow us to operate at a level of high compliance and avoid any areas of Risk.

The Compliance Officer will report on these findings to the Board of Directors so the board can continue to monitor the results to assess the effectiveness of the program.

VII. Audits and Monitoring

The Compliance Officer shall enforce the Compliance Program through monitoring, auditing and continuous reviewing and training. In order for the Compliance Program to be effective, the Compliance Officer shall communicate the standards and procedures of the Compliance Program to all employees, contractors and agents. The Compliance Officer shall conduct audits based on the risks identified in each Risk Assessment.

The Compliance Officer or other members of the Compliance Committee will audit these risk items throughout the year to ensure the education is impacting the results. Audits include reviewing the Reverse Quality Program, Site Visits, and documentation audits. A report will be presented each calendar year to the Compliance Committee.

VIII. Education

The Compliance Officer shall provide training programs annually and as needed to ensure employees' compliance. Upon hire, all employees receive compliance training during the orientation process. New Sales Representatives receive in-depth compliance training as it relates to their specific roles and paperwork requirements. Additionally, all employees shall receive annual training related to compliance and other training courses.

At a minimum, the following training is required at the time of hire and/or annually:

- a. New Hire Orientation
- b. Compliance Program Training
- c. Patient Rights and Responsibilities
- d. Sexual Harassment
- e. Infection Control
- f. Workplace Safety
- g. Emergency Preparedness
- h. Cultural Diversity and Communication Barriers
- i. Patient Complaints
- j. Ethics
- k. Incident Reporting
- l. Medical Device Act
- m. Driver Safety (OMs and Drivers only)

Employees shall receive training that includes the Code of Conduct, program requirements, ethics and proper submission of claims. Board Members will receive training regarding Cork Medical's CIA agreement requirements (if under CIA) and Compliance Program.

Budget Planning

Effective Date: 01/01/2012

Revisions: 03/26/2015, 11/30/2018, 01/06/2020

Summary:

Cork Medical prepares an annual budget to manage and monitor day to day operations and to assist in making decisions which provide the greatest opportunity for financial success.

Policy:

The Chief Executive Office, Chief Financial Officer and President develop the budget and monitor the budgetary process.

Procedure:

Cork Medical prepares an annual budget of revenue, expenses, and costs of goods sold.

Revenue projections are based on historical data by location:

- Changes in staff, reimbursement level by payer, and population demographics served, all contribute to the projected revenue.
- Adjustments to revenue on an accrual basis are recorded by location based on a calculated collection percentage of allowable charges.

Cost of Goods sold is based on historical data by location:

- Changes in sales, product make-up, and product demand, all contribute to the projected cost of goods sold.

Expense projections are based on historical data:

- Payroll expenses are adjusted based on staff volumes per location.
- Operating expense are reviewed and projected based on upcoming year's expectations.
- Corporate staff and expenses are allocated across locations based on revenue total percentage to total for the individual locations.

Financial results are compared to budget numbers monthly and on a cumulative year-to-date basis:

- Material variances are investigated and explained.
- Analysis of budget vs. actual monthly/YTD provides a basis for development of succeeding year's budgets.
- Budget to actual analysis are presented to the Board of Director's by the Chief Financial Officer at quarterly board meetings.

Fiscal Management

Effective Date: 01/01/2012
Revisions: 03/26/2015, 11/30/2018
Review: 04/25/2019

Summary:

Cork Medical provides fiscal management using sound business practices and the use of standard accounting procedures.

Policy:

A financial management information system is used to document and monitor all financial components and provide appropriate and timely reports to levels within the organization.

Procedure:**Revenue:**

All patient services, equipment and/or supplies billed are verified by signed invoice and/or delivery tickets to validate delivery of services/equipment. HME billing software is utilized to perform all billing of patients and transmission to third-party payers.

All revenues received are posted to the patient's account and deposited into the company checking account.

Accounts are reconciled using standard accounting procedures.

Cork Medical evaluates each account individually to determine financial hardships and any write-offs.

Cork Medical does not extend credit to patients. Patients are billed monthly for any insurance co-payments, insurance deductibles, spend-downs and/or insurance denials. Payment is expected upon receipt of the bill. After 90 days, the company may turn over patient accounts to a collection agency for nonpayment and partial payment of patient accounts.

Expenses:

The President, the Chief Financial Officer, and the Controller meet biweekly to review all expenses scheduled for weekly check run.

Representatives from the executive, financial, and operating team meet once a month to review major cost of goods sold and inventory levels.

Overall:

The CEO, CFO, and President meet monthly to review fiscal operating results.

Financial Record Retention

Effective Date: 01/01/2012

Revisions: 04/06/2015

Review: 11/30/2018, 07/25/2019

Summary:

Cork Medical retains financial records in accordance with IRS guidelines.

Policy:

Cork Medical retains financial records at its corporate office and utilizes a secured offsite storage service.

Procedure:

Cork Medical's governing body will review financial records each quarter.

The company follows IRS guidelines for document retention, documents that are not listed, but are substantially similar to those listed in the schedule will be retained for the appropriate length of time.

Records are stored in a safe, secure, and accessible manner. Documents and financial files that are essential to keeping the Organization operating in an emergency will be duplicated or backed up at least every week and maintained off site.

The CFO is responsible for the ongoing process of identifying its records, which have met the required retention period, and overseeing their destruction. Destruction of financial and personnel-related documents will be accomplished by shredding. Destruction will be suspended immediately, upon any indication of an official investigation or when a lawsuit is filed or appears imminent.

Reimbursement Disclosure Policy

Effective Date: 01/01/2012

Revisions: 03/26/2015, 2/21/2018, 10/16/2019

Summary:

Cork Medical develops and conveys charges associated with the products and services provided to patients.

Policy:

A list of estimated charges for services will be available to all Customer Service and Billing Staff and will be made available to any patient, prospective patient, any person or organization, and any regulatory or accrediting body upon request.

Prior to receipt of services or upon delivery of services or care, patients will be provided with the following information:

1. Product and/or service provided
2. Available reimbursement sources, including amounts expected from each source based on percentage and estimated patient responsibility
3. Phone number to call with billing questions

Personnel Management

Effective Date: 01/01/2012

Revisions: 02/29/2016, 11/30/2018

Reviewed: 04/25/2019

Summary:

The Human Resources Department is responsible for policies and procedures concerning personnel management.

Policy:

Cork Medical maintains a Human Resources department responsible for all employee related records and processes. These include:

- On-boarding Management for New Hires
- Talent Management/Recruitment
- Employee Development
 - New Hire Orientation
 - Specialized Training
- Employee Relations Management
 - Leave Administration
 - Workers Compensation
 - Department Organization
 - Personnel Reviews
- Payroll Management
- Company Employee Policy Management
 - Employee Handbook
 - Building Policy and Guidelines
 - Job Specific Policy
- Employee Benefit(s) Management
- Employee file retention
 - Employee records
 - Disciplinary records
 - Reviews
 - Health file

Procedure:

Each employee will receive an electronic copy of the Employee Handbook during orientation or upon first day of hire. Employees will be advised of any changes or revisions of the policies and procedures contained in the Handbook and will receive an electronic copy of an updated Handbook or of any new or revised Personnel Management policies or procedures.

Personnel File Management

Effective Date: 01/01/2012

Revisions: 02/29/2016, 11/30/2018

Review: 07/25/2019

Summary:

The Human Resources Department has sole access to personnel files. Personnel files are stored electronically on the server and current Human Resources Management System (Paycor). Medical files are stored in a separate electronic folder on the server only.

Policy:

At a minimum, Cork Medical requires the following items in an employee's personnel file:

- Resume or application
- Performance Evaluation(s)
- Disciplinary Action(s) (if applicable)
- Job Description
- Education/training credentials (if applicable)
- Reference checks (2)
- Criminal background screening
- TB Test results (if applicable)
- Payroll documentation
- Credit Card Agreement (if applicable)
- Hepatitis B Vaccination
- Non-Compete (if applicable)
- Signed offer letter
- Corporate Integrity Agreement
- HIPPA Acknowledgement

Procedure:

Employees who wish to review their personnel file must make a formal request to the Human Resources Department.

Retention requirements for Confidential Personnel Records:

- Personnel Files: 7 years
- Payroll Files: 7 years
- Medical Files (excluding Workers Compensation): 7 years
- Occupational exposure records are retained for the duration of employment plus 30 years
- Annual Training records are retained for a minimum of 3 years

Personnel Credentials

Effective Date: 01/01/2012

Revisions: 03/31/2015, 11/30/2018

Review: 01/017/2020

Summary:

Cork Medical employs and assigns personnel commensurate with their education and experience.

Policy:

Two reference checks will be performed on all new employees prior to hire. Any licensed, registered, or certified applicant must provide a copy of his or her credentials prior to hire.

Procedure:

Pre-employment reference checks will request, position held, dates of employment and eligibility for rehire. In the case of an applicant with no previous work experience, educational or personal references may be accepted.

The employee is required to provide proof of renewal of all mandated licenses, certifications, or registrations. A credentialed employee will not be allowed to work with an expired or lapsed credential. Failure to provide a copy of the renewed credential or license will result in the employee being placed on unpaid administrative leave until the renewal is obtained.

Personnel Requirements

Effective Date: 01/01/2012

Revisions: 02/29/2016, 11/30/2018

Review: 07/25/2019

Summary:

The health and safety of employees and clients is promoted and enhanced through education, current application of infection control practices and implementation of appropriate safety measures.

Policy:

Employees of Cork Medical who provide in-home patient care are required to have the following:

1. Annual TB testing
2. Hepatitis B vaccination or signed declination
3. Valid driver's license (CDL license if required)
4. Adequate automobile insurance
5. Motor Vehicle Record (MVR) check
6. Criminal background check

Copies of the above items will be placed in the employee's personnel file.

Procedure:

The Compliance Officer will maintain a list of employees that require TB testing and annually checkoffs. The staff member is required to complete a yearly TB questionnaire in January. Failure to complete the yearly questionnaire shall result in the staff member being placed on unpaid administrative leave until the questionnaire is completed.

All employees who are required to operate a motor vehicle in the course of their duties are required to have a valid state driver's license appropriate to the type of vehicle being operated, in compliance with state laws. Employees who drive their own vehicles on Company business are required to maintain adequate automobile insurance. A copy of the driver's license and current automobile insurance declaration page will be placed in the employee's personnel file. Each employee who is required to operate a motor vehicle in the course of their duties will sign a release to allow the Company to obtain a copy of his or her MVR at point of hire and at no more than every three (3) years thereafter. The President of Cork Medical, in consultation with the Company's insurance carrier, will determine what motor vehicle violations may result in termination of an employee. The Compliance Officer will maintain a list of employees required to have a driver's license; this list must include license expiration dates. The Compliance Officer will notify staff members 30 days prior to the expiration date of the driver's license. The staff member is required to provide a copy of his or her driver's license at least five (5) days before the expiration date of the driver's license. Failure to provide a copy of the renewed driver's license will result in the staff member being placed on unpaid administrative leave until the driver's license is obtained. Failure to obtain the driver's license within two (2) weeks of the warning may result in termination of the employee.

Staff members who require a Commercial Driver's License (CDL) to drive Company delivery vehicles must also provide a copy of a current medical certification to the Compliance Officer. The Compliance Officer will notify staff members 30 days prior to the expiration date of the medical certification. The staff member is required to provide a copy of his or her medical certification at least five (5) days before the expiration date of the medical certification. Failure to provide a copy of the medical certification will result in the staff member being placed on unpaid administrative leave until the medical certification is obtained. Failure to obtain the medical certification within two (2) weeks of the warning may result in termination of the employee.

Each employee who provides in-home patient care is required to sign a release allowing the Company to obtain a copy of his or her Criminal Background Record at time of hire and at no more than every three (3) years thereafter. The President of Cork Medical, in

consultation with the Company's attorney, will determine what criminal background may result in termination of an employee.

Background Screening Policy

Effective Date: 01/01/2012

Revisions: 11/20/2015, 02/21/2018, 04/25/2019

Summary:

Cork Medical obtains the following checks on each employee prior to the date of hire:

- Criminal Background Check
- National Sex Offender Registry Check
- Office of Inspector General Exclusion List Check
- System for Award Management Database Check
- State Maintained Healthcare Program Exclusion Databases

In addition to the screening process above, Cork Medical is responsible for conducting the following screenings for all Ohio employees:

- Bureau of Criminal Identification and Investigation (BCII)
- BCII every 5 years thereafter

All screenings are conducted prior to the BCII check. Hiring a person convicted of a crime is handled on a case by case basis. Ohio candidates may be hired conditionally for up to 60 days. If results are not received within 60 days, employment will be terminated until results are received and individual is eligible for hire.

Orientation Program

Effective Date: 01/01/2012
Revisions: 03/24/2015, 11/30/2018
Review: 07/25/2019

Summary:

Cork Medical's written plan details the orientation of new personnel and for personnel assigned to a new job classification. Components of the orientation plan may include mission and purpose of the organization, table of organization, lines of authority and responsibility, hours of work, job-related responsibilities, and personnel policies.

Policy:

Cork Medical provides a formal orientation program to assure that newly hired employees understand the policies and procedures of the company, as well as the specific policies of the duties to which they are assigned.

Procedure:

Orientation will take place during the employee's first 30 days of employment.

New employees will receive instruction on the following:

1. Review of the individual's job description, duties to be performed, and their role in the organization
2. Organizational chart and the chain of supervision
3. Employee Handbook
4. Mission Statement of Cork Medical
5. Confidentiality and Privacy of Protected Health Information (PHI)
6. Patient Bill of Rights and Responsibilities
7. Conflict of Interest Policy
8. Written procedures – job specific
9. Training specific to job requirements
10. Cultural Diversity
11. Ethics
12. Reverse Quality
13. Infection control
14. Compliance Program
15. Patient Complaint Process

An in depth, Orientation is completed by all office and sales personnel.

Day 1 – HR Policies, Company Overview, IT, Product Overview and Compliance

Day 2 – Company Workflow (Life Cycle Process) and Insurance Training

Day 3 – Specialized job specific training

Competency Assessment

Effective Date: 01/01/2012
Revisions: 02/26/2015, 11/30/2018
Review: 10/16/2019

Summary:

Cork Medical maintains a competent staff trained in the specific disciplines for which they provide service to Cork Medical Patients.

Policy:

Cork Medical will have periodic competency assessments of employees to ensure a level of competence that is consistent with Job Description specifications.

All patient-facing employees will receive a Competency Evaluation based on the service or care provided. The Competency Evaluation will be an ongoing process and will focus on the primary service or care being provided. The Competency Evaluation will be conducted at least annually or as required. Validation of skills will be specific to the employee's role and job responsibilities. Competency Evaluations for non-patient-facing employees will be documented during the Performance Evaluation.

Procedure:

Competency Evaluations will be accomplished through observation, skills lab review, supervisory visits, and/or knowledge-based tests. The evaluation is comprised of the following elements listed below.

- The Competency Evaluations will be performed by the employee's supervisor or a qualified designee.
- Evaluations shall be conducted during a service visit to a patient's home during which the employee's supervisor will observe the employee's competency and job performance.
- Any unsatisfactory performance noted in the Competency Evaluation will require further instruction in unsatisfactory areas and a follow-up supervisory visit.
- Remedial in-service education, outside continuing education or refresher courses may be mandated, if an employee does not meet competency requirements.
- The employee will be reassessed after completion of additional education or training.
- Employees who continue to be unable to meet competency requirements may be removed from their position.

Continuing Education

Effective Date: 01/01/2012

Revisions: 03/01/2015, 11/26/2018, 04/26/2019

Summary:

Cork Medical will provide in-services and continuing education for all employees on an ongoing basis.

Policy:

In-service education will be provided on an ongoing basis when there is evidence of initiation of new service or introduction of new equipment and is required to maintain accreditation and compliance program requirements. In-services topics will be determined on an as needed basis. Courses that may be completed are:

1. Patient Rights and Responsibilities
2. Workplace, Employee, Patient Safety
3. Sexual Harassment
4. Infection Control
5. Ethics
6. Compliance Program Guidelines
7. Emergency Preparedness
8. Patient Complaints
9. Cultural Diversity and Communication Barriers
10. Driver Safety (OM's and Drivers only)
11. Medical Device Act
12. Incident Reporting

Procedure:

A schedule of mandatory training will be completed for the upcoming calendar year. The Compliance Officer will add topics to the schedule as needed, to include new equipment and supplies, changes in policies and procedures, review of quality improvement findings, and other topics as needed. Employees may also suggest topics they wish to be added to the schedule.

In-Service requirements may also be met via various means, but not limited to, lectures, videos, and self-instruction. In-service education is to be documented on the In-Service Documentation Form, History report from on-line course system, testing documents, and/or Paycor acknowledgement of training, as applicable. In-Service logs and signed testing should be forwarded to the Compliance Officer and sent to HR for recording in the employee personnel file.

The In-Service Documentation Form will include the following:

1. The date and time of in-service
2. Topics presented/Key announcements
3. Employee's Signature

Employees, who do not complete their education requirements, including the acknowledgement forms in our HR System, will be restricted from working until training is completed. Area Managers and Supervisors will be held responsible for their staff's training completion and may be subject to progressive discipline if their direct reports are repeatedly non-compliant.

Cork Medical Training Requirements

Effective Date: 07/25/2019

Summary:

Mandatory training is a requirement of all positions of Cork Medical. Maintaining an educated and updated workforce is a high priority for excellence in performance.

Policy:

Cork Medical employees will participate and cooperate with all training requirements as a condition of their employment.

Process:

1. Cork will set quarter or Monthly education requirements.
2. Employees have until the end of the quarter or month to complete required courses.
3. Managers will be notified if their employee's fail to complete the course on time and asked to enter a Paycor memo in the employee's file.
4. HR will verify the coaching memo is entered into employee file.
5. Employees will be given 5 more business days to complete the course.
6. Employees that do not complete the courses within the designated timeframe will be suspended until such time as the training can be scheduled and completed. Managers will not be permitted to utilize employee until training is completed.
7. Employees with two or more occurrences will have progressive discipline applied up to and including termination as warranted.

Supervision

Effective Date: 01/01/2012
Revisions: 03/31/2015, 11/27/2018
Review: 04/25/2019

Summary:

Management staff at Cork Medical will direct, observe, and evaluate the job performance of new and experienced personnel.

Policy:

Supervisory and clinical/service staff demonstrates knowledge of organizational policy and procedure for ensuring delivery of care, services and products to clients.

Supervision of employees may be accomplished through

- direct one on one observation
- daily handling of job-related issues,
- documentation reviews, and
- review of work assignments

Supervision of new personnel shall include closer monitoring and more frequent supervision of performance than for employees with experience.

Supervisors will make themselves available to answer employee questions and to resolve any staff concerns. During the hours the office is closed, employees may contact the supervisor at home or by mobile communication device.

All supervisors have contact information for direct reports. The list will be reviewed and updated as needed. Employees receive contact information from supervisor at time of hire.

Performance Evaluation

Effective Date: 01/01/2012
Revisions: 02/26/2015, 02/21/2018
Review: 07/25/2019

Summary:

Cork Medical formally evaluates performance annually during the months of February/March for the previous January - December period.

Policy:

Each employee receives a formal evaluation and meeting with their immediate supervisor. Performance evaluations are based on the employee's job description and compliance with the company's policies and procedures.

A copy of the performance evaluation shall be reviewed by each individual and acknowledged by both the supervisor and the employee. The performance evaluation will be shared with the employee during a face-to-face conference when possible.

Contracted and Purchased Services

Effective Date: 01/01/2012
Revisions: 02/29/2016, 02/23/2018
Review: 10/16/2019

Summary:

Services that are either purchased from Cork Medical or sold to another entity, resulting in shared responsibility, will be governed by a written contract.

Policy:

Written contracts for these arrangements shall be on file at the corporate office. All contracts shall comply with best business practices and regulations where applicable.

The following services require a written contract between Cork Medical and the contracted entity:

1. Contract employees (i.e., any person or organization that is paid by the job or patient visit instead of hourly)
2. Personnel firms
3. Joint venture contracts

All Contracts should address, at a minimum, the following:

1. Name of the contractor
2. Type of services to be provided
3. Duration of the contract
4. Responsibilities of each organization
5. The manner in which services will be controlled, coordinated and evaluated by the primary organization
6. The procedures for payment for services furnished under contract
7. The amount of payment for services provided
8. Compliance with all Cork Medical's policies and procedures
9. Copies of liability insurance certificates, if applicable. If Cork Medical is responsible for providing liability insurance for a contracted individual, this must be noted in the contract.

Patient Record Documentation

Effective Date: 01/01/2012
Revisions: 01/26/2015, 11/26/2018
Review: 11/19/2019

Summary:

Cork Medical maintains files for patients who receive equipment, supplies, and/or services from the Company.

Policy:

Cork Medical stores patient data electronically in Salespilot and Brightree billing system. The records are assigned a specific category according to their position in the process. The statuses include: New, In Process, Ready to Deliver, Setup, and Cancelled. Along with the status, demographic information, payor source, products, and notes regarding the patient are recorded in the system as well.

Records contain the indicated items for equipment sold or rented. Client records document fulfillment of identified delivery personnel responsibilities.

Procedure:

Patient records are received via fax from the referral source and once reviewed and accepted are electronically saved in the patient record in Salespilot.

Each patient has their own file in Salespilot and is required to have the following content:

1. Identification and demographic data
2. Names of family/legal guardian and emergency contact
3. Referral source information
4. Insurance information
5. Diagnosis
6. Physician's orders and clinical documentation
7. Delivery paperwork (See Delivery Paperwork Policy)
8. Home assessment

Additional documentation such as insurance payments, explanation of benefits, denials, archived records as well as delivery information may be stored in the Brightree billing system.

Patient Record Management

Effective Date: 01/01/2012
Revisions: 04/08/2015, 11/26/2018
Reviewed: 04/25/2019

Summary:

Cork Medical protects each patient's privacy and records.

Policy:

Patient records are stored electronically in Salespilot and Brightree. Employees involved with the patient's order, service, financial claims and management staff have access to patient records. No employee may have access to the patient's record for purposes outside the company's business.

Procedure:

Electronic patient records are stored in a secure manner to maintain the integrity of the patient data. Each record is backed up to redundant systems at least nightly.

All electronic transmissions must include the following confidentiality statement prohibiting the disclosure of the contents to anyone except the person to whom it was sent.

"This communication and any files transmitted with it are confidential and intended solely for the use of the individual or entity to which they are addressed. If you are not the intended addressee, or the person responsible for delivering it to them, you may not copy, forward, disclose or otherwise use it or any part of it in any way. To do so may be unlawful. If you received this communication by mistake, please advise the sender immediately and destroy all copies of the original message."

Patient records are maintained for the current year plus seven years following the year services were provided. Records for minors will be retained at least 7 years past the age of majority. In the event the company ceases to exist, the President will hold the records.

Conditions for release of information are found in the HIPAA/Privacy Policy.

Data Breach Policy

Effective Date: 01/01/2012

Revisions: 01/23/2013

Review: 11/30/2018, 07/25/2019

Summary:

This policy is designed to assist in the security and safeguarding of Personal Information and/or Protected Health Information.

Policy:

Administrative, financial, client and personnel records are secured, retained and retrievable in accordance with a formal record retention policy that is in compliance with organizational policy and local, state and federal law.

Personal Information is defined as an individual's name (first name or first initial and last name), address, phone number, social security number, marital status, driver's license number, bank account information, credit/debit card information, income and credit history, tax return, and asset statement.

Protected Health Information is defined as information about an individual's health, health care, and payment for health care, if that information could be used to identify or does identify an individual.

Data Breach is defined as the intentional or unintentional release of Personal Information. A breach may involve a lost or stolen computer, smart phone, or documents. Leaving documents lying face up in a public area or sensitive material carelessly thrown in trash receptacles rather than shred bins are other examples.

Cork Medical responds to a reported or suspected data breach as required by law. Cork Medical has a process in place to prevent data breach of patient or employee information.

All employees are required to notify their supervisor of any possible or actual data breach immediately. If a data breach has occurred or is suspected, supervisors are required to notify the Compliance Officer and the IT Manager. In the event that a data breach has occurred, management will assist with the drafting and dissemination of appropriate notifications.

Procedure:

To safeguard against any potential risks, Cork Medical has taken the necessary steps to protect Personal Information by:

- All equipment is password protected (computers, laptop, phones)
- Virtual Private Network (VPN) – remote access through a secure connection
- Capability to wipe smart phones remotely
- Network security – firewall and spam filter
- Network passwords – password history, length, complexity requirements
- Voice Mail passwords – valid for 90 days
- Providing and requiring the use of secured shred bins for disposal of anything with personal information/identifying information into the shredding bin
- Employees are required to place all items in their personal workspace face down at the end of the business day

HIPAA/Privacy Policy

Effective Date: 01/01/2012

Review: 10/16/2019

Summary:

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

Cork Medical is required by law to maintain the privacy of certain health information about you, and to inform you of its practices with respect to the privacy of that information. This Notice of Privacy Practices is being provided to inform you of the ways that Cork Medical One may use the personal information it collects about you and how it may disclose that information. Federal and state laws require health care providers to protect the privacy of information about your health, your healthcare, and payment for your health care, if that information identifies you or could be used to identify you. The law permits us to use or disclose your protected health information only for certain specific purposes, unless you give us a written authorization permitting us to make other uses and disclosures. This notice describes the purposes for which we may use or disclose protected health information about you. The law also gives you certain rights with respect to your protected health information. This notice provides a summary of those rights.

USES AND DISCLOSURES FOR TREATMENT, PAYMENT AND HEALTH CARE OPERATIONS

Treatment - As it pertains to Cork Medical, treatment means providing to you home medical equipment and supplies as ordered by your physician. Treatment also includes coordination and consultation with your physician and other healthcare providers. As Cork Medical provides these services to you, information obtained during this process will be recorded in our records. Cork Medical may use this information, in coordination with your physician, to determine the best course of treatment for you.

Payment - We may use and disclose health information for activities required to obtain payment from you or your insurance carrier for the services provided to you by Cork Medical. These activities include eligibility determination, pre-certification, billing and collection activities, obtaining documentation required by your insurer, and when applicable, disclosure of limited information to consumer reporting agencies.

Health Care Operations - Health care operations include review of your protected health information by members of Cork Medical's professional staff to ensure compliance with all federal and state regulations. This information will then be utilized to continually improve the quality and effectiveness of the services provided to you by Cork Medical. Healthcare operations also include Cork Medical's business management and general administrative activities.

OTHER USES AND DISCLOSURES THAT DO NOT REQUIRE AUTHORIZATION

We may use or disclose protected health information when the use or disclosure is required by law.

We may use or disclose protected health information to avert a serious threat to your health or safety, or the health and safety of others.

We may use or disclose protected health information for certain public health activities, such as reporting certain communicable diseases, or reporting information to the Food and Drug Administration about treatments that are regulated by that agency.

We may disclose protected health information to a legally authorized government authority, such as a social service or protective services agency, if we reasonably believe you are a victim of abuse, neglect or domestic violence.

We may disclose protected health information to agencies authorized by law to conduct health oversight activities, such as licensing, inspections, inspections, and audits.

We may disclose protected health information in response to court orders or subpoenas, and for certain law enforcement purposes.

We may disclose protected health information to coroners, medical examiners and funeral directors to enable them to carry out their duties.

We may disclose protected health information to authorized government agencies when necessary for national security or intelligence purposes or for certain military and veteran's activities.

We may disclose health information to attorneys, accountants, and others acting on our behalf, provided they have signed written contracts agreeing to protect the confidentiality of the information.

Unless you object, we may disclose to a member of your family, other relative, or a close personal friend, or any other person identified by you, the protected health information directly relevant to that person's involvement with your health care or payment for your health care.

We may use your health information to contact you to provide information about treatment alternatives or other health-related benefits and services that may be of interest to you.

USES AND DISCLOSURES WITH YOUR AUTHORIZATION

We will obtain your authorization for any use or disclosure of your protected health information for purposes other than those summarized above. You may revoke your authorization at any time, except to the extent we have acted in reliance on the authorization, by sending a written notice of revocation to the address on the last page of this notice.

YOU'RE RIGHTS REGARDING YOUR PROTECTED HEALTH INFORMATION

You may request additional restrictions to the use or disclosure of your protected health information for treatment, payment or health care operations. However, we are not required to agree to the requested restrictions.

We normally contact you by telephone or mail at your home address. You may request that we contact you at some other address or telephone number, or by some other method, such as e-mail. We will accommodate reasonable requests.

You may inspect and obtain a copy of protected health information that is used to make decisions about your care or payment for your care. We may deny a request to inspect records only in a few limited circumstances. If you request copies of records, we may charge you a reasonable fee for the copies.

You have the right to request amendment of the protected health information we maintain about you. We may deny your request if we determine that the record is accurate and complete, or if we did not create the record, unless the creator of the record is no longer available, or if you do not have a right to access the record. If we deny your request, you have the right to submit a statement disagreeing with our decision and to have the statement attached to the record.

You may request an accounting of certain disclosures we have made of your protected health information after April 14, 2003. The accounting is not required to include disclosures for treatment, payment, or health care operations, disclosures to persons involved in your health care or payment, disclosures for notification purposes, or disclosures with your written authorization. You may receive one accounting free of charge within a twelve-month period. We may charge a reasonable fee for all subsequent requests during the same twelve-month period.

You have the right to obtain a paper copy of this notice upon request. We reserve the right to change the terms of this notice, and to make the new notice provisions effective for all protected health information that we maintain.

If you have questions or would like additional information, please write or call:

Cork Medical Inc.
Attn: Compliance Officer
8000 Castleway Drive
Indianapolis, Indiana 46250
(317) 849-2675

If you believe your rights have been violated, you may file a written complaint at the address above, or you may also file a complaint with the Secretary of Health and Human Services by writing or calling:

Office for Civil Rights
Health and Human Services
1961 Stout Street Room 1426
Denver, Colorado 80924
(303) 844-2024

Cork Medical Social Media Policy

Effective Date: 10/15/2018

Revisions: 11/02/2018,
11/19/2019

Policy:

Social Media are works of user-created video, audio, text or multimedia that are published and shared in an electronic environment, such as a blog, wiki, instant messaging, email, or video hosting site.

Social Media presents opportunities to engage Cork Medical employees, patients, and community, in conversation to improve people's everyday lives.

Our policy is that you, the employee, may use Social Media for personal use only during non-working time and in strict compliance with all other terms of this and other company policies.

Procedure:

Keep in mind that conduct that would be illegal or a violation of a Cork Medical policy in the “offline” world would still be illegal or a violation of the policy when it occurs online. While you are entitled to express your opinions and ideas, you have a responsibility not to violate Cork Medical policies or negatively affect the operations of the company. Violation of this policy may result in disciplinary action up to and including termination for employees

Following the policy will ensure that your actions reflect our core values “Energetic to Achieve, Hard Work with Balance, and Compassion” while exhibiting a level of professionalism that our customers expect and deserve. When online you are speaking in your personal capacity unless you have prior authorization from the Compliance and Marketing Departments to speak for Cork Medical, or hold such positions as President or CEO that are preapproved to speak for Cork Medical. This Policy requires adherence to the Social Media Participation Guidelines administered by Marketing and enforced by Compliance. Cork Medical reserves the right to restrict and monitor employee’s use of social media.

Social Media Participation Guidelines

What You Should Do:

1. Be smart. Be respectful. Be human.
2. Be authentic. When you post or comment in social media always state your name.
3. Be transparent. State that it is your opinion. Unless authorized to speak on behalf of Cork Medical you must state that the views expressed are your own.
 - If you mention an affiliation with Cork Medical in your social media account, such as in a bio or employment connection, you **MUST** include a disclaimer like: “Views and opinions are my own and do not reflect those of my company.”
4. Be careful. Protect what personal information you share online.
5. Be responsible and act ethically. When you are at work, your primary responsibility is the work of Cork Medical.

What You Should Never Disclose:

1. Confidential Cork Medical information: If you find yourself wondering whether you can talk about something you learned at work -- don't.
2. Patient information: You are prohibited from posting any content that is personal health information including patient images on any social media site.
3. Personnel Information: Do not refer to your co-workers in an abusive or harassing manner.
4. Legal Information: Do not disclose anything to do with a legal issue, legal case, or attorneys.

5. Materials that belong to someone else: Stick to posting your own creations. Do not share copyrighted publications, logos or other images that are trademarked. If you do use someone else's material, give them credit. In some cases you may also need their permission.

Social Media Best Practices

- Write in the first person. Where your connection to Cork Medical is apparent, make it clear that you are speaking for yourself and not on behalf of Cork Medical. In those circumstances, you should include this disclaimer: "The views expressed on this [blog; website] are my own and do not reflect the views of my employer." Consider adding this language in an "About me" section of your blog or social media profile.
- If you identify your affiliation to Cork Medical, your social media activities should be consistent with Cork Medical's high standards of professional conduct.
- If you communicate in the public internet about Cork Medical or Cork Medical - related matters, you must disclose your connection with Cork Medical.
- Be professional, use good judgment and be accurate and honest in your communications; errors, omissions or unprofessional language or behavior reflect poorly on Cork Medical, and may result in liability for you or Cork Medical. Be respectful and professional to fellow employees, business partners, competitors and patients.
- Cork Medical strongly discourages "friending" of patients on social media websites. Staff in patient care roles generally should not initiate or accept friend requests except in unusual circumstances such as the situation where an in-person friendship pre-dates the treatment relationship.
- Unless approved by Marketing, your social media name, handle and URL should not include Cork Medical's name or logo.

Contact the Marketing Department at marketing@corkmedical.com with questions.

PHI Shredding Policy

Effective Date: 01/20/2016
Revisions: 05/15/2018, 04/25/2019

Policy:

All Personal Health Information (PHI) documents and hard files containing patient information must be shredded after use. PHI should never be thrown away or kept for extended periods of time.

Procedure:

All PHI and patient files are required to be brought to the local office closest to the employee for proper disposal by shredding.

1. At a minimum of one time per month, the Sales Rep is required to bring in PHI and patient files not in use to the local office
2. The Sales Rep will place the PHI and patient files in the shredding bin

Patient Referral and Eligibility Guidelines

Effective Date: 01/01/2012
Revisions: 03/30/2015, 02/21/2018
Review: 07/25/2019

Summary:

Patient referrals require specific information, must be accepted by the appropriate personnel, and must meet eligibility requirements.

Policy:

Referrals may be received from the patient's physician, a hospital discharge planner, nurse, or social worker. A potential patient must meet the following eligibility requirements:

1. The patient needs a product that Cork Medical provides
2. The patient lives within the Company's defined geographic service area
 - a. The geographic service area is defined as a 200-mile radius from each Cork Medical location.
3. Payment for all equipment and services provided can be made via insurance and co-payment, check, cash or credit card.

Active Sales Representatives, Sales Managers, and the Patient Care Team may accept patient referrals. The following information is obtained when receiving a patient referral:

- Patient contact information
 - Phone, address, insurance information
- A written order from the prescriber

All orders are placed in the patient's file. Cork Medical will decline referrals or orders for equipment or services that are inconsistent with standard medical practice.

Unmet Needs

Effective Date: 01/01/2012
Revisions: 03/07/2016, 02/23/2018
Review: 10/16/2019

Policy:

All referrals or orders for services that are not provided by Cork Medical will be declined. Referrals that request orders and services that are not provided by Cork Medical will be notified. If Cork Medical is out of network with the patient's insurance, Cork Medical will attempt to refer the patient or referral source to another provider that is in network.

Performance Improvement and Quality Plans

Effective Date: 01/01/2012

Revisions: 07/14/2017, 11/30/2018

Review: 11/19/2019

Summary:

Each department measures, analyzes, and tracks quality indicators that enable the company to assess the quality of patient services and company operations.

Policy:

It is the policy of Cork Medical to develop, implement, and maintain an effective, on-going Performance Improvement and Quality plan. Performance improvement indicators used include:

- Reverse Quality

Results are reviewed quarterly during the compliance committee meeting. Recommendations are made for areas of special concern, and an action plan developed by department Directors and Managers.

Process:

Information from the above reports will be reduced to a quantitative measures allowing tracking and trending to enable the Compliance Committee to gauge performance.

Quarterly the Compliance Department will tabulate the Reverse Quality Scores and review the results with the Compliance Committee.

Review of data will be used to make decisions on changes in processes, or additional reporting required monitoring continued improvement.

Scores below 85 HR develops a performance plan with Manager.

Infection Control Policy

Effective Date: 01/01/2012

Revisions: 03/11/2015, 05/14/2018, 04/25/2019

Summary:

Cork Medical will conform to the acceptable standards of infection control for equipment and home health services to ensure the safety of patients and employees. Cork Medical has detailed procedures in place for Universal Precautions, Tuberculosis Infection Control, and Hepatitis B Infection Control.

Policy:

Each location will take appropriate measures to identify, prevent, and control infections. All employees will complete training about blood borne pathogens and infection control measures appropriate to the areas in which they will work. Online training will be completed annually for all employees.

The organization provides information and instruction to clients about infection control procedures related to the use of specific equipment and supplies.

Procedure:

New patient orders will be reviewed to determine if the patient has an infectious disease.

- Review – Insurance Review and Verification Teams

If a patient is suspected or known to have an infectious disease, the sales order/patient in Sales Pilot, will be updated with the information to alert staff that an infectious disease is present in the home.

- Code A = Airborne Disease
- Code B = Blood borne

The scheduler will check Sales Pilot for infectious disease, and advise technician:

- Code A = Airborne Disease
- Code B = Blood borne

Should the technicians want to know the specific disease, we can provide that information; however, it cannot be documented in writing on the paperwork, to protect the patient's privacy.

Cork Medical will provide all in-home care employees with Personal Protective Equipment (PPE).

Technicians will be equipped with a list of recommended PPE based on the transmission type of the infectious disease, and required to don the proper protective garments.

Patient infection control procedures include, but are not limited to, the following:

1. Wearing and changing gloves as necessary during patient care
2. Proper handling of infectious materials
3. Proper use of impervious containers for disposal of sharps
4. Proper hand washing
5. Covering nose and mouth when coughing or sneezing
6. Covering open sores or cuts on fingers or hands with clean bandages or gloves
7. Use of protective equipment including gloves, gowns, and masks when indicated

Environmental infection control procedures include, but are not limited to, the following:

1. Maintaining a clean work environment
2. Refrigerating food properly
3. Rinsing cans and bottles before disposal
4. Using assistive means to pick up broken glass
5. Washing garbage cans, dirty pails and trash cans with hot soapy water

6. Disposing of garbage properly
7. Keeping clean and dirty items separate
8. Keeping items off the floor and out of reach of children
9. Decontamination of equipment prior to servicing or shipping
10. Properly labeling equipment as clean or contaminated

To comply with industry best practices, Cork Medical will ensure that the infection control policy is complied with by:

1. Periodically evaluating all job responsibilities for potential risk.
2. Reviewing the policy's effectiveness at least annually and revising as necessary.
3. Evaluating incidents of exposure and revising policies and procedures as indicated.
4. Educating employees in the Infection Control Policy and any subsequent revisions upon employment, when changes occur and at least annually.
5. Monitoring compliance with the policy through on-site visits, performance evaluations, periodic review of personnel files, and records training.

Infectious Disease PPE Requirements				
Disease Codes	Delivery	Pick Up		
Code A (Airborne Transmission)	Gloves, Mask	Gloves, Mask		
Minimum Contact	Gloves, Mask	Gloves, Mask		
Maximum Contact	Gloves, Mask	Gloves, Mask		
Code B (Bloodborne Transmission)	Gloves	Gloves		
Minimum Contact	Gloves	Gloves		
Maximum Contact	Gloves, Gown	Gloves, Gown		
Minimum Contact	Delivering equipment which requires no physical contact with the patient			
Maximum Contact	Delivery or Pick-Up of equipment which requires contact with your person Examples: Bed Set Up, NPWT set up, ATP Evaluation, Bed pick up,			
PPE is a one time only use product, please throw away when pick-up or delivery completed				

Tuberculosis Infection Control Plan

Effective: 01/01/2012

Revised: 05/14/2018

Review: 07/25/2019

Summary:

It is the policy of Cork Medical to possess a written plan for Tuberculosis (TB) infection, which is based on the Centers of Disease Control & Prevention (CDC) guidelines for TB Exposure and prevention.

Policy:

Cork Medical's annual risk assessment classifies staff into risk categories. Supervisory responsibility for the TB Infection Control Program is the direct responsibility of the Compliance Team.

The CDC requires that an assessment of risk be performed. The location is responsible for risk assessments within their communities. It is the policy of Cork Medical to inform employees of their risk status based on their Job Risk Classification.

Job Risk Classifications are as follows:

- Very Low Risk – Corporate Office Staff , Patient Care Rep, Inside Sales
- Low Risk – Office Managers, Office Administrators
- Moderate Risk -Outside Sales Representative, Driver/Technicians, Area Managers and Clinical Staff

Procedure:

The TB Infection Control procedure is as follows:

1. Very Low Risk Employees
 - Employee education on tuberculosis transmission and policies and procedures related to tuberculosis prevention as a part of New Hire Employee Orientation and annually
 - Adherence to all infection control policies and procedures
2. Low Risk Employees
 - Employee education on tuberculosis transmission and policies and procedures related to tuberculosis prevention as a part of New Hire Employee Orientation and annually
 - 2 step TB testing per CDC recommendation (Reference CDC guidelines on 2 step process)
 - Yearly questionnaire form completed
 - Adherence to all infection control policies and procedures
3. Moderate Risk Employees
 - Employee education on tuberculosis transmission and policies and procedures related to tuberculosis prevention as a part of New Hire Employee Orientation and annually
 - 2 step TB testing per CDC recommendation (Reference CDC guidelines on 2 step process)
 - Yearly questionnaire form completed
 - Adherence to all infection control policies and procedures

Action plan for a positive test or yes answered on yearly questionnaire:

1. Positive test
 - Chest x-ray is completed by employee
 - If chest x-ray is negative, employee completes a yearly questionnaire form
 - Chest x-ray must be completed every 5 years
2. If yes is answered on yearly questionnaire
 - Test is initiated
 - If test is negative, go back to the yearly questionnaire form
 - If test is positive, follow the positive test protocol above

Action plan for a positive chest x-ray:

1. Positive chest x-ray

- Employee is referred to employee physician for treatment
- Treating physician will treat the employee
- Employee may not return to work until cleared by treating physician

Hepatitis B Infection Control

Effective Date: 01/01/2012
Revisions: 03/07/2016, 05/14/2018
Review: 10/16/2019

Summary:

Cork Medical exercises practices which inhibit the spread of bacteria and infectious disease.

Policy:

Cork Medical employees are instructed to use Universal Precautions to prevent exposure to Hepatitis B, and other infectious agents. All employees will complete training about Hepatitis B and infection control measures appropriate. Online training will be completed annually for all employees.

Cork Medical offers Hepatitis B vaccinations to employee's subject to exposure, (Patient facing employees).

Procedure:

If exposure to Hepatitis B occurs, employees must:

1. Immediately upon exposure, flush the area of the body that was exposed with warm water, and vigorously wash all areas with soap and water.
2. Notify supervisor. The supervisor will report the exposure incident to the Compliance Officer and Human Resources (reports will remain confidential) who will start follow up procedures.
3. Go to a walk in clinic, or emergency room immediately.
4. Follow the instructions provided by the physician.
5. If a HB Vaccination series has not been administered, series must be started within 24 hours.

Infectious Disease Reporting

Effective Date: 01/01/2012
Revisions: 02/15/2015, 05/14/2018
Review: 01/06/2020

Summary:

Cork Medical maintains a log of reportable nosocomial infectious diseases in its patients.

Policy:

Quarterly, the Infection Control Log will be reviewed for trends and appropriate follow-up action. If trends are identified, or suspected that the incident of infectious diseases is attributed to Company equipment, and/or employee transmission, immediate investigative action will be initiated. The results of such investigative action are to be documented with a copy sent to the Compliance Department.

If Cork Medical is informed of a previously unreported communicable disease, it will be reported according to state guidelines.

DISEASES CONSIDERED REPORTABLE:

- AIDS
- Amoebiasis
- Campylobacter
- Chancroid
- Chickenpox (Varicella)
- Chlamydia
- Cholera
- Influenza
- Leprosy (Hansen's Disease)
- Leptospirosis
- Malaria
- Measles (Rubella)
- Meningitis (Aseptic)
- Meningitis (Bacterial)
- Mumps
- Pertussis (whooping cough)
- Plague
- Poliomyelitis
- Psittacosis (Ornithosis)
- Rabies
- Reyes Syndrome
- Rubella (German Measles)
- Salmonella Infections
- Shigellosis
- Smallpox
- Syphilis
- Tetanus
- Trichinosis
- Tuberculosis

Safety Management

Effective Date: 01/01/2012
Revisions: 03/28/2016, 11/30/2018
Review: 04/25/2019

Summary:

Safety is the responsibility of each Cork Medical employee at all times in the workplace and when in the patient's home.

Policy:

The health and safety of the Cork Medical organization's employees is reviewed, promoted, and maintained. Cork Medical encourages a safe working environment and provides training in safe practices. Employees will receive instruction in safety management during orientation and annually.

Procedure:

Safety Management topics include, but are not limited to:

1. Body mechanics
2. Home safety
3. Employee safety
4. Fire safety

Each employee will receive instruction in the following safety topics during orientation and during annual safety training:

Body Mechanics:

1. Proper lifting techniques to reduce back strain
2. Use of back supports
3. How to prevent strains and sprains
4. How to prevent Carpal Tunnel Syndrome

Home Safety:

1. Each employee is required to read "Home Safety" in the patient handout that contains home safety information.
2. All patients will be given "Home Safety", the patient handout that contains home safety information, at start of service. The patient must sign that they have received a copy of this document.

Employee Safety:

General safety instructions for all employees:

1. Use common walkways in buildings; avoid isolated stairs
2. Always knock or ring the bell before entering a patient's home
3. If relatives or neighbors become a safety problem, make joint visits, arrange for an escort, or schedule visits when the unsafe individuals are not in the vicinity
4. Supervisors will evaluate the appropriateness of continuing this case

When traveling by personal or company vehicle:

1. Keep the vehicle in good working order with plenty of fuel
2. Store extra items in vehicle, appropriate to the current season, which may be needed if stranded (e.g., blankets, extra clothes, water, flashlights, etc.)
3. Keep snacks in the glove compartment (e.g., granola bars, crackers, etc.)
4. Turn on emergency flashers and wait for the police if you have mechanical trouble
5. Keep your vehicle locked when parked or driving. Keep windows rolled up if possible

6. Know your route. If you get lost, look for a safe place to get additional directions or to view a map.
7. When loading or unloading heavy equipment, always use the parking brake to prevent potential serious injury.

When an incident occurs:

1. Complete an incident report within 24 hours to document when personal safety was threatened while working
2. All incidents must be report to the immediate supervisor and Compliance Officer

Fire Safety:

Each employee must be aware of the fire safety and evacuation plan and be prepared to function accordingly. The fire safety and evacuation plan will be reviewed at least annually or after each emergency which required activation of the plan.

The Fire Safety and Evacuation Plans are specific to each location. Each includes an emergency contact number and the offsite meeting location.

Emergency Preparedness

Effective Date: 01/01/2012
Revisions: 03/28/2016, 11/30/2018
Review: 07/25/2019

Summary:

Cork Medical prepares for natural and manmade disasters.

Policy:

Each Cork Medical location shall have an individual emergency preparedness evacuation plan and action items posted and on file at the local office.

Disasters and emergencies that justify implementation of the Emergency Preparedness Plan include hurricanes, tornadoes with widespread destruction, earthquakes, electrical blackouts, floods, and other emergencies that may cause an interruption of services.

Procedure:

Fire: Call 911 and describe the location and extent of fire. Do not use elevators, internal staircases, do not go to the roof, and do not break windows. Windows should only be broken as a last resort if the smoke becomes too dense. Breaking a window will feed a fire.

Designated locations outside of the building have been identified for a central meeting place. After leaving the building, go directly to the assigned central meeting place outside the building. A headcount will be taken and any missing persons will be identified by the direct supervisor. If anyone is not accounted for, the Manager will alert the fire department. It is very important that you report to the site assigned and not go anywhere else.

Become familiar with exit routes that are displayed in the office. You will find the fire extinguishers located in the office and warehouse. Familiarize yourself with these locations. Become familiar with where the exit doors are located in relation to your office/desk. If the floor becomes smoke-filled, you may have to crawl to the nearest exit. Follow the Office Manager's instructions.

Most important, keep calm and follow the instructions you receive by the Manager and/or rescue workers.

Hurricane: If a hurricane is in the area, employees should listen to the radio, TV, or internet for information. Utilities should be turned off if instructed to do so. Stay indoors during the hurricane and away from window and glass doors. Close all interior doors; secure and brace external doors. Take refuge in a small interior room, closet or hallway on the lowest level and lie on the floor under a table or another sturdy object.

Tornado Warning: If a funnel cloud is spotted or the tornado sirens are sounding, there is a tornado threat. A warning is notification of possible immediate danger. A watch is notification of the possibility of severe conditions, but no sighting of a funnel cloud in the area.

Stay away from windows. Lower your window blinds to resist broken glass that may occur. If there is an announcement to "take cover", leave your desk, close any office doors, and proceed to internal rooms/offices. Remain under cover until the Manager gives the "all clear" message.

Earthquake: Upon shaking, employees should drop to the ground; take cover by getting under a sturdy piece of furniture; and hold on until the shaking stops and the Manager gives the "all clear". If there is not a table or desk near, cover your face and head with your arms and crouch in an inside corner of the building. The key is to minimize movements to a few steps to a nearby safe place.

In the event of an earthquake, it is the Manager's responsibility to contact the corporate office. Most essential business functions, including communication, can be carried out through the corporate office.

Bomb Threats: If you see a suspicious package somewhere inside or outside of the building, notify the police immediately. If there is a bomb threat received, the Manager will notify local authorities and await further instruction. A full evacuation will occur if a suspicious object has been identified or if instructed by the police.

Power Outage: The Manager will notify employees of a power outage and will communicate the expected duration of the outage and whether this is a need to evacuate the building. If it is necessary to evacuate the building, all persons will leave via the stairwells.

Nuclear Blast: A nuclear blast is an explosion with intense light and heat, a damaging pressure wave and widespread radioactive material that can contaminate the air, water and ground surface. The following procedures should be implemented:

- Take cover immediately, below ground if possible
- Quickly assess the situation. Determine if you can get out of the building or if it would be better to stay inside the building.

Biological Threat: A biological attack is a deliberate release of germs or other biological substances that can make you sick. Many agents must be inhaled, enter through a cut in the skin, or be eaten to make you sick.

If you become aware of an unusual and suspicious release of an unknown substance nearby, quickly get away from the area, cover your mouth and nose with layers of fabric or an N95 mask from the warehouse (if available) that can filter the air but still allow breathing. If that is not available, use several layers of tissue or paper towels.

In the event of a biological attack, public health officials may not immediately be able to provide information on what you should do. It will take time to determine exactly what the illness is, how it should be treated, and who is in danger. However, you should watch television, listen to the radio or check the Internet for official news to include the following:

- Are you in the group or area authorities consider in danger?
- What are the signs and symptoms of the disease?
- Are medications or vaccines being distributed? If so, where and who should get them?
- Where should you seek emergency medical care if you become sick?

Chemical Threat: A chemical attack is the deliberate release of a toxic gas, liquid or solid, that can poison people and the environment. Signs of a chemical threat are watering eyes, twitching, choking, having trouble breathing or losing coordination. These procedures should be followed:

- If the chemical is inside the building, get out of the building without passing through contaminated area if possible.

- If the chemical is outside the building, follow the plan for Shelter-in-Place (below).
- If you are outside, determine the fastest escape from the chemical. Consider if you can leave the area or if you need “Shelter-in-Place,” get into a building as fast as possible before it is locked off.
- If you think you have been exposed to a chemical, strip immediately and wash with soap and water, being sure not to scrub the chemical into your skin. Seek medical attention as soon as possible.

Shelter-in-Place: If any of the above situations requires a Shelter-in-Place protective action plan, it will be put into effect in the building, which means you will be temporarily separated from a hazardous outdoor atmosphere. The following procedures should be initiated immediately:

The Manager will shut down all heating, ventilation and air conditioning system as well as exhaust systems.

The Manager will lock all entry doors including garage access doors and disable all elevators (if any) after ensuring that no one is in them. Signs will be posted at all entrances stating that the building is in a “Shelter-in-Place” emergency.

No one will be permitted to leave the building.

Employees will find an internal space in the office/warehouse that is away from exterior windows. You are to remain in this space until the Manager announces the “all clear”. Doors to perimeter office should be closed and towels placed under those doors as well as the door to the shelter space you occupy.

Utilities Management

Effective Date: 01/01/2012
Revisions: 03/28/2016, 11/27/2018
Review: 10/16/2019

Summary:

Cork Medical maintains adequate systems to ensure patient care is provided.

Policy:

Cork Medical provides the appropriate maintenance and service for its utility systems as required. Backup systems are in place to protect electronics in the event of a power failure.

Utility backup systems include:

1. Battery back-up of the computer server to avoid loss of data
2. Battery back-up of exit signs
3. Battery-powered smoke detectors in addition to any electrically powered detectors
4. Battery back-up of alarm systems

Cell phones to back up the telephone system

Fire Safety

Effective Date: 01/01/2012

Revisions: 03/28/2016, 05/03/2018, 10/16/2019

Review: 11/19/2019

Summary:

Cork Medical maintains smoke detectors, smoke alarms and fire extinguishers in accordance with National Fire Protection Agency, Life Safety Code, and local fire codes. Cork Medical will cooperate with all local Fire Marshall Inspections and adhere to all recommendations.

Policy:

Cork Medical conducts annual Fire Safety training for all employees. Training includes fire prevention, what to do in case of fire, and fire drills.

Procedure:

Fire Extinguishers

Office and Warehouse fire extinguishers are inspected annually by a contracted fire safety company, selected by accounting, and are affixed with a label that states the last inspection date. Fire extinguishers are placed in all areas recommended by the local Fire Marshall.

- Area Mgr. or their designee inspect Fire Extinguishers monthly, initial and date
Confirming ready for use
- To replace an Office or Warehouse fire extinguisher – Notify accounting via email or call, Accounting will place the order for the new unit

Vehicle Fire Extinguishers are inspected monthly by Area Mgr. or their designee initialed and dated confirming ready for use. Vehicle Fire Extinguishers may be purchased when needed via office purchasing program.

Fire Exits

Fire Exits and Escape Routes are identified throughout each office. Fire exits and escape routes are always free from barriers or obstructions. Each exterior exit is marked by an illuminated exit sign with battery backup lighting.

- Area Mgr. or designee tests Emergency lighting and exit lighting monthly
- Malfunctioning emergency lighting or exit lighting is reported to accounting for review and approval of repair or replacement.

Smoking

Any form of smoking is prohibited in all Cork Medical buildings and delivery vehicles. No Smoking signs are posted in patient care/service area, each hallway, each utility area, and each warehouse/storage area. No Smoking signs will also be posted in any area that oxygen is stored.

Additional smoking restrictions are enforced for each location based on State and Federal requirements.

Fire Drill

All locations of Cork Medical shall conduct an emergency drill at least annually, Area Mgrs., or their designee are responsible for Branch and Warehouse locations, and Safety Officer is responsible for Executive/Corporate locations. The drill will be documented on the Fire/Emergency Drill Report form. Cork Medical staff members will receive an annual in-service education program on Fire Safety.

Hazardous Waste Management

Effective Date: 01/01/2012

Revision: 03/28/2015,

11/27/2018

Review: 04/25/2019

Summary:

Cork Medical identifies items contaminated with infectious disease.

Policy:

Hazardous waste includes, but is not limited to, discarded sharps, human blood, human blood products, laboratory waste, and body fluids.

Non-absorbent disposable devices which retain blood adhering to inner surfaces after use such as IV tubing and catheters or articles which have been contaminated with blood, body fluids or blood contaminated secretions and/or excretions that have not been sterilized or disinfected by an approved method.

Items contaminated with Biomedical/Biohazard waste are handled according to the applicable rules and regulations of federal and state agencies.

Procedure:

Biomedical/ Biohazard waste is identified and segregated from other waste.

All non-sharp Biomedical/Biohazard waste will be disposed of directly into red bags or identified with the Biohazard symbol.

All employees who handle Biomedical/Biohazard waste must wear personal protective equipment.

When filled, red bags will be sealed and labeled properly. Bagged Biomedical/Biohazard waste prepared for off-site transport must be enclosed in a rigid type container that conforms to the construction requirements as defined by DOT regulations (DOT 178.205). Disposal is arranged through a contracted off-site waste disposal company.

Biomedical/Biohazard waste returned to the office/warehouse for disposal must be labeled appropriately and stored in a separate designated area for such waste.

All containers will be labeled with their contents and used/stored as recommended by the manufacturer. The following materials have been designated as hazardous material and required specialized disposal techniques:

- acetaldehyde
- acetone
- acetylene
- adhesives
- ammonia
- ammonium picrate
- antifreeze compound
- benzene
- brake fluid
- butane or butane mixtures
- butanol
- camphor oil
- carbon remover
- cement (rubber, wallboard, etc.)
- chlorine
- disinfectants
- ethyl alcohol
- film drugs
- formaldehyde solutions
- gas oil
- gasoline

- hydrogen bromide
- hydrogen fluoride
- hydrogen sulfide
- isobetylene
- kerosene
- lighter fluid
- mercury fulminant
- motor fuel
- neon
- nitro urea
- nitrogen
- nitrous oxide
- oxygen
- paint or varnish dryers
- paints, enamels, lacquers, stains, shellac petroleum oil
- propylene
- rust preventive coating
- surface flares made with hydrogen chloride
- trinitrobenzenosulfonic acid
- zirconium picramic

Hazard Communication

Effective Date: 01/01/2012
Revisions: 04/07/2015, 11/26/2018
Review: 07/25/2019

Summary:

Cork Medical provides communication of hazards for the protection of employees. Safety Data Sheets are readily available to all employees on the Compliance page of SharePoint. SDS provide current information and protective measures for chemical health hazards present in the workplace including use of the appropriate PPE, and proper use, storage, and disposal of hazardous chemicals.

Policy:

The Compliance Officer will provide current Safety Data Sheets on routine hazardous chemicals used in the workplace. An SDS will be required at each physical office site in order to be readily available to employees and regulating agencies. Each Area Manager is responsible for maintaining the site specific SDS binder.

Procedure:

Employees will be provided with information and training on hazardous chemicals in the workplace during initial orientation and annually. Employee training will include:

1. Hazard communication
2. SDS requirements
3. Emergency procedures

Incident Reporting

Effective Date: 01/01/2012

Revisions: 03/28/2016, 06/04/2018, 7/25/2019

Summary:

Cork Medical tracks and monitors the occurrence of incidents related to its business operations.

Policy:

Incident reports are required for any event meeting the description of an Incident. An incident (defined for this policy) is any event that has caused or has the potential to cause harm.

Examples:

Patient or Employee injury

An Adverse event (related to the care provided by Cork Medical)

- Injuries

- Accidents

- Hospitalizations

- Unexpected death not resulting from client's medical condition

- Loss of body part

- Loss of body function

Compliance Violation

Threatening situation

Vehicular accidents (employee on the job)

This policy is designed to assist employees and patients through the incident reporting process. All incidents must be reported to the Compliance Officer immediately.

Procedure:

- Any and all incidents are documented on the incident report form
- The employee that witnesses an incident or is contacted about an incident will complete their portion of the incident report form
- All incident report forms will be given to the Compliance Officer to review immediately
- Compliance to forward any employee related incidents to Human Resources upon receipt
- Managers will review all incident report forms upon receipt

Future steps will be determined as necessary

Home Medical Equipment Scope of Services

Effective: 01/01/2012
Revision: 01/19/2015, 05/15/2018, 8/12/2019
Review: 11/19/2019

Summary:

Cork Medical provides Durable Medical Equipment and supplies for patients. Cork Medical publishes a patient handbook that is distributed to patients that details the types of equipment offered.

Policy:

Cork Medical provides the following equipment:

- Negative Pressure Wound Therapy
- Hospital Beds
- Non-Powered Pressure Reducing Support Surfaces
- Powered Pressure Reducing Support Surfaces
- Trapeze Bars
- Patient Lifts
- Cushions
- Overlays
- Wound Dressings

The company guides patients through the unique requirements of each insurance plan. The cost and patient responsibility portion are communicated to the patient in advance of supplying equipment.

Items requiring a physician prescription will not be dispensed without a prescription.

Cork Medical will secure the doctor's signature on the appropriate form for the equipment or services ordered by the physician as required by the payer source.

Vendor and Product Review Process

Effective Date: 02/06/2017

Review Date: 11/30/2018, 04/25/2019

Summary:

This policy defines Cork Medical's process for the discovery and merging of new products and vendors into the current line of product offerings.

Policy:

- 1. Identify need for Product Development/Product Advancement**
 - a. Cork Medical will continue to stay updated on the latest in product development. New or current product need may be identified through industry events, publications, referral sources, etc.
- 2. Meet with Vendor for product demonstration**
 - a. upon identifying need for a product, Cork Medical will invite the vendor for a product demonstration and discuss key areas including materials, warranty, repairs, documentation, competitors, etc.
- 3. Pricing and terms negotiation**
 - a. The company will negotiate pricing and payment terms as necessary.
- 4. Product Approval**
 - a. Upon negotiation of the details, product and pricing will be brought before the President and/or CEO for review and approval.
- 5. Review product and documentation requirements with staff –**
 - a. Once approved, staff will be introduced to the product, specifications, insurance guidelines, etc.
- 6. Implementation**
 - a. The Sales Staff will be given an implementation date to announce with patient and referral sources.

After Hours Response

Effective Date: 01/01/2012

Revisions: 01/19/2015, 11/26/2018, 10/16/2019

Summary:

Cork Medical does not provide life sustaining equipment, therefore does not maintain an after-hours response service. In the event of an emergency the patient should contact 911.

Policy:

Cork Medical must be responsive to the needs and requests of our patients. Cork Medical provides a 24 hour service line

Procedure:

The service department operates Monday through Friday 8:00am – 6:00pm EST. Calls after stated hours, are received by answering service. Answering service dispatches via email or an app based application to service email or to on call technician or clinician by defined policies and protocols.

Most often the primary means of contact from our patients is by calling into our Service Department. Patients may also place a service request in by visiting Cork Medical's website.

Plan of Service

Effective Date: 01/01/2012
Revisions: 06/11/2016, 02/21/2018
Review: 10/16/2019

Summary:

Cork Medical provides equipment based on medical necessity and authorization from the patient's prescribing physician.

Policy:

To begin the process, the patient must have a face-to-face evaluation by their physician in order to determine eligibility.

The following will constitute for the plan of service:

1. Physician's orders
2. Patient Referral form
3. Patient rental/sales contract
4. Completed home assessment
5. Patient visit report
6. Patient notes

The plan of service will be revised as needed when:

- The patient requires additional equipment or supplies
- The patient requires a change in equipment type
- The patient's equipment must be changed because of repair
- The patient's equipment must be changed due to preventive maintenance requirements of the manufacturer.
- The patient receives a home visit for any reason.

All changes in a patient's plan of service will be notated in the Company's databases.

Patient Education

Effective Date: 01/01/2012
Revisions: 04/01/2015, 05/15/2018

Summary:

Cork Medical provides education and product information to all patients and their caregivers during the initial set-up of the equipment at the patient's home.

Policy:

Patients are instructed by qualified personnel at a level understandable to the particular patient. Patient knowledge and ability to perform safety-related procedures will be monitored during delivery.

Education will include patient instruction including verbal and/or written instructions, demonstrations, and return demonstrations.

The following information will be covered:

1. Patient Bill of Rights and Responsibilities
2. Supplier Standards
3. Home Safety for Medical Care
4. HIPAA Notice of Privacy Practices
5. Emergency Planning
6. Advance Directives
7. Making Decisions about Your Health Care
8. Financial responsibilities
9. Physician's orders if appropriate
10. Plan of Service
11. Equipment/Supply description, operation and accessory use
12. Precautions/safety
13. Troubleshooting (for HME)
14. Maintenance/cleaning (for HME)
15. Warranty information
16. Maintenance of equipment after warranty expiration
17. Company Contact information
18. How to file a complaint

Patients' education and training is documented in the patient record. Patient or caregiver(s) signatures on the Patient Service Agreement shall constitute evidence that the patient has received instruction in the patient's financial responsibilities. Patient or caregiver(s) signatures on the Equipment Management Assessment and Plan of Service Form shall constitute evidence that the patient has received a copy of Patient Bill of Rights and Responsibilities, Medicare Supplier Standards, Emergency Preparedness and has received instruction in equipment use and maintenance, back-up systems and troubleshooting procedures and medical/surgical supply use, if applicable.

Patient Transfer of Discharge

Effective Date: 01/01/2012
Revisions: 03/28/2016, 11/26/2018
Review: 04/25/2019

Summary:

Cork Medical seeks to provide for the needs of its patients. Should a patient need or desire to be transferred Cork Medical will provide any needed assistance.

Policy:

Cork Medical will transfer an active patient to another company/provider;

- if the company cannot meet the patient's needs,
- the patient moves outside the company's geographic area
- if the patient changes to an insurance that the company cannot bill
- at patient request

Procedure:

Non-Routine patient transfers and discharges will be noted in the patient's account notes. The transfer summary will include:

1. The date the patient is transferred/discharged
2. The company the patient is transferred to (if known)
3. The reason for the transfer/discharge
4. The status of the patient at the time of transfer/discharge

Cork Medical will discharge an active patient if:

1. The patient's condition improves and his or her physician discontinues (D/C's) the service.
2. The patient stops using the product for any reason and signs an Against Medical Advice (AMA) Form if the patient's physician will not write a D/C order.
3. The patient expires.

Equipment Cleaning and Testing

Effective Date: 01/01/2012

Revisions: 03/28/2016, 05/22/2018, 10/16/2019

Review: 07/25/2019

Summary:

Cork Medical ensures that all equipment is in correct working condition and clean prior to being supplied to any patient.

Policy:

Equipment is routinely tested for safety and proper operation according to the manufacturer's guidelines. Personnel responsible for testing equipment are to be qualified by in-house training provided by the Area Manager. Documentation of training must be kept in the employee's personnel file.

Equipment cleaning and testing is documented in the warehouse Operational Verification Procedure (OVP) log. Cleaning of the equipment will be performed with a germicidal cleaning agent according to the manufacturer recommendations.

Properly functioning, fully assembled equipment is placed in the "Clean/Patient Ready" section of the warehouse. The clean equipment requires a clear plastic bag to be placed over it and a tag with technician initials and date cleaned.

Equipment pending repair is placed in the Quarantine Used section with a clear plastic bag placed over it and a tag indicating date the item was placed in Quarantine.

New equipment waiting for accessories is placed in the Quarantine New section of the warehouse with a clear plastic bag placed over it and a tag indicating date the item was placed in Quarantine.

Clean/Patient Ready area may consist of subsections for Demo, Loaner, New, or Used equipment.

Returned mattresses are disinfected with an anti-germicidal cleaning agent and anti-bedbug agent, and stored covered

Procedure:

1. The warehouse must designate clean and dirty areas for equipment brought in and stored. This may be done by designating separate areas as “dirty” and “patient ready” areas and by clearly marking these areas with signs and colored tape. There will be warehouse cleaning area designed with sufficient space for equipment needs and marked off with Orange tape and with signs on the wall above the respective area. Areas will be labeled “Dirty Area”, “Tested”, “Quarantine”, Clean/Patient ready”. These areas must be clearly separated and marked off with colored tape. Traffic from the “Dirty Area” should not cross the “Clean Area”.
2. All dirty equipment will be transported to the “Dirty Area” for cleaning. No equipment will be removed for use or placed on clean area shelving until cleaning and testing are successfully completed.
3. Location personnel will always wear gloves and use other appropriate protective attire when cleaning equipment.
4. All equipment must be cleaned and disinfected with a chemical germicide.
5. After equipment is cleaned, it will be tested by manufacturer’s operational verification procedure (OVP) and logged in the OVP log. If the equipment fails the OVP or is due for routine preventive maintenance, it will be transferred the Quarantine area and tagged to reflect the status.
6. Equipment passing OVP will be placed in the “patient ready” section of the warehouse.
7. The warehouse must be kept in a good state of repair and cleanliness and must be environmentally controlled. The area will be surveyed physically for removal of recalled items, obsolete equipment, and any expired items. Stock will be rotated so that old is used first.
8. Cleaned, tested small items may be placed on a shelf in the “patient ready” sections of the warehouse. Items can be clear bagged or covered with a clean, impervious material for transport, and placed in the clean area of the vehicle.
9. Returned mattresses are disinfected with an anti-germicide cleaning agent and anti-bed bug agent. Mattresses will be checked for rips and tears and covered and stored off the ground.
10. Mattresses or soft goods that have visible infestation of bugs are not to be processed and disposed of at the patient residence.

Equipment Setup and Delivery

Effective Date: 01/01/2012
Revisions: 05/31/2015, 11/27/2018
Review: 10/16/2019

Summary:

Cork Medical ensures that patients receive equipment and services appropriate to their needs in a timely manner.

Policy:

Delivery, set-up of equipment and supplies is provided in a timely manner agreed upon by the client, caregiver, physician, and HME organization. Service is initiated based on client needs.

Employees will demonstrate respect for the patients and their property, and possess knowledge of the equipment provided. Equipment will be set up in a safe, efficient, and professional manner. The proper operation of the equipment will be assured before releasing for patient use.

Procedure:

The following procedure is to be followed for patient set-up:

1. Confirm physician's order for type of equipment, special training, and initial assessment.
2. Ascertain any teaching or special needs from physician/hospital staff, if applicable.
3. Contact patient and/or responsible person and arrange time for set-up visit.
4. Secure required equipment and supplies.
5. Secure required patient set-up forms to include:
 - a. Delivery Packet
 - b. Patient Handbook
 - c. Home Assessment
 - d. Other paperwork pertinent to equipment/service being provided.
6. Greet Patient or Family politely and explain purpose of your visit
7. By means of inspection and discussion, assist the patient and/or family in determining a suitable location of the equipment that promotes ease of use and safety. Consider degree of ambulation, safety factors, room size, etc.
8. Unload equipment. Take special care to avoid injury to patient, self, furniture, environment, and equipment.
9. Check that a tag is present on rental equipment that contains the name of the Company and phone number. Place a tag on the equipment if not present.
10. Instruct the patient or responsible caregiver regarding use of equipment, including cleaning, safety, and troubleshooting, and document activities in the Equipment Management Admission Assessment and Plan of Service. Provide written instructions and educational materials to the patient, as appropriate, and have the patient and/or caregiver(s) demonstrate ability to operate the system. Complete the appropriate equipment training checklist(s) and obtain the patient's or caregiver's signature on the form(s).
11. Demonstrate respect for the patient by assuring privacy as appropriate and address the patient in a respectful, professional manner. Personnel will prevent exposure of patients and will seek the patient's permission to instruct on care of a personal nature if others are in the room.
12. Assess the status of the patient and ability to properly use the equipment and record data on the patient set-up form.
13. Complete the Assessment and Plan of Service.
14. Solicit questions. Ensure that the patient or caregiver(s) understands equipment use, safety procedures, and troubleshooting guidelines. Instruct patient where to call in the event of equipment problems, when needing medical supplies, and when medical problems are encountered.
15. Explain policy regarding callbacks and follow-up visits (depending upon equipment received).
16. Complete the Admission packet and contract, making certain to explain the following:

1. Proper use and Care of the Equipment
 2. How to Contact Cork Medical for Service
 3. Financial Responsibility
 4. Patient Handbook
 - a. Patient Bill of Rights and Responsibilities
 - b. Supplier Standards
 - c. How to Make Your Home Safe for Medical Care
 - d. HIPAA Notice of Privacy Practices
 - e. Advance Directives
 - f. Warranty information (for sale equipment only)
 - g. Maintenance of equipment after warranty expiration (for sale equipment only)
 17. Have patient or responsible party sign the appropriate forms/tablet and any financial liability forms required.
- Complete other documentation as required.

Home Safety Education

Effective Date: 01/01/2012
Revisions: 05/15/2015, 05/03/2018
Review: 11/19/2019

Summary:

Cork Medical educates patients in basic home safety.

Policy:

Cork Medical promotes patient safety thru home safety assessments, risk identification, education, and aids to assist its patients in maintaining a safe environment.

Procedure:

- Cork Medical completes a home safety assessment to identify areas of risk within the home.
 - Patients will be asked at set-up to provide information about the safety of their residence.
 - At the first home visit the home will be assessed and the patient or caregiver(s) informed of any hazards including fall risk, and suggest corrective measures, as appropriate.
 - This information is to be documented in the patient's medical record on the Assessment and Plan of Service Form.
1. Upon admission to service Home Safety Information is provided to the patient in the Patient Handbook, including:
 - Fire Safety and Prevention
 - Electrical Safety
 - Safety in the Bathroom, Bedroom, and Kitchen
 - Getting around safely

Equipment Maintenance and Repair

Effective Date: 01/01/2012

Revisions: 05/15/2015, 11/30/2018, 07/25/2019

Summary:

Equipment and supplies provided to clients are clean, safe, and in good working order.

Policy:

Cork Medical ensures that all rental equipment is maintained in safe working order and will have preventive maintenance performed in accordance with the manufacturer's recommendations. If no manufacturer's guidelines exist, maintenance will be performed when equipment is returned to the office location from patient use or when contacted by the patient.

Process:

Patients may be supplied with replacement equipment while repairs are being made on rental equipment if the inventory is available. Replacement equipment will also be offered, if available, while customer-owned equipment is being repaired. A history of maintenance and repairs will be kept up to a minimum of 7 years.

The maintenance history should contain the following information:

- Manufacturer/Model Serial Number
- Documentation of preventive maintenance (PM) per manufacturer guidelines.
- Cleaning of equipment between patients.
- Operational Verification Procedure (OVP) performed between patients and per manufacturer's guidelines.
- Repair of equipment when failing OVP.

All defective equipment shall be labeled as such and will be isolated from functional equipment. Cork Technicians will receive thorough training on the repair of equipment for which they are responsible. Persons without such training will not be permitted to attempt repairs. Manufacturer certified training should be obtained whenever possible. Written evidence of all training (whether by manufacturer or in-house) will be maintained in the personnel file and in the designated repair area.

Cork Medical will utilize three options for equipment repairs:

1. In-house repairs - this option is typically the most cost-effective and should be utilized whenever feasible
2. Factory repair service - this service is usually less expensive than an independent repair service, but tends to take longer
3. Independent outside repair service - biomedical companies used by the office location for repair of the equipment must be authorized by the manufacturer to perform such services

Equipment will not be modified without approval from a Director, and specific written approval from the manufacturer. Equipment Maintenance Forms will be kept on all equipment documenting preventive maintenance, safety checks and repairs as applicable.

Rental equipment will be repaired at no cost to the patient except equipment damaged by the patient or not under warranty. Equipment owned by the patient will be repaired at a set fee based on an hourly rate plus parts at fair market price. Unusual charge exceptions can be made with appropriate supervisory approval. Repairs on equipment owned by the office location and/or the patient will be within a timely manner unless extenuating circumstances exist (i.e., parts are on order).

Equipment Tracking

Effective Date: 01/01/2012
Revisions: 03/28/2016, 11/30/2018
Review: 07/25/2019

Summary:

Cork Medical documents equipment and services in the patients' chart.

Policy:

Cork Medical tracks all products having lot numbers and expiration dates that are distributed to patients.

Staff can describe mechanism for locating equipment in case of manufacturer's recall.

Procedure:

1. Items are purchased and received into inventory
2. Branch selects the item from warehouse and completes a delivery ticket
3. Branch assigns the item from inventory to the patient
4. When delivery is completed, the delivery ticket is sent to billing who confirms the sales order
5. Once confirmed the inventory is removed from the branch and assigned to the patient

All products, lot number(s) and expiration date(s) are logged in Brightree. All deliveries, maintenance, and pickups will be recorded.

Product Recall

Effective Date: 01/01/2012

Revisions: 03/28/2016, 11/30/2018, 10/16/2019

Summary:

Cork Medical shall take proper steps when a product recall occurs.

Policy:

Cork Medical receives and process recalls in a timely manner.

Procedure:

Review Group Product Recall Procedure

1. Notification of recall is received by purchasing from supplier with the serial numbers of the units affected.
2. Purchasing will give copy of recall letter to Compliance Officer.
3. Leadership team will be notified of all recalls by Compliance Officer.
4. Purchasing will get with billing to run a report of all patients within the serial number range of the product.
5. Once a list is established, a letter will be drafted by Compliance Officer explaining the situation and what the patient should do to remedy the problem.
6. A letter will be sent to each patient. A certified letter may be needed depending on circumstance.
7. The list of patients along with a copy of the recall notice will be sent to the Area Manager of each branch.
8. If any letter is returned, then the patients account will be noted that it was returned.
9. Once all letters are sent, no more will be done to contact patients.

Purchasing of Parts for Recall

1. Parts should be ordered per the process notated on recall notice.
2. Once an order is processed purchasing should be notified to order the part(s) per the recall notice.
3. The part number "Recall-Return" will also be added to purchase order in Brightree for total cost and so tracking number can be added once they are returned.
4. Office Local Manager will add tracking number into serial number field so parts can be tracked, and credit obtained

Medical Device Act

Chap Standard: CI.5f

Effective Date: 03/17/2017

Revisions: 11/30/2018, 04/26/2019, 7/25/19

Review: 11/19/2019

Summary:

Cork Medical policy and procedure addresses the requirements of the Medical Device Act (MDA) and delineate the mechanisms for reporting incidents, which result in serious injury, or death.

Policy:

The Compliance Officer of Cork Medical will report any adverse events caused by normal product use, to the manufacturer and/or the FDA as required.

An adverse event is:

- Device related death

- Device related serious injuries

Procedure:

- 1) Incident report is completed and sent to compliance
 - a) Patient Name
 - b) Address
 - c) Contact information
 - d) Device type and S/N
 - e) Circumstances of adverse event
- 2) Additional information will be gathered by Compliance upon receipt of the report, as needed
- 3) Report will be filed with the Manufacturer
- 4) Accurate documentation of findings includes
 - a) Investigative findings
 - b) Copies of reports sent to the manufacturer
- 5) Reports will be retained electronically for each event
- 6) In-service education on Medical Device Act reporting is provided to staff on an annual basis
 - (a) Written curriculum outlines describe training content
 - (b) Records of attendance are maintained

Vehicle Infection Control

Effective Date: 01/01/2012
Revisions: 11/12/2014, 05/14/2018
Review: 04/25/2019

Summary:

The purpose of this procedure is to ensure that all equipment is clean, thereby minimizing risk of infection to patients.

Policy:

Cork Medical maintains separation between clean and dirty equipment in its vehicles. All equipment and supplies shall be clean, in working order, and have a separation of clean and dirty areas within company vehicles.

Procedure:

The separation of clean and dirty equipment within vehicles must be utilized to prevent cross-contamination. A designated separate clean and dirty area within the vehicle must be identified. Equipment must be bagged at all times.

Personnel removing and transporting equipment that is visibly soiled or suspected of contamination must wear gloves. Equipment should be well secured within the vehicle.

Dirty equipment must be disinfected prior to being bagged or put in the vehicle. Dirty equipment must be placed in a black plastic bag prior to being placed in the van. Any dirty equipment too large to be placed inside a bag must be covered to separate it from the clean equipment. The equipment will be secured and covered in the delivery vehicle.

Delivery vehicles must be disinfected with a germicide and/or the cargo area washed out on a weekly basis to reduce infection concerns. Disinfection of the cargo area must also be performed after pickup of a known infected item that could not be completely bagged to separate it from the cargo area. Tie down straps should also be sprayed during this process.

Equipment Infection Control

Effective Date: 01/01/2012
Revisions: 11/12/2014, 05/14/2018
Review: 07/25/2019

Summary:

The purpose of this procedure is to ensure that all equipment is clean, thereby minimizing risk of infection to patients.

Policy:

It is Cork Medical's practice that proper hand washing techniques, protocols for handling contaminated equipment, bagging and labeling of equipment, and separation of clean and dirty equipment are adhered to for the prevention of infection disease.

Procedure:

The following procedures should be followed in order to limit infection transmission:

1. The warehouse must designate clean and dirty areas for equipment brought in and stored. This may be done by designating separate areas as “dirty” and “patient ready” areas and by clearly marking these areas with signs. There will be warehouse cleaning area designed with sufficient space for equipment needs and marked off with red tape and with signs on the wall above the respective area. One area will be labeled “Dirty Area” and one as “Patient ready”. The two areas must be clearly separated. Traffic from the “Dirty Area” should not cross the “Clean Area”.
2. All dirty equipment will be transported to the “Dirty Area” for cleaning. No equipment will be removed for use or placed on clean area shelving until cleaning and testing are successfully completed.
3. Location personnel will always wear gloves and use other appropriate protective attire when cleaning equipment.
4. All equipment must be cleaned and disinfected with a chemical germicide.
5. After equipment is cleaned, it will be tested by manufacturer’s operational verification procedure (OVP) and logged in the OVP log. If the equipment fails the OVP or is due for routine preventive maintenance, it will be transferred to the Quarantine area and tagged to reflect the status.
6. Equipment passing OVP will be placed in the “patient ready” section of the warehouse.
7. The warehouse must be kept in a good state of repair and cleanliness and must be environmentally controlled. The area will be surveyed physically for removal of recalled items, obsolete equipment, and any expired items. Stock will be rotated so that old is used first.
8. Cleaned, tested small items may be placed on a shelf in the “patient ready” sections of the warehouse. Items can be clear bagged or covered with a clean, impervious material for transport, and placed in the clean area of the vehicle.

Manufacturer Manuals and Instructions

Effective Date: 01/01/2012

Revisions: 11/26/2018

Review: 10/16/2019

Summary:

Cork Medical maintains Manufacturer resource materials

Policy:

Cork Medical maintains a copy of the manufacturer manuals and instruction sheets for each piece of equipment that is provided by Cork Medical locations.

The manuals and instruction sheets are retained and accessible to all employees. The employees are to review any manuals and instruction sheets as needed to maintain competency in set-up and instruction to the patient.

Patients receive a copy of applicable instruction sheets for equipment provided.

Manufacturer literature is copied or replaced as needed.

Vehicle Policy

Effective Date: 11/27/2018
Revised: 03/01/2019, 04/25/2019
Review: 11/19/2019

Summary:

Cork Medical maintains a fleet of vehicles to service its patients' medical equipment needs. The vehicles are maintained and monitored via monthly reports provided to the Area Managers.

Policy:

Cork Medical Vehicles will provide a reliable, safe and infection free method of transport for our employees and equipment to service the needs of our patients.

Procedure:

Operating Responsibilities

- Employee must hold a valid driver's license in order to operate a company vehicle
- If license is revoked/suspended for any reason, must notify Supervisor immediately
- Company Vehicles or Rental Cars are only to be operated by the assigned employee
- Cell phone use should be at a minimum while driving for company purposes
- Vehicles must remain locked when not attended
- All state and local laws must be obeyed
- No unauthorized personnel in the vehicle
- Driving under the influence is prohibited and will result in discipline up to and including termination
- Traffic violations must be reported to Supervisor and Compliance Officer
- Monthly Vehicle Inspections will be performed by the Delivery Technician and turned in to the Area Manager for follow up
- Maintain vehicle in clean, organized fashion at all times
- Retain sufficient PPE supplies to allow for proper use
- Check and initial vehicle fire extinguisher monthly
- Area Managers are responsible for maintenance of the fleet for their locations
- Area Managers are responsible to ensure the safety of the vehicles and respond to any identified issues with a vehicle reported by technicians.

Accident Responsibilities

Employee (Driver)

1. Stop immediately and secure the vehicle (shut off the engine and set the brakes)
2. Protect the area by properly placing emergency triangles or devices
3. Notify the police (the driver should not leave the scene of the accident)
4. Contact management to report accident
5. Keep calm, be courteous and don't argue. Get the Officer's name, department and badge number. Do not accept responsibility or apologize for anything.
6. Provide his/her name, the company's name, insurance policy information, and driver's license to the other party(ies)
7. Take pictures of the accident scene from all four sides of the vehicle
8. Get names phone numbers, license numbers and addresses of witness(es)
9. Do not discuss details of the accident with anyone, except management, insurance carriers, and the police
10. Complete a company accident report and turn into manager

Manager

1. Contact company Safety Officer (HR@corkmedical.com)
2. Address scheduled appointments
3. Arrange for drug and alcohol screening within 24 hours
4. Send in accident report to Safety Officer via email by sending to hr@corkmedical.com

Safety Officer

1. Provide manager and employee with drug testing information, location, and timeline
2. Notify insurance carrier
3. Notify Operations and Compliance Officer

Vehicle Maintenance and Repairs

Effective Date: 01/01/2012

Revisions: 03/31/2016, 11/27/2018, 04/25/2019

Summary:

General maintenance and repairs are a necessity and should be completed at recommended intervals based on the manufacturer.

Policy:

Office/Area Managers and Cork Technicians are responsible for ensuring the timeliness of general maintenance for all vehicles assigned to the respective offices. The following items will be considered general maintenance and should be completed at the recommended intervals.

Procedure:

General maintenance should be documented on the Vehicle Inspection Sheet that is submitted monthly to the Operations Manager.

- Oil Change Every 3,000-5,000 miles
- Tire Rotation Every 8,000-10,000 mile
- Bulb Replacement Replace during next scheduled service appointment
- Windshield Wiper Replace during next scheduled service appointment
- Fluids Most service centers offer fluid top offs between oil changes

All services other than general maintenance require approval from Operation Management. The requestor must provide two quotes for the repairs via email and will receive an email approval to have the service completed. Once complete, payment will be called in through the Accounting Department, if needed, and the requestor must email a copy of the invoice to the Operation Management to be kept in the vehicle file.

Vehicle replacements will occur when:

- Vehicle has reached 250,000 miles, deemed not safe, or;
- It is determined that the cost of service would be more than the cost per mile of the vehicle over the purchased rate for 250,000 miles
 - i.e., if a vehicle has 205,000 miles and 3 quotes for service are received that are over \$750.00, an internal review of that vehicle would occur by the Operation Management and a determination would be made based from past service records.

Once a determination is made, the Operation Management will contact the requestor.

Office Inspection Policy

Effective: 05/15/2018

Review: 07/25/2019

Summary:

Cork Medical maintains its facilities in accordance with Accreditation, State, and Federal guidelines.

Policy:

An office inspection may be completed by a Company Director or Manager within Operations. The office inspection is an internal audit designed to identify if company standards are being met at each location and to assist the local office in preparation for an inspection by a third party.

For any standard that is not met, the Area Manager, or their designee is responsible for completing a Corrective Action Plan to address any deficiencies. The Corrective Action Plan is reviewed by the Compliance Department which will perform follow up inspections as needed to ensure compliance. Action plans to noncompliant responses will be reviewed with Director of Operations and responded to on a case by case basis as appropriate.

Procedure:

Corrective Action Plan

- Area Manager will have three business days to return Corrective Action Plan to Compliance.
- Will have seven business days to provide proof of correcting the deficiencies.
- The Director of Operations will receive all Corrective Action Plans from Compliance for review.
- The Director of Operations will sign off on the Corrective Action Plan.

No Hands Policy

Effective Date: 01/01/2012

Revised: 05/03/2018

Reviewed: 10/16/2019

Summary:

Cork Medical does not provide hands on patient care.

Policy:

Cork Medical is a Durable Medical Equipment company that does not provide medical treatment, therapy, or home health services, therefore does not provide hands on patient care.

Ordering Product Scope of Services

Effective Date:

01/01/2012

Reviewed: 01/09/2020

Summary:

It is the policy of Cork Medical, Inc, to provide support surfaces in accordance with state and federal laws.

Policy:

Cork Medical's products will be delivered to the beneficiary with detailed instructions on proper use, maintenance, and safety precautions.

Process:

Each patient's order received will be reviewed by Cork Medical Inc to ensure patients medical condition qualifies patient for the prescribed equipment. Cork Medical LLC will work as part of an interdisciplinary team which may consist of physicians, registered nurses, and other health care professionals in requesting documentation to support the need of the prescribed support surface.

Process for determining and documenting needs will include:

- 1) Prescription
- 2) Length of need
- 3) Physician name/signature
- 4) Diagnosis
- 5) Patients ability to understand and use equipment
- 6) Patients understanding of how to contact Cork Medical in case of emergency
- 7) Supporting documentation from patient's medical chart

All patients and/or caregivers will be educated in:

- 1) Proper use of products provided
- 2) Safety Hazards associated with products provided
- 3) Maintenance of equipment
- 4) Plan of service
- 5) How to notify the company of problems, concerns and complaints

Complex Transfers and Discharges

Effective Date: 01/01/2012
Review: 11/30/2018, 04/25/2019

Summary:

Cork Medical will honor the wishes of its patients with regards to continuum of care.

Policy:

Patients will be transferred or discharged from service based on patient need and Cork Medical's ability to provide care.

Procedure:

A patient may be transferred to another provider in one or more of the following circumstances:

- Patient request
- The patient's needs are no longer being met
- The patient's needs are outside our scope of services
- The patient moves to a geographical area not serviceable by a qualified technician
- The patient changes to an insurance in which Cork is not a preferred provider

Copies of physician's orders, chart notes and Prior approval authorizations as well as a copy of the transfer summary and documentation of any equipment pick up will be given to the receiving facility/DME provider.

All transfers will be documented in the patient's record and will include:

1. Date of Transfer
2. The company receiving the transfer
3. The reason for transfer

A patient may be discharged from Cork Medical's services in one or more of the following circumstances:

- The patient's condition improves
- The patient refuses the equipment and request discontinuation of services
- The physician discontinues the order for the services
- The patient expires

Patients being discharged from a facility with the use of Cork Medical's services will have the following documented in the patient's records:

- Date
- Reason for discharge

Consumer Service of NPWT

Effective Date: 08/01/2019

Policy:

Ensure that the beneficiary will be able to contact Cork Medical on any technical problems after hours.

Objective:

1. Patient/Caregiver will understand how to contact Cork Medical after hours
2. Patient/Caregiver will know where to locate service number for Cork Medical
3. Education will be performed with patient/caregiver by member or Cork Medical

Consumer Service of NPWT con't.

Procedure:

1. Contact with Cork Medical
 - a. Patients will be provided with Patient Handbook
 - b. NPWT device will have service number on the unit
 - c. This number is the same after hours
 - d. NPWT support/service is 1-866-904-2946
 - e. A member of Cork Medical will be on call
2. Patient Education
 - a. Handbook will be reviewed with patients/caregivers upon delivery by a member of the Cork Medical team
 - b. Patients/Caregivers will be shown service number on the NPWT device
 - c. Patients/Caregivers will be instructed that they can call after hours

NPWT Intake and Assessment

Effective Date: 08/01/2019

Policy:

Cork Medical will consult with the prescribing physician as needed to confirm the order and recommend any necessary changes, refinements, or additional evaluations to the prescribed equipment, item(s), and/or services.

Objectives:

1. Ensure the physician order contains all of the documentation requirements, including the pump type and necessary supplies
 - a. Patient Name
 - b. Device
 - c. Type of Foam
 - d. Mode and pressure
 - e. Length of Need
 - f. Diagnosis
 - g. Start of Care
2. Gather wound care notes identifying and staging wounds being treated
3. Medical Records supporting need for therapy
4. Identify and document in patient record the Home Health Agency involved in patients care, if applicable.
5. Coordinate delivery with Home Health Agency (if applicable)
6. Provide training and equipment support to Home Health Agency (if applicable)

Intake and Assessment Con't.

Procedure:

1. Upon admission patient will have an assessment performed to ensure patient environment is appropriate for items ordered
2. Patient will be provided instructions in writing on proper use and care
3. Patient will acknowledge confirmation of training and exhibit proper use and care of equipment

