



Corporate Compliance Manual

St. Mary's Healthcare System for Children

St. Mary's Hospital for Children

St. Mary's Home Care

St. Mary's Community Care Professionals

St. Mary's Foundation for Children

St. Mary's Rehabilitation Center for Children

SMH Case Management, Inc.

SMH Administrative Services, Inc.

Extraordinary Pediatrics

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St. Mary's Healthcare System for Children Corporate Compliance Manual

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CHAPTER ONE

INTRODUCTION

St. Mary's Healthcare System for Children is a not-for-profit health system consisting of several member corporations providing services through inpatient, day, community and home care programs. St. Mary's member agencies include St. Mary's Hospital for Children (inpatient facility, Pediatric Day Health Care, Early Intervention, Care at Home, Medicaid Service Coordination), St. Mary's Home Care (Certified Home health Agency), St. Mary's Community Care Professionals Corp. (Licensed Home Care services Agency), St. Mary's Rehabilitation Center for Children, St. Mary's Foundation for Children and SMH Administrative Services. St. Mary's also provides management and administrative services to Extraordinary Pediatrics PC, a professional practice focusing on rehabilitation services.

St. Mary's Healthcare System for Children ("St. Mary's") is committed to conducting its operations in an ethical and lawful manner. Accordingly, St. Mary's has developed and implemented a Corporate Compliance Program that applies to all St. Mary's Employees and others who provide services on behalf of St. Mary's (collectively, "Employees"). The St. Mary's Corporate Compliance Program is intended to prevent, detect, and correct violations of applicable law, regulations, third-party payer requirements, St. Mary's policies/procedures, the Code of Conduct and other applicable standards.

The Corporate Compliance Program consists primarily of the key elements described in the Corporate Compliance Plan, St. Mary's Code of Conduct and various policies and procedures designed to implement the Compliance Program, all which are contained in this Corporate Compliance Manual. The Manual also contains a summary of the relevant health care fraud and abuse laws, including whistleblower protection laws. As described in greater detail in the Manual, St. Mary's has adopted a strict non-retaliation policy to protect its Employees for their good faith reporting of compliance-related concerns or issues.

Board of Directors' Authorization

The St. Mary's Board of Directors authorized the creation of a corporate compliance program. The purpose of the program is to promote and support the highest standards of conduct, legally, ethically and morally, on the part of St. Mary's, its personnel and vendors, regarding all laws that regulate St. Mary's, including, but not limited to, the applicable fraud and abuse laws.

The Board of Directors authorized the St. Mary's President and Chief Executive Officer to appoint a Corporate Compliance Officer. The Corporate Compliance Officer works with the Audit and Compliance Committee to oversee the St. Mary's Corporate Compliance Program.

Any questions concerning the St. Mary's Corporate Compliance Program should be directed to the CCO, or his/her designee.

Corporate Philosophy Statement

A corporate philosophy statement is a written articulation of the principles that guide the operations of St. Mary's. This manual includes St. Mary's corporate philosophy statement, designed as a model for the guiding principles that govern facility operations.

WHAT IS CORPORATE COMPLIANCE?

Simply stated, it is a written and operational commitment to organization wide compliance with all applicable laws. St. Mary's compliance program consists of:

- A written statement of corporate philosophy;
- Standards of conduct for employees;
- Policies and procedures to guide employee conduct and facility operations;
- Systems to educate employees about compliance matters; and
- Methods to monitor, detect, prevent, and punish violations of applicable laws and the compliance program.

Compliance with applicable laws is, of course, mandatory, and compliance plans are designed to help a provider better understand its operations and to monitor, on an ongoing basis, compliance with applicable laws and the provider's own policies and procedures.

Compliance programs are rooted in the U.S. Federal Sentencing Guidelines, used by enforcement agencies and courts to determine applicable sanctions for violations of federal criminal laws, including criminal health care statutes and regulations. In addition to prescribing standard sentences, the sentencing guidelines also identify factors that may mitigate or reduce a prescribed criminal sanction. One such mitigating factor is the operation of an effective corporate compliance program.

Thus, apart from the self-knowledge a provider may gain from implementing an effective compliance program, sanctions may be reduced for a provider with a corporate compliance program that discovers that it or its employees have violated federal criminal laws governing health care. Regardless of the primary motive providers may have for implementing such programs, the OIG has made it clear that federal policy and regulatory agencies expect health care providers to design, implement, and maintain effective compliance programs.

Supporting Documents

While the core of a corporate compliance program are the policies and procedures that guide the operations of the facility and the conduct of its employees, a comprehensive corporate compliance program also should include several accompanying pieces that underscore the importance of the program as well as provide ongoing education for staff. The accompanying documents described below are elements of St. Mary's compliance program.

EMPLOYEE STANDARDS AND CODE OF CONDUCT

Another key component of our corporate compliance program is the Employee Standards and Code of Conduct. This document is the primary tool that informs

employees of St. Mary's expectations regarding compliance issues. The Standards are not a replication of the larger, more detailed policies and procedures found in this manual. Rather, they summarize the basic legal principles and policies for employees, and teach employees how to raise questions or submit reports regarding workplace practices that may violate the Standards or appear questionable. In most instances, this is the only document that should routinely be given to employees. Employees should, however, have access to the larger, more detailed written compliance program and be invited to review it as appropriate.

The facility's Standards and Code of Conduct are easily readable, and contain general principles. In addition to the essential list of substantive "do's and don'ts" for employees, key provisions include the name or position of the individual employees should contact with compliance questions and to whom employees should report alleged or suspected violations.

Employees should be directed to the Compliance Officer only when the employee's direct supervisor cannot or will not address the employee's concerns. Supervisors should be directed to transmit all employee reports of suspect activity, or questions the supervisor cannot answer, to the Compliance Officer. If the employee's supervisor is the subject of a question, concern, or report, the employee should be instructed to report the matter directly to the Compliance Officer.

The Compliance Officer understands that federal and state compliance investigators expect all employees to be familiar with the information contained in the Standards. Thus, this information will be the subject of ongoing, periodic training for all employees. To facilitate employee understanding of these principles, upon hire and on an annual basis, St. Mary's will provide the Employee Standards and Code of Conduct to all employees.

All employees and supervisors, as appropriate, will sign employee and supervisor affirmation statements. These statements are written acknowledgments by employees and supervisors that they have read the Employee Standards and Code of Conduct, understand them, and agree to abide by them. These statements may be useful in demonstrating the facility's efforts to educate employees about the compliance program to enforcement authorities and in rebutting allegations by employees that they were not informed about the program. On a periodic basis or as often as needed, updates to the compliance program are disseminated with payroll distribution and in leadership forums. During the introductory period, employees are also serviced by the respective supervisors on specific corporate compliance practices that affect their respective positions. They also provide an additional basis for employee discipline for violations of the compliance program.

COMPLIANCE CHECKLISTS

The Compliance Officer Checklist (see page 86) summarizes in one place the major components of a compliance program and the major functions of the Compliance Officer. This document will serve as a guide when reviewing and revising our corporate compliance program. This document can be used as a roadmap for the Compliance Officer as they maintain a compliance program. The checklist will help

the Compliance Officer ensure that all key steps in developing the compliance program are completed. Likewise, the Compliance Checklist for Supervisors contains elements supervisors should follow to ensure that the compliance program is followed.

CHAPTER TWO

Corporate Philosophy Statement

The laws governing the conduct of health care providers are constantly evolving and have become increasingly complex. To ensure the provision of quality health care in compliance with those laws, St. Mary's has developed a compliance program, of which this corporate compliance manual is an integral part. The compliance manual establishes St. Mary's standards, policies, and procedures regarding compliance with applicable law governing financial relationships among health care providers or other potential sources of referrals, and is designed to ensure that the business and billing practices of St. Mary's comply with applicable laws. This compliance manual is intended to apply to all relationships between St. Mary's and other institutional health providers and/or physicians, and between St. Mary's and its vendors and suppliers. This compliance manual also reaffirms St. Mary's commitment to delivery of quality health care consistent with applicable state and federal health and safety standards.

St. Mary's is dedicated to the provision of quality health care and living accommodations for its residents, and to accomplishing its mission by:

- Responding to the needs of residents, healthy and ill;
- Providing excellent care through multiple levels of service in selected locations;
- Providing an environment that enhances each resident's awareness of his or her medical condition, treatment and prognosis, dignity, security, comfort, and peace of mind;
- Ensuring that services are provided and that facilities are maintained in a fiscally responsible manner; and
- Providing through people, facilities, and programs, a balance between security and independence for residents, which assist in achieving and maintaining the residents' highest practicable physical, mental, and psychosocial well-being, in accordance with residents' comprehensive assessment and plan of care.

St. Mary's and its employees shall act in accordance with the following goals:

- To serve the needs of residents in health and illness in a committed and caring environment;
- To further a commitment to integrity, quality, excellence, and continuous improvement in all areas of service to residents;
- To manage human and material resources ethically, with creativity and vision, always mindful of changing needs and environments and the capacity to serve;
- To esteem all personnel, including volunteers, as the providers of service, encouraging their professional development, caring for them, and nurturing their growth as capable and compassionate people;

- To serve through providing multiple levels of care, and to facilitate resident transfers based on a consistently applied resident assessment process that considers the physical, mental, and emotional well-being in providing the highest quality of life for residents.

To achieve these goals, St. Mary's is committed to conducting all of its business activities in compliance with ethical standards and all applicable laws, rules, and regulations. Employees must recognize their duty to act in accordance with this essential directive.

All questions regarding the application of this compliance manual should be directed to the immediate supervisor. If an employee's immediate supervisor cannot or does not answer the questions or resolve the concerns to the satisfaction of the employee, the employee should address the issue with the Compliance Officer. Employees should be familiar with the laws governing the matters set forth in this compliance manual. Demonstrated familiarity shall be part of every employee's job performance and a regular part of each employee's review.

Any action taken in violation of this compliance manual is beyond the scope of employment and will subject the employee to sanctions by St. Mary's including, but not limited to, termination of employment.

This compliance manual does not address every aspect of St. Mary's compliance activities and their applicable legal issues. As such, employees should consult St. Mary's established policies and procedures and seek the guidance of their supervisor with respect to any other compliance issues that may arise. Employees shall receive education regarding the compliance program. An anonymous Compliance Hotline has been established to provide employees and others with a confidential method for raising concerns about violations or suspected violations of the compliance program.

All violations, suspected violations, questionable conduct, or questionable practices shall be reported to St. Mary's by:

- Reporting to the employee's immediate supervisor;
- filing a report through the anonymous Compliance Hotline,
- reporting to the Compliance Officer; or
- issuing a verbal or written report to any of the officers designated to receive such report.
- The author may report all information anonymously, and St. Mary's will attempt to preserve the confidentiality on the matter and anonymity of the author to the fullest extent permitted by law. However, confidentiality and anonymity cannot be guaranteed in all situations.

Any documents, reports, or other products of St. Mary's compliance program shall be protected to the extent allowed by law under the copyright, self-evaluative, ombudsman, attorney client work product, and any other applicable privileges.

CHAPTER THREE

Employee Standards and Code of Conduct

All employees shall:

- Perform their duties in good faith and to the best of their ability;
- Refrain from any illegal conduct. When an employee is uncertain of the meaning or application of a statute, regulation, or policy, or the legality of a certain practice or activity, he or she shall seek guidance from his or her immediate supervisor or the Compliance Officer;
- Comply with St. Mary's policy regarding the receipt, acceptance, offering, or giving of gifts in connection with an employee's role or status as an employee of St. Mary's.
- Disclose to their immediate supervisor any financial interest, ownership interest, or any other relationship they (or a member of their immediate family) have with St. Mary's residents, customers, vendors, or competitors;
- Participate in scheduled training regarding St. Mary's compliance program and applicable state and federal laws and standards;
- Comply with all St. Mary's policies governing the workplace, including but not limited to:
 - Sexual harassment
 - Drug and alcohol use
 - Confidentiality of medical, personnel, and similar information
 - Political contributions
 - Personal use of company equipment, products, and/or services
 - Conflicts of interest
 - Compliance with specific federal laws;
- Employees shall promptly report all violations or suspected violations of this compliance manual or any other part of the compliance program by other employees to the anonymous Compliance Hotline, or the Compliance Officer through a written report. The author may report such information anonymously or shall notify their immediate supervisor, who will in turn notify the Compliance Officer.

All employees shall NOT:

- Obtain any improper personal benefit by virtue of their employment with St. Mary's;
- Destroy or alter St. Mary's information or documents in anticipation of, or in response to, a request for documents by any applicable government agency or from a court of competent jurisdiction;
- Engage in any business practice intended to unlawfully obtain favorable treatment or business from any government entity, physician, resident, vendor, or any other party in a position to provide such treatment or business;

- Accept any gift, hospitality, or entertainment in any amount from or on behalf of a resident of St. Mary's; and shall not accept from any other person any cash or cash equivalents, any gift of more than the nominal value of \$25.00 per gift or an aggregate of \$50.00 per year from any particular person or entity, or any hospitality or entertainment that because of its source or value might influence the employee's independent judgment in transactions involving St. Mary's. If any gift is received as allowed under the terms of this provision, employee shall notify his or her immediate supervisor promptly.
- Participate in any false billing of residents, government entities, or other party;
- Use confidential or proprietary or intellectual information of St. Mary's for their own personal benefit or for the benefit of any other person or entity, except St. Mary's, during or after being employed by St. Mary's;
- Disclose confidential medical or personal information pertaining to St. Mary's residents without the express written consent of the resident or appropriate legal representative and in accordance with HIPAA regulations and St. Mary's policies and procedures;
- Participate in any agreement or understanding (including agreements based on a course of conduct) with a competitor of St. Mary's to illegally fix prices, agree to labor costs, allocate markets, or engage in-group boycotts. Before considering any agreements or entering into discussions with a competitor concerning any of these issues, all employees shall first speak with their immediate supervisor regarding the matter or obtain the advice of the Compliance Officer concerning antitrust issues;
- St. Mary's has developed a corporate compliance program that includes detailed explanations of the legal and ethical standards governing the conduct of St. Mary's and its employees in business activities. Employees who wish to read the full text of the corporate compliance program are encouraged to do so and may ask their immediate supervisor for a copy. Below is a brief summary of the process used by St. Mary's to ensure corporate compliance.

Background Screening

State and federal laws prohibit St. Mary's from hiring employees if it knows or should know that the individual has engaged in certain illegal activity. Therefore, background checks are conducted on all potential employees and volunteers in accordance with state and federal laws. St. Mary's also investigates with other licensing and related bodies, including the certified nurse assistant registry, to ensure that prospective employees currently have the licensing or other status required have not engaged in illegal activity.

Responsibility for Corporate Compliance

All employees have the duty to promptly report any actual or suspected violations of the corporate compliance plan. An employee who fails to promptly report any such activity will be subject to appropriate disciplinary action, which may include termination of employment.

St. Mary's has designated Adam Waxer, Esq. as Corporate Compliance Officer. The Compliance Officer may seek advice from outside legal counsel when necessary to ensure compliance with the law and St. Mary's policies. The Compliance Officer may be reached by:

Calling 718-281-8585; or in writing at:

St. Mary's Healthcare System for Children
29-01 216th Street
Bayside, New York 11360

St. Mary's has also appointed an Audit and Corporate Compliance Committee. The Committee shall operate in accordance with the Audit and Compliance Committee Charter adopted by the Board of Directors as found in Chapter 6 of this Manual.

CHAPTER FOUR

POLICIES AND PROCEDURES

This chapter provides statements of policy and procedure addressing the major compliance issues facing skilled nursing facility providers. Our policies contain a statement of general policy, followed by a list of policy elements.

Educational and training programs covering these policies and procedures will be provided to employees at least annually, and documented by or at the direction of the Compliance Officer.

These policies represent the major issues that have been receiving attention from CMS, the OIG, and state fraud regulators in recent years. This portion of St. Mary's compliance manual will be reviewed and updated as laws or their interpretations change, or as new issues arise from St. Mary's ongoing operations. The following policies and procedures are based on federal law. New York also has laws covering many of these issues.

Quality and Risk Management Committee

The Board of Directors has appointed a Quality and Risk Management Committee to oversee the quality and risk management functions of St. Mary's. The Board has adopted a committee charter, found in Chapter 6 of this Manual.

QUALITY OF CARE –SKILLED NURSING FACILITY - POLICY STATEMENT

It is the policy of St. Mary's that each resident receives the necessary care to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the resident's comprehensive assessment and plan of care.

- The facility will conduct initially and periodically a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity. The assessment may be based on a uniform data set specified by the state and approved by the Department of Health and Human Services as well as facility identified situations;
- The facility will develop a comprehensive care plan for each resident that includes measurable objectives and timetables to meet a resident's medical, nursing, mental, and psychosocial needs that are identified in the comprehensive assessment;
- Each resident will receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care;
- A resident will be given the appropriate treatment and services to maintain or improve his or her ability to bathe, dress, groom, transfer, and ambulate;
- The facility will ensure that a resident who enters the facility without pressure sores does not develop them unless the resident's clinical condition demonstrates that they were unavoidable. A resident with pressure sores must receive necessary treatment and services to promote healing, prevent infection, and prevent new sores from developing;

- A resident who enters the facility without an indwelling catheter may not be catheterized unless the resident's clinical condition demonstrates that catheterization is necessary;
- A resident who is incontinent of bladder (other than age appropriate – infants) must receive appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible;
- A resident who displays mental or psychosocial adjustment difficulty must receive a psychological evaluation with appropriate treatment and services to correct the assessed problem;
- The facility must ensure that a resident whose assessment did not reveal a mental or psychosocial adjustment difficulty does not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors, unless the resident's clinical condition demonstrates that such a pattern was unavoidable;
- The facility must ensure that the resident's environment remains as free of accident hazards as possible and must provide adequate supervision and assistive devices to prevent accidents;
- The facility must ensure that a resident maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible;
- Each resident's drug regimen must be free from unnecessary drugs. Residents must be free of medication errors;
- The drug regimen of each resident will be reviewed at least once a month by a licensed pharmacist;
- The facility will have sufficient nursing staff to provide nursing and related services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and plans of care;
- The facility will use the services of a registered nurse (RN), seven days a week;
- The facility will employ a qualified dietitian;
- Menus will meet the nutritional needs of residents in accordance with the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences;
- Each resident will receive and the facility must provide at least three meals daily, at regular times comparable to normal mealtimes in the community;
- The medical care of each resident will be supervised by a physician. The resident must be seen by a physician at least once every 30 days for the first 90 days after admission and at least once every 60 days thereafter. The facility will provide or arrange for the provision of physician services 24 hours a day, in case of an emergency;

- If required by the written order of a physician, the facility will provide or obtain specialized rehabilitative services including, but not limited to, physical therapy, speech language pathology, occupational therapy, and mental health services;
- The facility will assist residents in obtaining routine and 24-hour emergency dental care, including assistance in making appointments and arranging for transportation;
- The facility will provide pharmaceutical services, and have in place procedures that assure accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals, to meet the needs of each resident;
- The facility has an established infection control program under which it investigates, controls, and prevents the spread of infections in the facility.

QUALITY COUNCIL - POLICY STATEMENT

It is the policy of St. Mary's to maintain a Quality Council. The committee will consist of the Administrator, Director of Nursing Services, a physician designated by the facility, and at least three other facility staff members.

The committee will be responsible for identifying issues needing action that affect quality of care and services provided to residents. The committee will meet at least quarterly to identify quality assessment and assurance issues, and to develop and implement, or oversee implementation of, appropriate plans of correction for identified quality deficiencies.

SKILLED NURSING FACILITY SERVICES - POLICY STATEMENT

It is the policy of St. Mary's to provide skilled nursing services consistent with applicable legal requirements and standards of practice.

Skilled nursing facility services will:

- Be required by the resident (be medically necessary);
- Be performed by or under the supervision of licensed professional or technical personnel;
- Be required by the resident on a daily basis; and
- Be provided only on an inpatient basis.

ANCILLARY SERVICES - POLICY STATEMENT

St. Mary's will provide any ancillary services it offers through affiliated or related companies in accordance with all statutes, regulations, and standards of professional practice applicable to such services.

RESIDENT'S RIGHTS AND QUALITY OF LIFE - POLICY STATEMENT

It is the policy of St. Mary's that all residents have the right to a dignified existence, self-determination, and communication with and access to people and services inside and outside the facility. Resident's rights will be explained to the child's parents or legal guardian as appropriate.

A resident has the right:

- To exercise his or her rights as a resident of the facility and a citizen or resident of the U.S. and be free of interference, coercion, discrimination, or reprisal by St. Mary's or its employees for the exercise of such rights;
- To be fully informed of his or her rights and all rules and regulations governing resident conduct and responsibilities during the stay in the facility;
- To access personal records within 48 hours of request; to purchase copies of records with two working days' advance notice to the facility;
- To be fully informed of his or her health status and medical condition;
- To refuse treatment;
- To be informed of the items and services paid for by Medicaid and for which Medicaid covered residents may not be charged, and to be informed of items and services for which the resident may be charged and the amount of such charges;
- To be informed of his or her legal rights, including the manner of protecting personal funds, a description of the requirements and procedures for qualifying for Medicaid, a posting of the names, addresses, and telephone numbers of all pertinent state client advocacy groups, and a statement that the resident may file complaints with the state survey and certification agency;
- To be advised of the name, specialty, and manner of contacting the physician for his or her care;
- To receive information on how to apply for and use Medicaid and Medicare benefits;
- To be notified, and have his or her physician and legal representative or family member notified, of accidents resulting in injury or requiring the intervention of a physician, of significant changes in condition, of a need to significantly alter treatment, or of a decision to be transferred;
- To be notified of a change in room or roommate or a change in residents' rights under state or federal law;
- To manage his or her financial affairs;
- To have the facility hold and manage his or her personal funds;
- To have a full and complete accounting of personal funds managed by the facility; Not to have any charge made against personal funds for items paid for by Medicaid or Medicare;
- To choose a personal physician, to be informed in advance about care and treatment and any changes in care or treatment that may affect his or her well-being, and to participate in planning care or treatment unless adjudged incompetent or incapacitated under state law; To personal privacy and confidentiality of personal and clinical records;
- To file grievances without discrimination or reprisal; and be provided with a reasonable outcome;
- To examine facility survey results;
- To visitation by people of the resident's choosing, including family members, state representatives, the ombudsman, and others, subject to reasonable restrictions;
- Not to be transferred except in the situations and according to the procedure described at 42 C.F.R. Part 483.12;

- To be free from physical or chemical restraints imposed for the purpose of discipline or convenience and not required to treat medical symptoms;
- To be free from verbal, sexual, physical and mental abuse, corporal punishment, and involuntary seclusion; and
- To receive services in a facility environment that is safe, clean, and comfortable with adequate space for all activities.
- St. Mary's will not require residents or potential residents to waive their rights under Medicaid, nor require oral or written assurances that residents or potential residents are not eligible or will not apply for Medicaid or Medicare benefits;
- St. Mary's will not require a third party guarantee of payment as a condition of admission, expedited admission, or continued stay at the facility.
- St. Mary's may require a person who has legal access to and/or control over a resident's income or resources to pay for facility care or sign a contract to provide payment for the resident's services, without requiring the person to assume personal financial liability for such care; For Medicaid eligible residents, St. Mary's will not charge, solicit, accept, nor receive for services covered by Medicaid any gift, money, donation, or other consideration, in addition to any amount required to be paid under the state Medicaid plan, as a precondition of admission, expedited admission, or continued stay at the facility;
- St. Mary's may charge residents amounts above and beyond payment received by Medicaid for items and services requested by the resident and not included in the Medicaid package of "nursing facility services" as long as the facility gives proper notice of the availability and cost of such services or items and does not condition the resident's admission or continued stay on the purchase of such items or services; and
- St. Mary's may solicit, accept, or receive charitable, religious, or philanthropic contributions from an organization or a person unrelated to a Medicaid resident as long as such contribution is not a condition of a resident's admission or continued stay. All offers for the donation of such contributions shall be reported to the facility Administrator, Compliance Officer, legal counsel or other person designated by the facility for a determination that such contribution is allowed under applicable law.

Discrimination Against Residents and Payment Provisions - Policy Statement

It is the policy of St. Mary's to maintain identical policies and practices for all individuals regarding transfer and discharge, without regard to race, color, sex, handicaps, religious creed, national origin, political beliefs or payment source, and to comply with all applicable law with respect to admission decisions, as well as the provision of services under the state Medicaid plan.

Quality of Life - Policy Statement

It is the policy of St. Mary's that residents will be cared for in a manner and in an environment that promotes, maintains and enhances the quality of life for all residents.

Resident Privacy and Confidentiality - Policy Statement

It is the policy of St. Mary's to ensure that each resident has the right to privacy and confidentiality of his/her personal and clinical records.

For purposes of this policy, the term "personal privacy" includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but does not include the right to a private room.

- Clinical Records - The resident may approve or refuse the release of his or her personal and clinical records in part or in whole to any individual outside St. Mary's except when the resident is transferred to another health care institution, or the record release is authorized or required by law.
- Mail - It is the policy of St. Mary's that each resident has the right to privacy in written communications, including the right to send and promptly receive mail that is unopened, and access to stationery, postage, and writing implements at the resident's expense.
- Telephone - It is the policy of St. Mary's that each resident has the right to reasonable access to the use of a telephone where calls can be made without being overheard.

TRANSLATION SERVICES

In accordance with the Federal Office for Civil Rights Revised Guidance on Compliance with Title VI Language Assistance Requirements, it is the policy of St. Mary's Healthcare System for Children to provide language assistance to Limited English Proficiency (LEP) residents and families.

For each inpatient admission to St. Mary's will:

- Take reasonable steps to ensure that LEP persons have meaningful access to the facility's programs and activities.
- Determine the number or proportion of LEP persons from a particular language group served. The level of prior experiences with LEP persons will be used to determine the necessary mix of language assistance services needed. Data repositories used for this determination will include, but is not limited to, MDS, facility network and through interactions between social workers and residents and families.
- Identify, upon admission, or as soon as feasible the primary language of the LEP resident/family and seek to provide translation services in that language, as often as possible.
- Provide language assistance to LEP persons based on the frequency with which they have contact with LEP individuals. The more frequent the contact, the higher the expectation that LEP services should be made available. In cases where there is less frequent contact with a particular language group, efforts for this group need not be "intricate" and telephonic interpretation services can be utilized.
- Immediate language assistance to LEP persons would be provided in the event of a serious or life-threatening situation. In the event the situation is important but not urgent, the provision of language services, while necessary, will be made available in a reasonable period of time.

- Recognize the financial impact of providing the level of resources that may be required and will make every attempt to provide such services for the LEP person. In the event that cost is a factor in limiting language assistance obligations, these will be documented in the medical record.
- Will ensure the quality and accuracy of oral and written language services with the following options:
 1. Hiring of bilingual staff to meet the needs of the LEP persons served;
 2. Providing in-service education to all bilingual staff that will be used as interpreters. This will include the review of interpreter guidelines including impartiality, establishing respectful relationships, professionalism, completion of a confidentiality acknowledgment and a competency assessment.
 3. Creating a language bank to facilitate the clinical team in securing the services of interpreters;
 4. Contracting for interpreters where it has been identified that no regular need to interpret in a particular language is required;
 5. Providing interpreters that are competent to interpret technical terms through telephone interpreters;
 6. Allowing family members or friends to serve as interpreters when issues of competence, appropriateness and conflict of interest have been assessed, even at the request of the LEP person. Plan and implement language assistance efforts in a manner that will minimize the situation where family members and friends are necessary.
 7. Providing timely services in a manner that does not have the effect of denying service or delaying rights to an LEP resident when language services are important.
 8. Providing the translation of vital documents for the most frequently encountered languages. The document will be considered “vital” if the information therein imparts or elicits information that is critical to providing services accurately and in a timely manner. Vital documents may include medical record documentation, notices, announcements, resident education material, agreements and consents.

Office of Civil Rights recognizes a “safe harbor” definition to guide the facility in determining whether it is providing the appropriate level of written translation services. The “safe harbor” definition indicates that the following actions will be considered strong evidence that St. Mary’s is meeting its obligations to provide written translation:

- a. When it provides written translations of vital documents for each eligible LEP language group that constitutes five percent or 1,000 whichever is less, of the population of persons eligible to be services or likely to be affected or encountered. Translation of other documents, if needed, can be provided orally; or
- b. If there are fewer than 50 persons in a language group even if that reaches the five percent trigger, St. Mary’s will not be required to translate vital written

materials but will provide written notice in the primary language of the LEP language group of the right to receive competent oral interpretation of those materials, free of cost.

This “safe harbor” definition only applies to the provision of written translation services. There is no “safe harbor” definition for the provision of oral translation services.

EMPLOYEE SCREENING - POLICY STATEMENT

It is the policy of St. Mary’s to undertake criminal history background checks of all employees to the fullest extent required and/or permitted by applicable federal and state law and available sources and to retain on file applicable records of current employees regarding such investigations.

Additionally, St. Mary’s will abide by federal law, which precludes providers from contracting with vendors, suppliers, and other health care providers that have been excluded from the Medicare and/or Medicaid program.

At a minimum, St. Mary’s will:

- Check all prospective employees through state nurse assistant registry prior to beginning work to ensure no prior convictions for resident abuse, neglect or mistreatment.
- Check with all applicable licensing and certification authorities to ensure that employees hold the requisite license and/or certification status to perform their job functions.
- Require that all potential employees certify as part of the employment application process that they:
 - Have not been convicted of an offense or otherwise been found under applicable local, state, or federal law to have committed an offense that would preclude employment in a nursing facility; and
 - Have not been excluded from participation in any state or federal health care program, including Medicaid and Medicare.

St. Mary’s contracts with Government Management Services, Inc. (GMS) to search for healthcare employees and entities that have been excluded from federal healthcare programs as well as adverse actions taken by licensing boards of State governments. The database is called the Fraud and Abuse Control Information System (FACIS). This database search is conducted annually for all current employees and independent contractors. All new vendors and independent contractors are queried prior to implementation of new contracts.

It is the ongoing and continuous obligation of all employees of St. Mary’s to alert our Human Resources Department of any conviction or finding that would disqualify them from continued employment with St. Mary’s under state or federal law.

GIFTS - POLICY STATEMENT

It is the policy of St. Mary's that its employees shall not obtain any improper personal benefit by virtue of his or her employment with St. Mary's.

Employees shall not:

- Solicit, receive, or accept from any person or entity, nor offer or give to any person or entity, anything of material value if that person or entity is in a position to refer business to St. Mary's or if St. Mary's is in a position to refer business to that person or entity except as permitted by law; or
- Provide any gifts or gratuities to any government or public agency representatives except as permitted by law;
- Make payments for a physician's travel to or participation in conferences unless the subject matter of the conference is of direct benefit to St. Mary's. Similarly, there shall be no payments of a physician's continuing education fees, no discounted billing services, no interest free loans, and no forgiveness of loans as part of any gift to a physician unless such benefits are specifically allowed as part of a permissible physician agreement; and
- Pay or receive anything of financial benefit in exchange for Medicare or Medicaid referrals, such as receiving non-covered medical products at no charge in exchange for ordering Medicare reimbursed products.

St. Mary's staff will not give gifts and entertainment to family members, potential referral sources, and other individuals and entities with which the facility has a business relationship in more than a nominal value of \$25.00 per gift or an aggregate of \$50.00 per year.

RESIDENT/FAMILY INDUCEMENTS - POLICY STATEMENT

It is the policy that St. Mary's and its employees shall not knowingly and willfully solicit or receive any remuneration directly or indirectly, overtly or covertly, in cash or in kind in return for referring an individual to a person for furnishing (or arranging for the furnishing) of any item or service for which payment may be made in whole or in part under a federal health care program, or in return for purchasing, leasing, ordering, or arranging for, or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a federal health care program. Furthermore, St. Mary's and its employees shall not offer or transfer remuneration to any individual eligible for benefits under federal or state health care programs (including Medicare or Medicaid) that St. Mary's and its employees know or should know is likely to influence the individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, by a federal or state health care program.

St. Mary's and its employees shall not:

- Offer or provide any gift, hospitality, or entertainment of more than nominal value to any Medicare or Medicaid beneficiary. Examples of permissible items include pens, T-shirts, water bottles, etc., valued at less than \$15.00 per item, as long as such items are not offered or provided to influence health care decisions by a beneficiary, family member, or responsible party;
- Offer waivers of coinsurance or deductible amounts as part of any advertisement or solicitation;

- Routinely waive coinsurance or deductible amounts, and shall only waive such amounts after determining in good faith that the resident is in financial need, or after making reasonable efforts to collect the cost sharing amounts from the resident;
- Participate in any arrangement with a health care plan that effectively requires St. Mary's and its employees to forgo certain Medicare cost sharing amounts; and
- Participate in any arrangement with a health care plan that requires St. Mary's and its employees to waive charges for co-payments and deductibles when Medicare is the primary payer and the applicable Medicare reimbursement is higher than the plan fee schedule amount.

VENDOR AGREEMENTS - POLICY STATEMENT

To comply with applicable laws regarding referrals, neither St. Mary's nor a vendor shall solicit or receive from any person or entity, nor offer or give to any person or entity, anything of value if that person or entity is in a position to refer business and/or residents to St. Mary's, or if St. Mary's is in a position to refer business to that person or entity, except as permitted by law. This policy does not preclude the purchase, rental, lease, or other acquisition or provision of reasonable and necessary services or items for fair market value by St. Mary's or its employees.

All vendor agreements shall meet the requirements listed below when any item(s) or service(s) supplied by the vendor are reimbursable under any state or federal health care program. This list is not exhaustive, and will be reviewed annually for additions.

Vendor agreements:

- Shall be in writing; Shall specify the particular services or supplies to be provided;
- Shall specify the fee or payment to be made to the vendor, which shall be set at the fair market value for such services or supplies and/or be based upon applicable fee schedules or other payment guidelines established by CMS or its designees, the state Medicaid agency or its designees, or other applicable third party payers, and shall not take into consideration the value or volume of referrals provided to or by St. Mary's;
- Shall specify that vendor will submit all bills in accordance with the payment method and amount set forth in the vendor agreement;
- Shall be signed by all parties; and
- Shall certify that the vendor currently is eligible for participation in the Medicare and, where applicable, Medicaid programs.
- Involving services or supplies with a value in excess of \$100,000 per year shall meet the following additional requirements:
 - Shall be negotiated only by the Chief Executive Officer, CFO, Administrator and/or the facility legal counsel, or their designees or other people selected by the provider;

- Shall be reviewed and approved by legal counsel, his designee or other people selected by St. Mary's Chief Executive Officer;
- If the value or cost of the services or supplies to be provided under the vendor agreement equals or exceeds \$10,000 over a 12-month period, the vendor will, for a period of at least four years after the furnishing of the services and supplies, retain records to verify the nature and extent of the costs of such services and supplies and make such records available upon request by St. Mary's; and the vendor shall impose similar obligations on any subcontractor it uses to provide the services and supplies under the vendor agreement; and
- The vendor and any subcontractor of the vendor shall cooperate with St. Mary's in the event that any third party payer, including the Medicare or Medicaid program, conducts an audit or otherwise requests documentation regarding services or supplies provided by the vendor or its subcontractor. All payments to vendor shall be specified in the vendor agreement.

VENDORS/CONTRACTORS - SCREENING OF EMPLOYEES

Vendors and Contractors wishing to conduct business with St. Mary's must ensure that their employees and contractors are not excluded from the Medicare and/or Medicaid programs. As such, all vendors and contractors shall be responsible for the following:

1. Vendors will screen all individuals providing services to St. Mary's under this Agreement to ensure that they are not excluded from participating in public health care programs including Medicare and Medicaid by reviewing the following websites:
 - a. Department of Health and Human Services Office of Inspector General (<http://oig.hhs.gov/fraud/exclusions.asp>)
 - b. New York State Office of Medicaid Inspector General (<http://omig.ny.gov>) list of excluded individuals and entities
 - c. General Services Administration's lists of Excluded Parties and Entities (<https://www.sam.gov/portal/public/SAM/>)
2. Vendors will maintain documentation of pre-employment screening and clearance in the personnel record of each employee or independent contractor.
3. Vendors will on a monthly basis screen all employees and independent contractors using the three websites listed above.
4. Vendors will maintain documentation of monthly screening for all employees and independent contractors.
5. Vendors will notify St. Mary's of any personnel identified as an excluded individual within three business days of discovery.

The above language shall be inserted in contracts or as an appendix to such contracts.

Non-affiliated physicians who order medical services for St. Mary's patients in home care programs shall be screened by the Compliance Officer or designee using the above criteria.

PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING

For services provided on or after the effective date upon which St. Mary's must bill Medicare under the prospective payment system (PPS) for items and services provided to Medicare Part A residents receiving services in the facility or under the facility's plan of care, all vendor agreements shall, in addition to the requirements described above:

- Provide that the vendor will bill St. Mary's for services provided to Medicare Part A residents, and that the vendor will not submit bills directly to Medicare for such services, except for those services specifically excluded from PPS;
- Provide that the vendor or its subcontractors will ensure that St. Mary's receives any orders or certifications necessary before providing the service, as well as supporting documentation required to receive payment from Medicare or Medicaid for such service;
- Provide that the vendor or its subcontractors will participate fully, as reasonably requested by St. Mary's, in any appeals by St. Mary's of payment decisions by any third party payer in connection with items or services rendered by the vendor or its subcontractors;
- Provide that the vendor and its subcontractors will participate, as reasonably requested by St. Mary's, in St. Mary's compliance program and quality assurance program, including any internal or external audits by St. Mary's of St. Mary's billing, payment, and/or collection procedures and quality assessments; and
- Require that the vendor and its subcontractors notify St. Mary's prior to execution of a contract and on an ongoing basis of the imposition of any remedies or sanctions, including termination of Medicare and/or Medicaid program participation imposed by the OIG or a state Medicaid agency, and of the initiation of any audit or investigation of the vendor and/or its subcontractors by any such agency.

MEDICARE PART B SERVICES

For services provided on or after the effective date upon which St. Mary's must submit consolidated bills to the Medicare program for certain items and services provided to Medicare Part B residents receiving services in the facility or under the facility's plan of care, all vendor agreements shall, in addition to the requirements described above:

- Provide that the vendor will bill St. Mary's for those Part B services provided to Medicare residents and that are subject to consolidated billing requirements, and that the vendor will not submit bills directly to Medicare for such services;
- Provide that the vendor or its sub-contractors will ensure that St. Mary's receives any orders or certifications necessary to provide the service, as well as supporting documentation required to receive payment from Medicare or Medicaid for such service;

- Provide that the vendor or its subcontractors will participate fully, as reasonably requested by St. Mary's, in any appeals by St. Mary's of payment decisions by any third party payer in connection with items or services rendered by the vendor or its subcontractors; Provide that the vendor and its sub-contractors will participate, as reasonably requested by St. Mary's, in St. Mary's compliance program and quality assurance program, including any internal or external audits by St. Mary's of St. Mary's billing, payment, and/or collection procedures and quality assessments; and
- Require that the vendor and its subcontractors notify St. Mary's prior to execution of a contract and on an ongoing basis of the imposition of any remedies or sanctions, including termination of Medicare and/or Medicaid program participation imposed by CMS, the OIG, or any state Medicaid agency, and of the initiation of any audit or investigation of the vendor and/or its subcontractors by any such agency.

Verifying Vendor Certification For Medicare/Medicaid Participation

No vendor contracts shall be executed until St. Mary's has reviewed the OIG's Cumulative Sanctions Report or other applicable source and verified that the vendor currently is certified to participate in the Medicare and Medicaid programs, and is not subject to any sanction that would render St. Mary's unable to legally contract with vendor.

BEDHOLD RESERVATIONS

It is the policy of St. Mary's to ensure appropriate billing of bedhold days for any resident that departs the facility for temporary hospitalization or for a leave of absence.

In accordance with 18 NYCRR 505.9(d), "the day the resident departs for temporary hospitalization or the leave of absence begins is counted as a reserved bed day. The day the resident returns is not counted as a reserved bed day." A bed reservation (bedhold status) is initiated if it is expected that the resident will return to the facility within 20 days and the resident desires to have the bed reserved. A bed may be reserved for a resident who is pending Medicaid eligibility.

1. At the time of admission and again at the time of transfer for any reason, St. Mary's will verbally inform and provide written information to the resident's family that specifies the duration of the bed-hold policy during which the resident is permitted to return and resume residence in the facility and the facility's policies regarding bed hold periods.
2. Upon therapeutic leave, St. Mary's will provide written notice to the resident and the designated representative, which explains the bed hold policy.
3. If a resident has reached a bedhold status, upon transfer to an acute care facility, the resident's bed will be reserved according to policy if the resident wishes to return to St. Mary's.
4. If the resident has not reached bedhold status, he/she will be given priority for a bed over other residents awaiting placement.

5. If a resident has been deemed to be transferred to an acute care facility or is on a leave of absence at the time the census is taken (generally midnight), the census will reflect the absence of the resident. The census is forwarded to the Resident Accounts Department on a daily basis.
6. The Admissions Office will not admit another resident to a bed that is in bed reservation status.

Medicaid will pay an institution for a resident's reserved bed days when the resident has been at St. Mary's for at least 30 days since the date of his or her initial admission. The 30 days are cumulative, need not be consecutive and can even include a temporary absence. The intent of the current bed reservation policy is to provide reimbursement permitting a resident to return to St. Mary's where he/she has lived for a considerable period of time and which is considered his/her home.

A resident must be a resident of a facility for 30 days since the date of initial admission before Medicaid and Managed Medicaid will reimburse for bed reservations. Days do not have to be consecutive but must be within the same facility to be considered a valid period of residency. St. Mary's will not accept any pre-admission payments under any circumstance from a Medicaid-eligible person seeking admission or from any other party on his/her behalf. St. Mary's will only accept payment from a prospective resident, family member or friend to hold a bed if the person is going to be private pay.

Someone other than the resident, such as a friend or relative, can make a payment to the facility in order to ensure the availability of a nursing facility bed upon the resident's discharge from the acute care facility.

VACANCY RATES

Billing will be submitted for a resident's reserved bed days when "the part of the institution to which the resident will return has a vacancy rate of no more than 5 percent on the first day the resident is hospitalized or on leave of absence." The vacancy rate is defined as the ratio of empty to total certified beds at St. Mary's. The vacancy rate calculation is made as of the day the resident seeking the bed reservation is temporarily discharged to the hospital or to therapeutic leave. When the vacancy rate exceeds 5% for the Medicaid-covered bed reservations, the facility will refrain from billing for the bed reservation days for those residents that are on bed reservation. When there are 4 empty beds at St. Mary's Hospital or 2 empty beds at St. Mary's Rehabilitation Center, St. Mary's will refrain from billing for reservation beds. For the purposes of the vacancy calculation rate, respite beds (2) are excluded and "Medicaid-covered" will also apply to Medicaid Managed Care residents.

There are no limitations on the number of times the resident's bed may be reserved as long as appropriate residency and vacancy requirements are met and there is at least one day of nursing facility reimbursement between each reserved bed period. A bed reservation can be requested any time after the resident's formal readmission to the nursing facility. The facility claim must show a readmission so that the series of bed reservation days are divided into two discrete segments.

St. Mary's will reserve a resident's bed when the resident is hospitalized and expected to return to St. Mary's in 15 or fewer days. When St. Mary's reserves a resident's bed, St. Mary's will notify the hospital by telephone and in writing, according to department instructions, that the resident's bed has been reserved;

The hospital discharge planning coordinator must notify:

1. St. Mary's by telephone of any changes in the resident's condition during the period that the resident's bed is reserved; and
2. St. Mary's of the resident's planned discharge date.
3. St. Mary's clinical marketing liaison to discuss if the resident's planned discharge date must be adjusted after the third and before the 16th day of hospital care because his or her condition has changed or additional medical information has become available.
4. St. Mary's will confirm in writing all bed reservation telephone communications.

St. Mary's is not obligated to reserve a resident's bed when:

1. It is clear the resident is hospitalized and he/she will not return to St. Mary's within 15 days or fewer;
2. After hospitalization, the resident will need a level of care St. Mary's does not provide; or
3. The resident does not wish to return to St. Mary's.

St. Mary's may terminate the resident's bed reservation when:

1. The planned discharge date determined by the hospital is more than 15 days from the day the resident was admitted; or
2. The hospital adjusted the resident's planned discharge date and the new discharge will not permit the resident to return to St. Mary's within 20 days of the hospital admission date; or
3. If the resident dies while on bed reservation.

MEDICAL DIRECTOR CONTRACTS

All contracts with any physician serving as the medical director of St. Mary's must comply with the provisions of this manual governing vendor and physician agreements and be approved by The Board of Directors and legal counsel prior to execution.

Contracts between St. Mary's and any entity in which St. Mary's medical director has an ownership or financial interest present special issues under federal and state law. No contract may be executed between St. Mary's and any entity in which St. Mary's medical director has an ownership, investment, or other financial interest without approval. Approval will be by the Board of Directors and legal counsel of St. Mary's.

RESIDENT REFERRALS - POLICY STATEMENT

To comply with the federal anti-kickback and physician self-referral (Stark) laws, all agreements between St. Mary's and a hospital, home health agency, hospice, managed care organization or alliance, or other entity that involves the referral or transfer of any resident to or by St. Mary's shall be reviewed by legal counsel or his designee prior to execution.

Any such agreement shall:

- Be in writing;
- Be negotiated only by legal counsel and/or the Chief Executive Officer, facility administrator, Board of Directors or their designees;
- Be approved by legal counsel or his designee prior to execution;
- Be signed by all parties;
- Specify all of the obligations of the parties;
- Specify the fee or payment, if any, which shall be set at fair market value for the items or services provided;
- When taken as a whole, be reasonable in its entirety;
- Not take into consideration the value or volume of referrals provided by or to St. Mary's except as is specifically permitted by the "safe harbors" found at 42 C.F.R. Part 1001.952;
- Not involve free or discounted goods or services or goods or services below fair market value to induce a referral to or by St. Mary's except as specifically permitted by the "safe harbors"; and
- Not involve the referral or transfer of any resident to or by St. Mary's to induce the other party to refer or obtain referrals of residents from St. Mary's.

REFERRALS TO OR BY HOSPICES - POLICY STATEMENT

St. Mary's is committed to making available appropriate hospice services to residents who elect hospice coverage. For residents who are eligible for hospice benefits under Medicare or Medicaid, St. Mary's and employees shall:

- Provide services pursuant to a written agreement with a hospice program that meets the conditions of participation for hospices (42 C.F.R. Part 418) upon evidence that the resident qualifies for and has properly elected the hospice benefit;
- Develop and implement, in conjunction with the hospice program, a coordinated plan of care;
- Bill the Medicare and/or Medicaid programs only for the treatment of conditions unrelated to the terminal illness, as permitted by law;

- For residents eligible for Medicare hospice benefits and Medicaid coverage of the resident's room and board, St. Mary's shall not accept payment by a hospice for room and board provided to a hospice resident in excess of the amount that St. Mary's would have received if the resident had not been enrolled in hospice. Any additional payment from the hospice for items and services purchased from the facility must represent the fair market value of such additional items and services actually provided to the resident that are not included in the Medicaid daily rate;
- Provide only those services St. Mary's is allowed to provide to hospice residents under applicable law (see note); and not engage in any arrangement in which St. Mary's offers, accepts, provides, or receives free services to or from a hospice in exchange for a promise or agreement to refer nursing facility residents to the hospice, or vice versa.

Note: Federal law expressly requires that a hospice provider provide certain core services, either directly or under contract. The OIG has expressed concern that other providers, including nursing facilities, may be providing some care services the hospice is required to provide.

BUILDING AND EQUIPMENT LEASES - POLICY STATEMENT

All building and/or equipment leases shall meet the requirements below and shall be reviewed and approved by legal counsel or his designee prior to execution to avoid violation of federal anti-kickback or Stark laws.

In general, leases shall:

- Be in writing;
- Have a term of at least one year;
- Specify the premises or equipment covered by the lease;
- Set the rental charge in advance;
- Specify the exact schedule of access or use, the precise length, and the exact rent if the lease is for part time or periodic access;
- Charge a rental or lease consistent with fair market value, and which does not take into consideration the value of business or referrals between the parties; and
- Be commercially reasonable and not exceed what is necessary for the legitimate business purpose of the lease.

PHYSICIAN AGREEMENTS - POLICY STATEMENT

Federal and state anti-kickback and physician self-referral laws prohibit the offer or payment of any compensation to any party for the referral of residents. All physician agreements shall be reviewed and approved by legal counsel prior to execution to avoid violation of federal anti-kickback or self-referral laws. Similar state laws also may apply.

To comply with applicable laws regarding resident referrals, St. Mary's shall:

- Comply with the policies governing gifts set forth in this compliance manual;
- Not submit nor cause a bill or claim for reimbursement be submitted for services provided pursuant to a prohibited referral; and
- Not accept or solicit a referral from a physician to an entity in which the physician (or an immediate family member) has a financial relationship (broadly defined to encompass any ownership interest, investment interest, or compensation arrangement) for a designated health service as defined in 42 U.S.C. Part 1395nn(h)(6), except as permitted by law.

Designated health services include:

- Clinical laboratory services;
- Physical, occupational, speech therapy services;
- Radiology services, including magnetic resonance imaging (MRI); computerized axial tomography (CAT) scans, and ultrasound services;
- Radiation therapy services and supplies;
- Durable medical equipment and supplies;
- Parenteral and enteral nutrients, equipment, and supplies;
- Prosthetics, orthotics, and prosthetic devices and supplies;
- Home health services;
- Outpatient prescription drugs and outpatient hospital services.

In addition, physician agreements shall:

- Be in writing; shall be approved by legal counsel or his designee prior to execution;
- Be negotiated by legal counsel, Chief Executive Officer, the facility administrator, Board of Directors or their designees;
- Be signed by all parties;
- When taken as a whole, be reasonable in its entirety; shall specify the terms under which compensation and any other benefits are provided, and compensation and benefits shall be consistent with the fair market value of the services provided;
- Specify all obligations of the parties; shall not take into consideration the value or volume of referrals provided to St. Mary's; and
- Be for a term of at least one year.

St. Mary's also shall ensure that any physician with whom an agreement is executed, and/or who serves as an attending physician in the facility, has current valid licenses as required by law and has not been excluded from participation in the Medicare and Medicaid programs.

THERAPY CONTRACTS AND SERVICES - POLICY STATEMENT

St. Mary's is committed to providing quality therapy services and to providing only those therapy services that are reasonable and necessary to a resident's appropriate care, and consistent with government and third party payer coverage guidelines and the criteria set forth.

Physical Therapy Services - Medicare

Physical therapy services provided to Medicare residents by St. Mary's must:

- Relate directly and specifically to an active written treatment regimen established by the resident's physician after any needed consultation with the qualified physical therapist;
- Be reasonable and necessary to the treatment of the resident's illness or injury;
- Be of such a level of complexity and sophistication, or the condition of the resident must be such that the services required can be safely and effectively performed only by a qualified physical therapist or under his or her supervision. Services not requiring the performance or supervision of a physical therapist are not considered reasonable or necessary physical therapy services, even if they are performed or supervised by a physical therapist;
- Be provided pursuant to an expectation that the condition will improve significantly in a reasonable (and generally predictable) period of time based on the assessment made by the physician, or the services must be necessary to the establishment of a safe and effective maintenance program required in connection with a specific disease state; and is reasonable in terms of amount, frequency, and duration.

Occupational Therapy Services - Medicare

Occupational therapy services provided to Medicare residents by St. Mary's must:

- Be prescribed by a physician;
- Be performed by a qualified occupational therapist or a qualified occupational therapy assistant under the general supervision of a qualified occupational therapist; and
- Be reasonable and necessary for the treatment of the resident's illness or injury.
- Be provided pursuant to an expectation that the therapy will result in a significant practical improvement in the resident's level of functioning within a reasonable period of time.

Speech Therapy Services - Medicare

Speech therapy services provided to Medicare residents by St. Mary's must:

- Be reasonable and necessary to the treatment of the resident's illness or injury;
- Relate directly and specifically to a written treatment regimen established by the resident's physician after any needed consultation with the qualified speech pathologist; is considered under accepted standards of practice to be a specific and effective treatment for the resident's condition;
- Be of such a level of complexity and sophistication, or the resident's condition must be such that the services required can be safely and effectively performed only by or under the supervision of a qualified speech pathologist;
- Be provided pursuant to an expectation that the resident's condition will improve significantly in a reasonable (and generally predictable) period of time based on the assessment by the physician, or the services must be necessary to the

establishment of a safe and effective maintenance program required in connection with a specific disease state; and

- Be reasonable in terms of amount, frequency, and duration under accepted standards of practice.

Outpatient PT, OT and ST Services- Medicare

Outpatient Physical, Occupational, and/or Speech Therapy Services provided to Medicare residents by St. Mary's must:

- Provided only to residents who were or are under the care of a physician. The resident's clinical record must reflect that a physician has seen the resident at least every 30 days;
- Be provided pursuant to a written plan established by a physician, physical therapist, occupational therapist, or speech pathologist for furnishing such services, and which periodically is reviewed and ordered by the physician;
- Be required by the resident; and
- Be recertified by the resident's physician at least once every 30 days if the services continue over a period of time.

Physical/Occupational/Speech Therapy Services - Medicaid

Physical therapy services, including all necessary supplies and equipment, provided to Medicaid residents by St. Mary's must:

- Be prescribed by a physician and
- Be provided to a resident by or under the direction of a qualified physical, occupational therapist, speech pathologist or audiologist.

Outpatient PT, OT and ST Services- Medicaid

- Be prescribed by a physician and
- Be provided to a resident by or under the direction of a physical, occupational and/or a speech pathologist or audiologist.

LICENSING AND CERTIFICATION - POLICY STATEMENT

Employees who become aware of potential violations of licensing and certification requirements are to report them promptly through the Compliance Hotline or to their immediate supervisor, the administrator, or the Compliance Officer. If the perceived violation could place any resident of St. Mary's in substantial jeopardy, the employee shall immediately report directly to his or her supervisor or the administrator and to the Compliance Officer.

DEFICIT REDUCTION ACT 2005

It is the policy of St. Mary's to provide all employees and officers with detailed information regarding the False Claims Act of 2005 (S.08450/A. 12015). The program will include written policies and procedures that set forth a code of conduct, implement the compliance program, provide guidance to employees on dealing with potential compliance issues, identify how to communicate compliance issues, and describe how compliance problems of fraud and abuse are investigated and resolved.

The Compliance Officer, reporting directly to the CEO, is responsible for the day-to-day operation of the program as well as providing all employees and governing body with training and education on compliance. The program contains:

1. Provisions for anonymous reporting of compliance issues; disciplinary policies, including sanctions for failure to report, for participating in non-compliant behavior, or facilitating or permitting non-compliant behavior;
 - During new employee orientation and annually thereafter, all employees will receive in-service training on the facility's Corporate Compliance Program including information on the Deficit Reduction Act (DRA). Competency assessment is conducted upon completion of training.
2. A system to identify compliance risk areas;
 - Risk areas are identified during financial audits, chart reviews, upon notification, verbally, in writing or anonymously, during the course of an exit interview or during inspections by regulatory agencies. All complaints are thoroughly investigated by the Compliance Officer or designee and findings reported to the Corporate Audit and Corporate Compliance Committee for further action and/or recommendations.
3. A system for responding to compliance issues;
 - Once the Compliance Department is made aware of a potential corporate compliance issue, the Compliance Officer will make a determination of the most appropriate administrator or manager, with department subject matter expertise, to conduct the investigation, under the supervision of the .An investigation will be conducted that includes review of all relevant documentation, interviews with staff, managers and/or senior administration and feedback is provided to the Audit and Corporate Compliance Committee. Should the issue be of an egregious nature warranting immediate action, the Compliance Officer will request an adhoc Committee meeting. Depending on the nature of the issue, reporting to the Office of Inspector General or the Office of Professionals may be warranted.
4. A policy of non-intimidation and non-retaliation for participation in compliance program.
 - During in-service training, staff is informed of the facility's policy regarding non-intimidation and non-retaliation for providing information relevant to the corporate compliance program at St. Mary's.
 - Upon hire, all employees complete the Mandatory Program that includes St. Mary's program for corporate compliance. The employee is also provided with the Employee Handbook that contains the Employee Code of Conduct.
 - Within 30 days of hire, the employee attends the Quality Orientation Program that includes information on St. Mary's Corporate Compliance Program and DRA.
 - On an annual basis, each employee completes the Annual Mandatory Program that contains information on the facility's Corporate Compliance

Program. A competency assessment is conducted annually and placed in the employee's Human Resource file.

- Upon receipt or notification of information leading to a compliance investigation, the CCO will conduct such investigation in a totally confidential manner and will report findings to the Audit and Corporate Compliance Committee. Such investigation may include review of all relevant documentation, interviews with staff, managers and/or senior administration.
- After thorough review of all relevant facts, the CCO will provide a full report with recommendations to the Audit and Corporate Compliance Committee. In the event an issue is of a nature that requires reporting to a regulatory agency, an adhoc Committee meeting may be called and the CCO, in agreement with the Audit and Corporate Compliance Committee, will conduct such reporting.
- Should an investigation warrant the dismissal of an employee, the VP for that division is notified and informs the employee of said actions. The employee is required to return all property of St. Mary's and report to Human Resources for benefit information.
- A summary of the corporate compliance inquiries are reported to the Audit and Corporate Compliance Committee and Quality Forum and is reviewed by the Board of Directors.

Annual Compliance Certifications

Under New York State Social Services Law §363-d and 18 NYCRR Part 52, and under the Federal Deficit Reduction Act (DRA), St. Mary's must certify its Compliance Program annually by submitting certification forms to the Office of the Medicaid Inspector General. St. Mary's will submit such certifications in December of each year.

For the New York State requirements, St. Mary's must certify that it has an "effective compliance program" such that the compliance program meets the requirements of the Mandatory Compliance Law, incorporating the eight core elements of an effective compliance program as found in the Social Services Law and NYCRR sections noted above. They are as follows:

(1) written policies and procedures that describe compliance expectations as embodied in a code of conduct or code of ethics, implement the operation of the compliance program, provide guidance to employees and others on dealing with potential compliance issues, identify how to communicate compliance issues to appropriate compliance personnel and describe how potential compliance problems are investigated and resolved;

(2) designate an employee vested with responsibility for the day-to-day operation of the compliance program; such employee's duties may solely relate to compliance or may be combined with other duties so long as compliance responsibilities are satisfactorily carried out; such employee shall report directly to the entity's chief executive or other senior

administrator designated by the chief executive and shall periodically report directly to the governing body on the activities of the compliance program;

(3) training and education of all affected employees and persons associated with the provider, including executives and governing body members, on compliance issues, expectations and the compliance program operation; such training shall occur periodically and shall be made a part of the orientation for a new employee, appointee or associate, executive and governing body member;

(4) communication lines to the responsible compliance position, as described in paragraph (2) of this subdivision, that are accessible to all employees, persons associated with the provider, executives and governing body members, to allow compliance issues to be reported; such communication lines shall include a method for anonymous and confidential good faith reporting of potential compliance issues as they are identified;

(5) disciplinary policies to encourage good faith participation in the compliance program by all affected individuals, including policies that articulate expectations for reporting compliance issues and assist in their resolution and outline sanctions for:

- (i) failing to report suspected problems;
- (ii) participating in non-compliant behavior; or
- (iii) encouraging, directing, facilitating or permitting either actively or passively non-compliant behavior;

such disciplinary policies shall be fairly and firmly enforced;

(6) a system for routine identification of compliance risk areas specific to the provider type, for self-evaluation of such risk areas, including but not limited to internal audits and as appropriate external audits, and for evaluation of potential or actual non-compliance as a result of such self-evaluations and audits, credentialing of providers and persons associated with providers, mandatory reporting, governance, and quality of care of medical assistance program beneficiaries;

(7) a system for responding to compliance issues as they are raised; for investigating potential compliance problems; responding to compliance problems as identified in the course of self-evaluations and audits; correcting such problems promptly and thoroughly and implementing procedures, policies and systems as necessary to reduce the potential for recurrence; identifying and reporting compliance issues to the department or the office of Medicaid inspector general; and refunding overpayments;

(8) a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, self-evaluations, audits and remedial actions, and reporting to appropriate officials as provided in sections seven hundred forty and seven hundred forty-one of the labor law.

This certification will be prepared by the Compliance Officer, but in accordance with OMIG recommendations, the Chief Executive Officer or other senior executive shall execute the certification.

For the DRA requirements, St. Mary's must establish and disseminate detailed written policies regarding:

- the federal False Claims Act; the New York State False Claims Act;
- the specific statutory and regulatory provisions named in section 1902(a)(68)(A) of the Social Security Act;

- any other applicable state civil or criminal laws and state and federal whistleblower protections; and
- information regarding the health care entity's policies and procedures for detecting and preventing waste, fraud and abuse to all employees (including management), contractors or agents of the health care entity.

Written policies may be on paper or in electronic form, but must be readily available to all employees, contractors, or agents of the health care entity.

The St. Mary's Employee Handbook must include

- a specific discussion of the laws described in the written policies,
- the rights of employees to be protected as whistleblowers and
- a specific discussion of St. Mary's policies and procedures for detecting and preventing fraud, waste, and abuse.

The annual certification indicates that St. Mary's maintains the written policies noted above, and that the employee handbook includes materials, required under the above mandates and that they have been properly adopted and published by the health care entity, and disseminated among employees, contractors and agents.

The DRA certification shall be prepared by the Compliance Officer, and shall be executed by the Compliance Officer, or other individual with oversight responsibility for DRA compliance.

Billing and Cost Reports - Policy Statement

St. Mary's is committed to prompt, complete, and accurate billing of all services provided to residents for payment by residents, government agencies, or other third party payers. Billing shall be made only for services actually provided, directly or under contract, pursuant to all terms and conditions specified by the government or third party payer and consistent with industry practice.

St. Mary's and its employees shall not make or submit any false or misleading entries on any bills or claim forms, and no employee shall engage in any arrangement, or participate in such an arrangement at the direction of another employee (including any officer of St. Mary's or a supervisor), that results in such prohibited acts. Any false statement on any bill or claim form or in the medical record shall subject the employee to disciplinary action by St. Mary's, including possible termination of employment.

False claims and billing fraud may take a variety of different forms, including, but not limited to, false statements supporting claims for payment, misrepresentation of material facts, concealment of material facts, or theft of benefits or payments from the party entitled to receive them. St. Mary's and employees shall specifically refrain from engaging in the following billing practices:

- Making claims for items or services not rendered or not provided as claimed (such as billing for "Pass-through" medications that were not provided);

- Submitting claims to Medicare Part A for residents who are not eligible for Part A coverage; in other words, who do not require services that are so complex that they can only be effectively and efficiently provided by, or under the supervision of, professional or technical personnel;
- Submitting claims to any payer, including Medicare or Medicaid, for services or supplies that are not medically necessary or that were not ordered by the resident's physician or other authorized caregiver;
- Submitting claims for items or services that are not provided as claimed;
- Submitting claims to any payer, including Medicare and Medicaid, for individual items or services when such items or services either are included in the health facility's per diem rate for a resident or are of the type that may be billed only as a unit and not unbundled;
- Double billings (billing for the same item or service more than once);
- Providing inaccurate or misleading information including but not limited to misrepresenting a resident's medical condition on the minimum data set (MDS);
- Paying or receiving anything of financial benefit in exchange for Medicare or Medicaid referrals or
- Billing residents for services or supplies that are included in the per diem payment from Medicare, Medicaid, a managed care plan, or other payer.

If an employee has any reason to believe that anyone (including the employee himself or herself) is engaging in false billing practices, that employee shall immediately report the practice to his or her immediate supervisor, the anonymous Compliance Hotline, the Compliance Officer or any of the officers designated to receive such report verbally or in writing. Failure to act when an employee has knowledge that someone is engaged in false billing practices shall be considered a breach of that employee's responsibilities and shall subject the employee to disciplinary action by St. Mary's, including possible termination of employment.

COST REPORTING - POLICY STATEMENT

St. Mary's is required to submit various cost reports to federal and state governments in connection with its operation and to receive payment. Such reports will be prepared as accurately as possible and in conformity with applicable law and regulations. If errors are discovered, billing personnel shall contact an immediate supervisor promptly for advice concerning how to correct the error(s) and notify the appropriate payer.

In the preparation of cost reports or home office cost statements for Medicare or Medicaid, all employees involved in the preparation shall ensure that:

- Information provided for or used in the cost report is adequately supported by documentation;
- Non-allowable costs are properly identified and removed;
- Statistics are based on reliable information;
- Related parties are identified and their services treated in accordance with program rules; and

- Costs claimed in nonconformity with program rules, as interpreted by the Medicare or Medicaid program or the fiscal intermediary, either are disclosed in a letter accompanying the cost report or are included in protested amounts.

RECORD KEEPING AND DOCUMENTATION - POLICY STATEMENT

The OIG recommends that each provider appoint a Compliance Officer to serve as the focal point for all compliance activities. This individual should have sufficient authority to implement and enforce the compliance program; have direct access to the Board of Directors, Chief Executive Officer, Administrator, and key management personnel; have access to key documents, including resident, billing, and marketing records; and have sufficient staff and funding to carry out the compliance functions.

Accurate and complete record keeping and documentation is critical to virtually every aspect of St. Mary's operations. It is the policy of St. Mary's that all documentation shall be timely, accurate, and consistent with applicable professional, legal, and facility guidelines and standards. This includes all aspects of the facility's documentation, including resident assessments and care plans, clinical records, and all billing and payment documentation. Falsification of records is strictly prohibited, including backdating of records, with the exception of appropriate late entries duly noted and under applicable professional and legal standards. All records will be maintained on file by the Compliance Officer for a period of no less than three years.

HEMOCARE – POLICY STATEMENT

Home Care contracts with vendors and/or other contractors will be made in good faith and will be of fair market value.

Contracts must:

- Be in writing, signed by the parties, and cover only identifiable items or services;
- Specify the timeframe for the contract, which can be for any period, and contain a termination clause;
- Specify the compensation which must be set in advance, must be consistent with fair market value, and cannot take into account referrals or payment for referrals for medical services that are covered by Medicare or Medicaid, or any other business generated between the parties;
- Involve a transaction that is commercially reasonable and furthers the legitimate business purposes of the parties;
- Not violate the Anti-Kickback Statute.

Discounts

Discounts must be made at the time of the sale. If an item or service is claimed separately for payment, the discount must be reported. Information about the amount of discount will be provided to Medicare and/or Medicaid on request.

Gifts

Gifts from vendors or healthcare companies could be considered a kickback under the Anti-Kickback Statute. Soliciting or receiving kickbacks, bribes or rebates in return for referring residents for Medicare/Medicaid-covered services or for buying an item or service covered by Medicare/Medicaid, is expressly prohibited.

De minimis Compensation

Small items and things of minimal value may be accepted from companies that are contracted vendors—such as coffee mugs, pens. Gifts must not be offered or received in circumstances where it could appear that the purpose of the gift is to improperly influence the organization’s relationship with a vendor, regulator, or other person or entity.

Space Rental

Leases must be written and signed for a period of at least one year, have a specified location, have the rent set in advance, charge rent at fair market value, and not be linked to referrals.

Equipment Rental

The same terms apply as for space rental, and the equipment must be specified in the lease.

Warranties

Materials Management can accept warranties from manufacturers and suppliers. Warranties can only be for goods, not services.

Materials Management must:

- Report as part of a claim or cost report any price reduction or free item obtained under warranty;
- Provide on request to the Department of Health and Human Services, or to a State agency, the manufacturer’s warranty information.

VENDOR AGREEMENTS

The following language must be added to all vendor, MD, PC, and independent contractor agreements:

[Name of Entity] hereby warrants and represents that [Name of Entity] has not been subject to any adverse action by any state licensing board, professional disciplinary or enforcement agency and has never been suspended, excluded or terminated from participation in the Medicare, Medicaid and/or other Federal health care programs.

[Name of Entity] hereby warrants and represents that [Name of Entity] shall abide by the terms and conditions of St. Mary’s Healthcare System for Children Code of Conduct.

[Name of Entity] shall defend, indemnify and hold harmless St. Mary’s Healthcare System for Children, their officers, employees and agents from and against all claims, losses, damages or liabilities (including attorney’s fees) in connection with [Name of Entity’s] breach of the representations and warranties contained in paragraphs as outlined above. This paragraph shall survive termination of this Agreement.

TRAINING/MONITORING

The CCO (Compliance Officer) shall review and – when the CCO determines that it is reasonable to do so – disseminate to the appropriate parties i.e. the Department of Health and Human Services’ (HHS) Office of Inspector General’s (OIG) monthly program exclusion listing published in the Federal Register. The CCO will also regularly review and disseminate new statutes, regulations, pronouncements, or directives of the federal or state government, the government’s fiscal intermediary, any third-party payers, or any homecare association or trade publication that might affect these standards.

The CCO shall also monitor this homecare program’s continued compliance with the terms and conditions set forth in any settlement agreement that might be executed by this agency with the federal or state government.

REPORTING VIOLATIONS

It is the duty of each employee to promptly report any suspected violations of these standards to the CCO.

St. Mary’s Healthcare System for Children Homecare Program is organized for the promotion of the health of the individuals provided this service. This agency, its board, officers, employees, and agents hereby express the following commitments to:

- The Community: This homecare program is committed to the promotion of health and to using the agency’s best efforts to satisfy the medical needs of the community while operating in a fiscally responsible manner.
- This homecare program’s employees: This program will implement and maintain employment practices and programs that comply with all applicable federal and state laws.
- This homecare program’s residents: This program is committed to providing appropriate quality of care, consistent with the agency’s facilities and resources, that is responsive to resident needs and complies with government laws and resources. This agency is also committed to maintaining accreditation by the NYS Department of Health is required.
- Third-party payers, both private and public: This homecare program is committed to submitting bills for resident services in a timely and accurate fashion and reporting all reimbursable costs to the Medicare and Medicaid program and to any other third party in a legally appropriate manner.
- This homecare program’s suppliers: This program stresses a sense of responsibility that enables it to be a good customer. It is committed to being fair and equitable.
- All who do business with this homecare program: This program shall conduct its business in a manner that is consistent with all applicable laws and regulations.

It is the policy of St. Mary’s to comply with all applicable Federal, state, and local laws and regulations—both civil and criminal. No employee has any authority to act contrary to the provision of the law or to authorize, direct, or condone violations offered by any other employee. Any employee or agent of St. Mary’s who has knowledge of facts concerning this

program's activities that he or she believes might violate the law has an obligation, promptly after learning such facts, to report the matter to his or her immediate superiors or to the Compliance Officer (CCO).

The CCO will take steps to effectively communicate its standards and procedures to all employees and agents by requiring participation in training programs and by disseminating publications that explain in a practical manner what is required. To achieve compliance with its standards, the homecare program will employ monitoring and auditing systems that are reasonably designed to detect illegal activity by its employees and agents. The program will also implement and publicize a reporting system that employees and other agents can use, without fear of retribution, to report criminal conduct within the program.

This compliance policy will be consistently enforced through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect an offense and those individuals who actually committed or conducted an offense. The appropriate form of discipline will be case-specific.

After an offense has been detected, the program will take all reasonable steps to respond appropriately to the offense and to prevent further similar offenses including any necessary modifications to detect and to prevent violations of law.

MANDATORY SELF-DISCLOSURE AND REPAYMENT OF OVERPAYMENTS – POLICY STATEMENT

Self-disclosure is the process whereby a facility informs the government it has billed the government for services or items for which the facility was not permitted by statute or regulation to bill. Depending on the issue and the payor, self-disclosures can be made to the US Department of Justice, US Department of Health and Human Services Office of Inspector General (OIG), US Centers for Medicare and Medicaid Services (CMS) or the NYS Office of Medicaid Inspector General (OMIG). OIG, CMS and OMIG have self-disclosure protocols available on their websites. A determination of the correct agency to direct a self-disclosure shall be made by the Compliance Officer in consultation with legal counsel.

Self-disclosure and repayment of overpayments within 60 days of identification has become mandatory for Medicare and Medicaid providers under section 6402(a) of the Affordable Care Act (ACA) of 2010 and a mandatory part of New York State compliance programs under 18 NYCRR §521.

When a possible overpayment is discovered, a prompt and thorough investigation shall be conducted by the Compliance Officer, and may include the participation of the Finance Department and any department(s) responsible for the program under which the possible incorrect payment was received. Such participation shall be at the discretion of the Compliance Officer.

The Compliance Officer shall review the investigation findings and determine whether a self-disclosure is indicated in accordance with Federal and/or State requirements. If a self-disclosure is warranted, the Compliance Officer shall work with legal counsel to prepare the

self-disclosure documents in accordance with relevant agency protocols. The Chief Executive Officer shall be notified of this action prior to submission, and the Audit and Compliance Committee shall be notified of this action at the next Committee meeting, or earlier if deemed necessary by the Compliance Officer or Chief Executive Officer.

If a self-disclosure is not required but a refund of an overpayment is still necessary, the Compliance Officer shall work with the Finance Department to make such refund, and a report of the investigation and manner in which the refund was made shall be recorded by the Finance Department and reported to the Audit and Compliance Committee by the Compliance Officer.

CHAPTER FIVE

HEALTH INSURANCE PORTABILITY & ACCOUNTABILITY ACT (HIPAA)

The United States Department of Health and Human Services has passed comprehensive privacy regulations that implement and enforce the requirements of HIPAA. The requirements were established by the federal law known as the Health Insurance Portability and Accountability Act of 1996 (HIPAA). These regulations went into effect as of April 14, 2003 and replace existing federal and state laws that currently protect patient/residents' privacy, but will interact with the existing laws. St. Mary's policies will reflect this interaction and establish requirements for health care professionals and program staff.

The HIPAA privacy regulations are concerned with controlling the use and disclosure of a resident's health information where the information could potentially reveal the identity of the resident. This type of health information is referred to as "Protected Health Information" or "PHI." HIPAA regulates the use and disclosure of PHI by health care providers, health plans, and health care clearinghouses (which are entities that process or facilitate the processing of nonstandard data elements of health information into standard data elements, or vice versa). HIPAA generally prohibits health care providers, from using or disclosing PHI except as authorized by St. Mary's resident who is the subject of the information, or as permitted or required by the regulations. The privacy regulations, however, do not regulate or restrict St. Mary's use or disclosure of health information that is "de-identified" so that it no longer has the potential to reveal the identity of the resident.

With the exception of certain types of information, St. Mary's may use and disclose PHI for treatment, payment and business operations if it has obtained a general written consent form from the patient/resident that will cover these activities on an ongoing basis. A specific authorization form is not required every time these activities are performed.

As a result, once St. Mary's has obtained the patient/resident's general written consent, information may be shared between program staff members where necessary for those individuals to provide treatment or care to the resident, obtain payment for the treatment or care and carry out business operations of the program. Information may also be shared with health care professionals for the same purposes if the health care professionals are part of an "organized health care arrangement" - which is discussed below.

In addition, St. Mary's may disclose PHI without a St. Mary's patient/resident's consent or authorization to further certain public policy objectives, including:

- Where disclosure is required by law;
- For a judicial or administrative proceeding;
- For public health activities;
- For health oversight activities;
- To report incidents of abuse, neglect or domestic violence;
- For law enforcement purposes;
- To avert a serious threat to health or safety;
- For national security, intelligence activities and protective services;
- To facilitate organ, eye or tissue donation; and to coroners, medical examiners, and funeral directors.

Certain types of information receive special protection. Under HIPAA, psychotherapy notes – which are notes by a mental health professional that document or analyze the contents of a counseling session and are kept separate from the medical record – are subject to heightened protection so that their use and disclosure generally requires specific authorization from the patient/resident. HIPAA also generally provides special protection to those types of information that have special protection under state law. New York provides special protection to mental health information, HIV-related information, alcohol and substance abuse treatment information and genetic information.

PHI may be used or disclosed for research purposes only: (i) with resident authorization; (ii) after an IRB or privacy board approves the alteration or waiver of resident authorization; (iii) by/to a researcher for reviews preparatory to research; or (iv) by/to a researcher for research on the PHI of deceased persons.

As a general rule, St. Mary's must take reasonable steps to limit the PHI that it uses and discloses, or that it requests from others, to the minimum amount that is necessary to accomplish the purpose of the use, disclosure, or request. This rule, however, does not apply when St. Mary's is disclosing or requesting PHI for treatment purposes, or when St. Mary's is using or disclosing PHI in a manner that is required by law.

Legally separate health care providers that are clinically or operationally integrated may designate themselves as an "organized health care arrangement." For example, St. Mary's may be part of an organized health care arrangement with outside health care professionals who provide treatment or care to residents within the clinically integrated St. Mary's setting. As members of an organized health care arrangement, St. Mary's staff and health care professionals are permitted to share PHI for the health care operations of their joint enterprise, and may develop and use a joint notice of privacy practices covering all PHI created or received in connection with their joint enterprise.

St. Mary's has adopted policies and procedures to implement certain administrative requirements designed to protect the privacy of PHI, including:

Designation of a privacy officer, who will in turn oversee the development, implementation and enforcement of St. Mary's privacy policies and procedures;

Employee training about St. Mary's privacy policies and procedures; and

Sanctions for employees who fail to follow St. Mary's privacy policies and procedures.

The privacy regulations also require that the program limit its employees' access to PHI. Specifically, the program may permit access to PHI only by those employees with a "need to know" this information. Moreover, the program to the extent feasible will permit such employees to access only the information that is relevant to their job responsibilities.

The privacy regulations grant St. Mary's patient/residents the following rights regarding their PHI:

The right to notice of St. Mary's privacy practices for PHI.

This notice must (i) generally explain the purposes for which St. Mary's may use and disclose the resident's PHI, (ii) inform the resident of his or her rights with respect to his or her PHI, and

(iii) explain St. Mary's legal duties under HIPAA. St. Mary's makes a good faith effort to obtain a resident's written acknowledgement that he or she has received this notice of privacy practices. The right to inspect and obtain a copy of their PHI.

The right to request amendment or correction of their PHI.

The right to receive an accounting list that provides information about disclosures of their PHI that were made to third parties for purposes other than treatment, payment and health care operations.

The right to request that St. Mary's further restrict the way it uses or discloses their PHI.

The right to request that St. Mary's communicate with them or with their personal representatives by alternative means or at alternative locations. St. Mary's must accommodate all reasonable requests.

If a person or organization will create or receive PHI in order to perform an activity, function or service for St. Mary's, that entity will be considered a "business associate" of St. Mary's. Examples of business associates include billing services companies and transcription companies. Under the HIPAA privacy regulations, St. Mary's is required to enter into a contract with each business associate. The contract must include certain specific provisions to ensure that the business associate limits its uses and disclosures, and adequately safeguards the privacy, of the PHI that it receives from, or creates for, St. Mary's.

St. Mary's can generally share PHI with other health care providers where St. Mary's has obtained a general written consent from the resident and the information is being shared so that St. Mary's or other health care provider can provide treatment to the resident or collect payment for that treatment. St. Mary's may also share PHI with other health care providers for certain health care operations (such as quality assurance, utilization review, or accreditation) as long as the resident health care provider is required to comply with the HIPAA privacy regulations and the information relates to a relationship the provider has or had with the resident.

HIPAA provides civil penalties for a failure to comply with the privacy regulations. The United States Department of Health and Human Services may impose civil monetary penalties of up to \$100 for each violation (capped at \$25,000 per person/entity per year for each standard violated). In addition, HIPAA provides for criminal penalties for intentionally obtaining or disclosing PHI in violation of the privacy regulations. Criminal sanctions may be imposed up to \$250,000 and 10 years in prison.

CONFIDENTIALITY OF PROTECTED HEALTH INFORMATION

This policy applies to all St. Mary's staff members and health care professionals providing care at St. Mary's. St. Mary's staff members include all employees, students, trainees, residents, interns, volunteers, consultants, contractors and subcontractors at St. Mary's. Health care professionals include physicians, allied health professionals and other licensed health care professionals providing treatment or care to residents in St. Mary's, regardless of whether they are employees.

St. Mary's is committed to protecting the privacy and confidentiality of health information about its residents. Protected health information is strictly confidential and should never be given, nor confirmed to anyone who is not authorized under St. Mary's policies or applicable law to receive this information.

A. Definition of Protected Health Information

For purposes of this policy, the term "protected health information" means any information, including very basic information such as name or address, that (1) relates to the past, present, or future physical or mental health or condition of a patient/resident, the provision of health care to the resident, or the past, present, or future payment for the provision of health care to the resident, and (2) either identifies the resident or could reasonably be used to identify the resident.

This policy applies to protected health information in any form, including spoken, written, or electronic form. It is the responsibility of every staff member and health care professional at St. Mary's to protect the privacy and preserve the confidentiality of all protected health information. This includes, but is not limited to, compliance with the protective procedures below.

B. Public Viewing/Hearing

St. Mary's staff and health care professionals providing care at St. Mary's are expected to keep protected health information out of public viewing and hearing. For example, protected health information should not be left in conference rooms, out on desks, or on counters or other areas where the information may be accessible to the public or to other employees or individuals who do not have a need to know the protected health information. St. Mary's staff and health care professionals providing care at St. Mary's should also refrain from discussing protected health information in public areas, such as elevators and reception areas, unless doing so is necessary to provide treatment to one or more residents. St. Mary's staff and health care professionals should also take care in sharing protected health information with families and friends of residents. Such information may generally only be shared with a personal representative in accordance with the advance directives as designated by the resident or the resident's legal representative. Information cannot be disclosed unless the resident has had an opportunity to agree or object to the disclosure, and St. Mary's staff and health care professionals may only disclose information that is relevant to the involvement of that family member, relative or close personal friend in the resident's care or payment for the resident's care, as the case may be.

C. Databases and Workstations

St. Mary's staff and health care professionals providing care at St. Mary's are expected to ensure that they exit any confidential database upon leaving their workstations so that protected health information is not left on a computer screen where it may be viewed by individuals who are not authorized to see the information. St. Mary's staff and health care professionals are also expected not to disclose or release to other persons any item or process which is used to verify their authority to access or amend protected health information, including but not limited to, any password, personal identification number, token or access card, or electronic signature. Each St. Mary's staff member and health care professional will be liable for all activity occurring under his or her account, password and/or electronic signature. These activities may be monitored.

D. Downloading, Copying or Removing

St. Mary's staff and health care professionals providing care at St. Mary's should not download, copy or remove from St. Mary's any protected health information, except as necessary to perform their duties at St. Mary's. Upon termination of employment or contract with St. Mary's, or upon termination of authorization to access protected health information, St. Mary's staff members and health care professionals must return to St. Mary's any and all copies of protected health information in their possession or under their control.

E. Emailing and Faxing Information

St. Mary's staff and health care professionals should not transmit protected health information over the Internet (including email) and other unsecured networks unless using a secure encryption procedure. Transmission of protected health information is permitted by fax only if St. Mary's staff member or health care professional sending the information ensures that the intended resident is available to receive the fax as it arrives, or confirms that there is a dedicated fax machine that is monitored for transmission of sensitive information. St. Mary's staff and health care professionals providing care at St. Mary's should use fax cover sheets that include standard confidentiality notices, and should request that the recipient call back upon receipt of the fax.

PRIVACY RIGHTS OF MINORS

St. Mary's staff and health care professionals providing care at St. Mary's should note that individuals under the age of 18 are emancipated from the care of a parent or guardian if they are married or have children, or have been determined emancipated by a court. A pregnant individual under the age of 18 is considered emancipated with respect to medical, dental, health, and program services relating to prenatal care. *Emancipated individuals will be afforded the same privacy rights as all adults in accordance with all other St. Mary's policies.*

As a general rule, only the parent, guardian or other person acting in the place of a parent (collectively referred to as "parents or guardians") has the authority to control, access and protect the confidentiality of protected health information about a minor. In limited circumstances,

however, a minor will have the authority to exercise these rights on his or her own behalf. St. Mary's staff and health care professionals providing care at St. Mary's are expected to protect the privacy of health information about minors in accordance with the procedures below.

A. General Rule Control by Parent or Guardian

Parents or guardians ordinarily have the authority to control the health information of a minor by exercising the rights granted to a resident concerning his or her health information. For example, a parent or guardian typically has the authority to do the following:

- Sign a consent form permitting St. Mary's to use and disclose the minor's information for treatment, payment and health care operations;
- Sign an authorization form permitting the use and disclosure of the minor's information for other purposes;
- Object to use and disclosure of the minor's information in St. Mary's directory, or to friends and family involved in the minor's health care;
- Inspect or copy the minor's information;
- Request amendment of the minor's information;
- Request an accounting of disclosures of the minor's information;
- Request additional privacy protections, including confidential communications, with respect to the minor's information;
- Request a copy of the program's Notice of Privacy Practices;
- File privacy complaints with St. Mary's or with the United States Department of Health and Human Services.

B. Exception to General Rule: Minor's Authority to Exercise Privacy Rights

There are exceptions to the general rule under which the minor is permitted to exercise the privacy rights of this policy on his or her own behalf. These exceptions are described further below:

1. When the minor may lawfully obtain a health care service without the consent of a parent, guardian or other person acting *in loco parentis*, and the minor, a court, or another person authorized by law consents to such health care service. When law requires only the consent of the minor, the minor has the authority to exercise his or her own privacy rights even if a parent or guardian has also consented to the health care service or the minor has voluntarily chosen to involve the parent or guardian in his or her health care.

EXAMPLE: All minors may be diagnosed and treated for a sexually transmissible disease without the consent or knowledge of a parent or guardian. If a minor at St. Mary's needs treatment for any of the aforementioned diseases, the minor is permitted to exercise the privacy rights provided in Section A of this policy. This is true even if the parent or guardian has also consented to such treatment.

2. When a parent, guardian, or other person acting in loco parentis agrees to confidentiality between St. Mary's and the minor with respect to a particular health care treatment or service.

Although minors are permitted to exercise the privacy rights as listed in the aforementioned section, *minors are not always permitted to exercise those rights to prevent disclosures of their protected health information to parents or guardians.* Unless an exception is specified, St. Mary's staff members should continue to follow already established policies addressing parental access to a minor's protected health information. These policies establish specific standards, in accordance with state and federal law, for (1) *disclosure of a minor's health information to parents and guardians* (for example, through conversations with parents or guardians in person or over the phone), and for (2) response to requests by parents or guardians to inspect or obtain copies of records containing a minor's protected health information.

EXAMPLE: St. Mary's staff and health care professionals providing care at St. Mary's should follow other St. Mary's policies when they authorize St. Mary's to disclose a minor's health information to a parent or guardian. A minor cannot exercise the rights provided in Section A to prevent St. Mary's from making such disclosure.

EXAMPLE: St. Mary's staff and health care professionals providing care at St. Mary's should follow other St. Mary's policies that permit St. Mary's to deny a parent or guardian's request to access the protected health information of a minor over the age of 12 when the minor objects to such access by the parent or guardian.

In all cases, disclosure to, or access by, a parent to or guardian to the minor's protected health information should be decided by a licensed health care professional within St. Mary's. The licensed health care professional should make a decision in accordance with the procedures set forth in St. Mary's other policies addressing the relationship between minors and their parents or guardians, unless an exception in Section B of this policy applies.

3. Abuse, Neglect, Mistreatment or Endangerment

Regardless of any other St. Mary's policy to the contrary, a licensed health care professional at St. Mary's may deny a parent or guardian the authority to exercise the privacy rights of a minor if he or she:

- Reasonably believes that the minor (1) has been or may be subjected to violence, abuse or neglect by the parent or guardian, or (2) could be endangered if the parent or guardian is treated as a personal representative, and

- Decides, using his or her professional judgment, that it is not in the best interest of the minor to treat the parent or guardian as a personal representative.

In such situations, the licensed health care professional may refuse to disclose the minor's protected health information to the parent or guardian (e.g., in person or over the phone) and may deny the parent or guardian's request to inspect or copy the minor's protected health information. Rather, the minor has the *sole authority* to control the privacy of his or her information.

HIPAA PRIVACY AND DISCLOSURES IN EMERGENCY SITUATIONS

It is the policy of St. Mary's to provide accessibility to resident's health care information when attempting to contact family/caregivers in the event of an emergency situation in accordance with the HIPAA Privacy Rule. The sharing of resident health information during an emergency situation will be under the direction of the Administrator (Incident Commander) or the alternate Administrator on duty at the time of the emergency.

1. St. Mary's will share the resident's private health information as necessary with other providers and/or agencies as necessary to provide treatment.

Treatment includes:

- Sharing information with other hospitals or clinics.
- Referring residents for treatment.
- Coordinating resident care with emergency relief workers or others that can help in finding appropriate health services.
- Resident's information may be shared to the extent necessary to seek payment for these health care services.

2. Notification includes:

- Locating and notifying family members, guardians, or anyone else responsible for the resident's care, location, condition or death.
- Notifying the police, press or the public at large to help locate, identify or otherwise notify family members and others as to the location and condition of their child.

3. Imminent danger includes:

- Sharing resident information with anyone as necessary to prevent or lessen a serious and imminent threat to the health and safety of a person or the public – consistent with applicable law and ethical conduct.

4. Facility Directory includes:

- Maintaining a directory of residents to provide family members or guardians with information of the location of the resident and general condition.

Note: The HIPAA Privacy Rule does not apply to disclosures if they are not made by entities covered by the Privacy Rule. Thus, for instance, the HIPAA Privacy Rule does not restrict the American Red Cross from sharing resident information.

There are certain circumstances, such as a medical emergency, under which St. Mary's may provide treatment to a minor without the consent or other written permission of a parent or guardian. In these circumstances, the parent or guardian nevertheless retains the authority to control the privacy of the minor's protected health information. For example, if a ten-year-old disabled resident suffers from a seizure, he may be provided with emergency treatment without the consent of a parent or guardian. St. Mary's staff would not, however, be permitted to treat the ten year old resident as having independent authority to exercise his or her privacy rights (and thereby, for example, allow the boy to object to the use of his information in St. Mary's directory). The boy's parent or guardian has the authority to exercise the boy's privacy rights, and St. Mary's staff should obtain appropriate consents or authorizations from the parent or guardian as soon as practicable after the medical emergency has ended.

PRIVACY OFFICER JOB DESCRIPTION

The Privacy Officer reports directly to the Chief Executive Officer and works in conjunction with the Chief Executive Officer, Chief Administrative Officer, and facility Administrator. The Privacy Officer is responsible for overseeing the development and implementation of the program's policies, procedures and systems for protecting the privacy of health information, maintained by the program or its business associates, that has the potential to reveal the identity of patient/residents ("protected health information"). Specific duties and responsibilities are as follows:

Other responsibilities of the Privacy Officer include developing and implementing the program's policies and procedures for protecting the privacy of protected health information. At a minimum, this includes:

- Overseeing the development and implementation of formal written policies and procedures relating to the privacy of protected health information.
- Ensuring that the program has and maintains appropriate forms and notices necessary to comply with federal and state health information privacy laws, rules and regulations.
- Overseeing the development and implementation of, standards for limiting the program's uses and disclosures of, and requests for, protected health information to the minimum amounts necessary to accomplish the purposes of such uses, disclosures and requests.
- Working with program administration to develop administrative, technical and physical safeguards to protect the privacy of protected health information.
- Working with the program's Security Officer to coordinate and align the program's policies and practices on privacy and security of protected health information.
- Identifying Business Associates of the program and participating in the development and implementation of all Business Associate Agreements to ensure that all privacy concerns, requirements, and responsibilities under the program's policies, and under applicable law, are addressed.

Privacy Training, Awareness and Consultation. The Privacy Officer is responsible for developing and implementing the program's privacy training and awareness programs. At a minimum, this includes:

- Overseeing and ensuring the delivery of initial and periodic follow-up privacy training to all employees, volunteers, health care professionals, business associates and other appropriate third parties.
- Promoting information privacy awareness among all program departments, staff members and business associates.
- Serving as a member of, or liaison to, the program's IRB or Privacy Board (as applicable).
- Serving as information privacy consultant for all program departments, staff members and business associates.

Response to Resident Requests and Requests by Certain Third Parties. The Privacy Officer is responsible for overseeing the program's response to resident requests related to the privacy of their protected health information. The Privacy Officer also oversees the program's response to court and administrative orders, or requests by law enforcement officers, seeking access to records that may contain protected health information. At a minimum, this includes:

- Overseeing the program's response to resident requests for access to or amendment of resident records that include protected health information.
- Overseeing the program's response to resident requests for accountings of disclosures of protected health information.
- Overseeing the program's response to resident requests for restrictions on program uses and disclosures of protected health information.
- Overseeing the program's response to resident requests for confidential communications.
- Overseeing the program's response to court orders, subpoenas, or administrative requests seeking access to protected health information.
- Overseeing the program's response to any requests for the release of protected health information to law enforcement officers or federal officials conducting national security and intelligence activities.

Compliance Monitoring, Investigation and Enforcement. The Privacy Officer is responsible for monitoring ongoing compliance with the program's privacy policies and procedures. He or she is also responsible for investigating and responding to privacy complaints and violations. At a minimum, this includes:

- Performing initial and periodic information privacy risk assessments, audits and related ongoing compliance monitoring activities.
- Establishing and administering a process for receiving, documenting, tracking, investigating and responding to all complaints concerning the content of the program's privacy policies and procedures or the program's compliance with those policies and procedures.

- Developing and implementing a process for mitigating any harmful effect of an unauthorized use or disclosure of protected health information that is known to the program.
- Establishing and administering sanctions applicable to all program staff, and all business associates of the program, who fail to comply with the program's privacy policies.
- Cooperating with the Office of Civil Rights and other governmental agencies or accrediting organizations during any compliance review or investigation of the program's privacy policies or practices.
- Working with legal counsel and program administration to oversee modifications of the program's model Business Associate Agreement for specific contractors.

New Developments in Health Information Privacy Law. The Privacy Officer is responsible for monitoring new developments in health information privacy law. At a minimum, this includes:

- Working with legal counsel and the program's Security Officer to review new or revised health care laws, regulations and accreditation standards pertaining to the privacy of resident health information to determine whether establishment of new program policies, or modification of current program policies, are needed.
- Working with program administration and legal counsel to represent the program's interests before federal, state or local governments that undertake to adopt or amend privacy legislation, regulations or standards.

DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR FUNDRAISING ACTIVITIES

Fundraising activities include any activities undertaken to raise money or other things of value on behalf of St. Mary's or another organization. This policy applies to any fundraising activities undertaken by St. Mary's, St. Mary's staff (including volunteers), health care professionals providing care to residents at St. Mary's, St. Mary's business associates or St. Mary's foundation. Examples of fundraising activities include:

- Requests for general donations to benefit St. Mary's;
- Requests for special-purpose donations (for example, to benefit Alzheimer's research or to remodel a reception area);
- Requests for sponsorship of St. Mary's events or activities (for example, a charity dinner); and
- Auctions, rummage sales, or bake sales.

The fundraising activities are subject to this policy only if the activities involve the use or disclosure of resident information. Donation requests directed at residents would involve the use of resident information, while rummage sales conducted by St. Mary's volunteers and open to the general public (and for which invitations have not been sent or given to residents) would not.

Different requirements apply to the use and disclosure of protected health information about residents in connection with different types of fundraising activities. Some fundraising activities to benefit the program may be conducted as long as only limited resident information is used and the resident has an opportunity to opt out of future fundraising communications. Other fundraising activities require the resident's authorization before being undertaken. Proposed fundraising activities must therefore be examined to determine (1) what type of activity is involved and (2) what requirements will apply. Fundraising activities may only be approved if all applicable requirements for the use and disclosure of resident information set forth below have been met. In some cases, a personal representative may sign an opt-out form or authorization form on behalf of the resident. This does not mean, however, that St. Mary's staff may direct fundraising requests without the resident's authorization to family members other than in their role as personal representatives.

Fundraising staff responsible for complying with this policy should be aware that special privacy protections apply to HIV-related information, alcohol and substance abuse information, and mental health information. Some activities, which are permitted under this policy, may not be permitted when using or disclosing these types of information. Fundraising staff must comply with St. Mary's policies on privacy and confidentiality of HIV-related information, alcohol and substance abuse treatment information, and mental health information when using or disclosing these sensitive types of information for any reason. They are expected to be aware of the requirements under those policies.

A. Fundraising With Limited Information And Opportunity For Resident To Opt Out

Authorized fundraising staff may use the following *limited* information about a resident to raise funds or solicit donations for the benefit of St. Mary's:

- Resident name;
- Contact information (including, for example, street address, city, county, state and zip code);
- Age;
- Gender;
- Insurance status; and
- Dates of treatment or care provided by the program.
- Fundraising staff may also disclose this information to a business associate or to St. Mary's foundation to undertake such fundraising activities on behalf of St. Mary's.

B. Fundraising Requiring Resident Authorization

Any use or disclosure of a resident's protected health information for fundraising purposes requires the resident's individual authorization. An authorization is therefore necessary if:

- Resident information is used or disclosed;
- Resident information is used by, or disclosed to, individuals or entities other than health care professionals, program staff or business associates undertaking fundraising activities for St. Mary's; or

- The purpose of the fundraising effort is to raise money or other things of value for the benefit of an organization other than St. Mary's.

For example, our fundraising staff must obtain a resident's authorization before using the resident's protected health information to solicit funds from residents for or on behalf of an outside nonprofit organization that engages in research, education, and awareness efforts about a particular disease.

SECURITY OF PROTECTED HEALTH INFORMATION FOR MEDICAL STAFF

Membership and Privilege Requirements

In order to obtain or maintain membership on the Medical Staff or be granted clinical privilege, applicants must document their commitment to abide by the By-laws, Rules and Regulations, and Policies of the Medical Staff and of St. Mary's, including policies regarding the privacy, confidentiality, and security of protected health information.

Medical Records

All members of the Medical Staff and Allied Health Professionals associated with that staff, and their respective employees and agents, shall maintain the confidentiality, privacy, security and availability of all protected health information in records maintained by St. Mary's, or by business associates of St. Mary's, in accordance with any and all health information privacy policies adopted by St. Mary's to comply with current federal, state and local laws and regulations, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). Protected health information shall not be requested, accessed, used, shared, removed, released or disclosed except in accordance with such health information privacy policies of St. Mary's and HIPAA.

Health Information Privacy Authorizations

Members of the Medical Staff and Allied Health Professionals associated with that staff, and their respective employees and agents, shall cooperate with St. Mary's personnel in obtaining and maintaining in the medical record any and all resident authorizations required under any and all health information privacy policies adopted by St. Mary's to comply with current federal, state and local laws and regulations, including, but not limited to, HIPAA.

SECURITY OF PROTECTED HEALTH INFORMATION FOR MARKETING ACTIVITIES

Our marketing policy permits marketing activities that are sensitive to the needs of our residents and consistent with our charitable mission. St. Mary's will carefully evaluate participation in any marketing for third parties. Most marketing communications involving the use of protected health information about St. Mary's residents cannot be made without first obtaining the resident's written authorization. Proposed marketing activities must therefore be examined to determine whether such resident authorization will be required. Proposed marketing activities may only be approved if all applicable requirements for the use and disclosure of resident information set forth below have been met. In some cases, a personal representative may sign an authorization form on behalf of the resident. This does not mean, however, that the marketing staff may send marketing communications without the resident's authorization to family members other than in their role as personal representatives.

Marketing staff responsible for complying with this policy should be aware that special privacy protections apply to HIV-related information, alcohol and substance abuse information, and mental health information. Some activities that are permitted under this policy may not be permitted when using or disclosing these types of information. Marketing staff must comply with St. Mary's policies on privacy and confidentiality of HIV-related information, alcohol and substance abuse information, and mental health information when using or disclosing, or approving marketing activities involving the use or disclosure of, these sensitive types of information for any reason. Marketing staff is expected to be aware of the requirements under those policies.

A. Marketing Activities Subject To This Policy

Marketing activities generally include all oral or written communications with a resident or personal representative about a product or service that encourage the resident or personal representative to purchase or use that product or service. Marketing activities, which involve the use or disclosure of resident information, are covered by this policy. Marketing also includes distributing resident information to another organization so that it may market its own products and services if St. Mary's receives direct or indirect remuneration for providing the organization with this resident information.

This policy does not generally apply to various activities related to the routine treatment of residents or routine operations of St. Mary's even if those activities involve communications with residents concerning products or services. Examples include: (1) indicating whether a product or service is provided by St. Mary's, (2) indicating whether a product or service will be covered by insurance, (3) discussing products or services that may further a particular resident's treatment, (4) describing potentially beneficial products or services in the course of managing or coordinating a particular resident's care or treatment or (5) recommending alternative treatments, therapies, health care providers or settings of care.

B. Marketing Activities That Do Not Require Resident Authorization

A resident's written authorization is not required to use and disclose the resident's protected health information in connection with the following marketing communications made directly to residents:

- Communications that occur face to face (including giving the resident a product sample); or
- Communications involving a promotional gift of nominal value (including giving a resident pens, calendars, or other merchandise that generally promotes St. Mary's).

C. Marketing Activities That Require Resident Authorization

For all other types of marketing communications, a resident's protected health information may only be used or disclosed if the resident signs a written authorization for the communication. St. Mary's standard authorization form for marketing communications is included in the Appendix to this policy. Examples of marketing communications that require written authorization include:

- Sending current or former residents brochures endorsing the use of another organization's products or services when not necessary for a specific resident's course of treatment (for example, sending brochures generally promoting the products and services of a home health agency); and
- Disclosing resident information to third parties, in exchange for direct or indirect remuneration, so that such third parties may use the information for their own marketing activities (for example, selling resident names to pharmaceutical manufacturers for their drug promotions).

The resident's written authorization is required even if St. Mary's staff or health care professionals providing care at the program intend to use an outside vendor or business associate to make the marketing communication on behalf of St. Mary's or on their own behalf.

D. Accounting For Disclosures

Marketing staff should ensure that all disclosures of protected health information in connection with marketing activities are recorded when required by St. Mary's policy.

USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

This policy applies to all program staff members and health care professionals providing care at the program. Program staff members include all employees, medical or other students, trainees, residents, interns, volunteers, consultants, contractors and subcontractors at the program. Health care professionals include physicians, allied health professionals and other licensed health care professionals providing treatment or care to residents in the program, regardless of whether they are employees.

Protected health information obtained by the program may *not* be used internally or disclosed to any persons or organizations outside the program for research purposes without the prior

approval of the program's Privacy Officer or his or her designee. All requests for access to protected health information for research purposes should be forwarded to the Privacy Officer. The Privacy Officer will be responsible for ensuring that strict policies and procedures regarding the access, use, and disclosure of protected health information for research purposes are followed. This means that no research may be conducted by any program staff members, health care professionals, or any other persons on the program's premises without the prior approval of the Privacy Officer.

PRIVACY OFFICER: USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

This policy applies to the program's Privacy Officer, the Privacy Officer's designees, and any persons requesting to access or use for research purposes any protected health information obtained by the program. Protected health information obtained by the program may *not* be used internally or disclosed to any persons or organizations outside the program for research purposes without the prior approval of the program's Privacy Officer. The Privacy Officer may designate one or more persons to act on his or her behalf in any or all aspects covered by this policy. All references to the Privacy Officer in this policy include the Privacy Officer's designees. All requests for access to protected health information for research purposes must be made and reviewed in accordance with the procedures explained below.

Certain requirements apply to the use and disclosure of protected health information in connection with all research involving human subjects. As a general rule, the Privacy Officer may *not* authorize the use or disclosure of protected health information for research purposes except:

- for reviews preparatory to research;
- for research on the protected health information of a decedent;
- if the program has obtained the informed consent of the individual to participate in the research, or a waiver of such informed consent, prior to April 14, 2003 (this exception ceases to apply if informed consent is sought from the individual after April 14, 2003);
- if the information is "completely de-identified;"
- if the information is partially de-identified into a "limited data set" and the resident of the information signs a data use agreement to protect the privacy of such information;
- if the program has obtained a valid authorization from the individual subject of the information; or
- if an Institutional Review Board (an "IRB") or a Privacy Board approves a waiver of the individual authorization requirement.

The specific requirements for each of these exceptions are discussed below. Special rules apply to the use and/or disclosure for research purposes of the following types of information:

- Genetic tests and results from genetic tests;
- HIV-related information;
- Alcohol and substance abuse treatment information;
- Psychotherapy notes; and
- Mental health information

The Privacy Officer must determine that one of the exceptions described below applies before permitting the use or disclosure of any protected health information for research purposes. The Privacy Officer should require either an individual authorization or a waiver of authorization if he or she has any doubt about whether any other exception is applicable. All program research activities must also comply with other applicable program policies relating to research (such as our policies addressing Common Rule and FDA requirements for research) and with any additional requirements that apply to the specific types of information identified above as having special rules. Finally, to the extent program staff and other health care professionals provide treatment to subjects as part of a research study, they must follow other program policies to the extent those policies apply to the provision of health care to individuals. Any questions should be directed to the Privacy Officer.

Research Defined

For purposes of this policy, *research* includes any systematic investigation (including research development, testing, and evaluation) that has as its *primary purpose* the development of or contribution to *generalizable knowledge*.

- *Generalizable knowledge.* Knowledge may be generalizable even if a research study only uses protected health information held within the program and the results are generalizable only to the population served by the program. Research is therefore not limited to clinical trials funded by government sponsors (such as the National Institutes of Health) or commercial sponsors. Quality assurance and utilization management activities do not typically result in generalizable knowledge and thus ordinarily would not be governed by this policy.
- *Primary purpose.* The development or contribution to generalizable knowledge must be the *primary purpose* of the investigation for this policy to be applicable. In some instances, the primary purpose of the activity may change as preliminary results are analyzed. An activity that was initiated as an internal program outcomes evaluation, for example, may produce information that the program administration intends to generalize. If the purpose of a study changes and the results will be generalized, the Privacy Officer must document the change in status of the activity to establish that the requirements of this policy were not violated. If an activity would be considered “research” under other applicable program policies, it should be considered research for purposes of this policy.

General Prohibition and Exceptions

The Privacy Officer may not authorize the use or disclosure of protected health information for research purposes unless at least one of the following exceptions applies:

Reviews Preparatory to Research. The Privacy Officer may permit the use and disclosure of protected health information to develop a research protocol or for similar purposes preparatory to research (*e.g.*, to determine whether the program has information about prospective research participants that would meet the eligibility criteria for enrollment in a research study). Researchers should be aware that this exception does *not* permit the continued use or disclosure of the protected health information once the Principal Investigator has determined to go forward with the study. For example, using protected health information to contact eligible subjects for recruitment purposes would *not* be permitted under this exception.

In order to permit a use or disclosure of protected health information under this exception, the Privacy Officer must obtain representations from the Principal Investigator that:

- The use or disclosure is sought solely to prepare a research protocol or for similar purposes preparatory to research;
- No researcher will remove any protected health information from the program's premises in the course of the review; and
- The protected health information for which use or access is sought is necessary for the research purposes.

During the preparatory review, those granted access may only record information in a form that is "de-identified."

Informed Consents or Waivers of Informed Consent Obtained Prior to April 14, 2003. The Privacy Officer may approve the use or disclosure of protected health information for a specific research project provided that one of the three following requirements are met:

- Express Legal Permission For Use and Disclosure Of Protected Health Information. If the researcher has obtained, prior to April 14, 2003, express legal permission from the individual that *specifically authorizes* a use or disclosure of protected health information for purposes of the research project, the Privacy Officer may permit such use or disclosure for purposes of that project. However, any restrictions on the use and disclosure of health information provided in such express legal permission must be honored. The resident's right to assent should be taken into account, where possible.
- General Informed Consent. If the researcher has obtained, prior to April 14, 2003, the individual's *informed consent* to participate in a specific research project, the Privacy Officer may permit a use or disclosure for purposes of that project even though the informed consent *does not* specifically authorize the use or disclosure of protected health information for purposes of the research project. However, any restrictions on the use and disclosure of health information provided in such informed consent must be honored.
- Waiver of Informed Consent. If the researcher has obtained, prior to April 14, 2003, an IRB waiver of the informed consent requirement (in accordance with the Common Rule) for a specific research project, the Privacy Officer may permit a use or disclosure of the individual's protected health information for purposes of that project. However, if the researcher obtains an individual subject's informed consent at any time after April 14, 2003, the researcher will also be required to obtain the individual's Research Authorization (as provided in this policy) at that time.

Completely De-identified Information. The Privacy Officer may allow completely de-identified information to be used and disclosed for research purposes without restriction. Information may only be considered completely de-identified when either (1) a qualified statistician documents his or her determination that the risk of identification is very small, or (2) the information meets the definition of de-identified information. If the Privacy Officer has any doubts as to whether protected health information has been completely de-identified within the

meaning of this policy, the information should be treated as though it were *not* completely de-identified and neither used nor disclosed for research purposes without meeting another exception.

Limited Data Set. The Privacy Officer may allow the use and disclosure for research purposes of a *limited data set* including a partially de-identified subset of the individual's protected health information, provided that the person using or receiving the information has signed a Data Use Agreement through which he or she agrees to protect the privacy of the information received.

Subject Authorization for Research. The Privacy Officer may allow the use and disclosure of protected health information pursuant to a completed and signed Research Authorization form. Permissible uses and disclosures are limited to those described in the authorization, even though those permissible uses and disclosures may be more limited than what the program's Notice of Privacy Practices describes. The Research Authorization form must be completed by the Principal Investigator for the research subject's review and signature. It is the responsibility of the Principal Investigator to ensure that the Research Authorization form covers the uses and disclosures necessary for the research study. Instructions on preparing the Research Authorization form are included with the form.

In addition to the Research Authorization, if program staff or other health care professionals will provide any treatment to subjects on program premises in connection with the study, the program or the Principal Investigator must collect a signed consent form (for the use and disclosure of protected health information for treatment, payment and health care operations) from every research subject who does not already have one on file at the program.

When obtaining a Research Authorization, an individual's ability to receive research-related treatment as part of a research study may be conditioned upon the individual's agreement to sign the Research Authorization form. However, in presenting the Research Authorization form to prospective subjects, researchers should never suggest that failure to sign the form will limit access to any treatment or care that may be available outside the study. Any questions about the availability of such treatment or care outside the study should be referred to the prospective subject's physician(s). Any other questions about the Research Authorization form should be directed to the Privacy Officer or to the Privacy Officer's designee who has assessed, or who will assess, the Principal Investigator's request for permission to use or disclose protected health information for research.

Retention of Documentation

The Privacy Officer must retain any writings or documentation required by this policy for *six years* from the date of its creation or the date when it last was in effect, whichever is later.

HITECH ACT AND BREACH NOTIFICATION REQUIREMENTS

The Health Information Technology for Economic and Clinical Health Act (HITECH) expanded and refined HIPAA privacy and security requirements, and provided specific Breach Notification

requirements and guidelines . The St. Mary’s Business Associate Agreement (BAA) was revised to reflect these new requirements, and a BAA is now required of contractors including all independent contractors providing services to St. Mary’s.

HITECH’s major new requirements relate to dealing with breaches of unsecured Protected Health Information. The US HHS Office of Civil Rights provides the following information regarding Breach Notification requirements:

Definition of Breach

A breach is, generally, an impermissible use or disclosure under the HIPAA Privacy Rule that compromises the security or privacy of the protected health information such that the use or disclosure poses a significant risk of financial, reputational, or other harm to the affected individual.

There are three exceptions to the definition of “breach.” The **first exception** applies to the unintentional acquisition, access, or use of protected health information by a workforce member acting under the authority of a covered entity or business associate. The **second exception** applies to the inadvertent disclosure of protected health information from a person authorized to access protected health information at a covered entity or business associate to another person authorized to access protected health information at the covered entity or business associate. In both cases, the information cannot be further used or disclosed in a manner not permitted by the Privacy Rule. The **final exception** to breach applies if the covered entity or business associate has a good faith belief that the unauthorized individual, to whom the impermissible disclosure was made, would not have been able to retain the information.

Unsecured Protected Health Information and Guidance

Covered entities and business associates must only provide the required notification if the breach involved unsecured protected health information. Unsecured protected health information is protected health information that has not been rendered unusable, unreadable, or indecipherable to unauthorized individuals through the use of a technology or methodology specified by the Secretary in guidance.

Breach Notification Requirements

Following a breach of unsecured protected health information covered entities must provide notification of the breach to affected individuals, the Secretary, and, in certain circumstances, to the media. In addition, business associates must notify covered entities that a breach has occurred.

- Individual Notice

Covered entities must notify affected individuals following the discovery of a breach of unsecured protected health information. Covered entities must provide this individual notice in written form by first-class mail, or alternatively, by e-mail if the affected individual has agreed to receive such notices electronically. If the covered entity has insufficient or out-of-date contact information for 10 or more individuals, the covered entity must provide substitute individual notice by either posting the notice on the home page of its web site or by providing the notice in major print or broadcast media where the affected individuals likely reside. If the covered entity has insufficient or out-of-date

contact information for fewer than 10 individuals, the covered entity may provide substitute notice by an alternative form of written, telephone, or other means.

These individual notifications must be provided without unreasonable delay and in no case later than 60 days following the discovery of a breach and must include, to the extent possible, a description of the breach, a description of the types of information that were involved in the breach, the steps affected individuals should take to protect themselves from potential harm, a brief description of what the covered entity is doing to investigate the breach, mitigate the harm, and prevent further breaches, as well as contact information for the covered entity. Additionally, for substitute notice provided via web posting or major print or broadcast media, the notification must include a toll-free number for individuals to contact the covered entity to determine if their protected health information was involved in the breach.

- Media Notice

Covered entities that experience a breach affecting more than 500 residents of a State or jurisdiction are, in addition to notifying the affected individuals, required to provide notice to prominent media outlets serving the State or jurisdiction. Covered entities will likely provide this notification in the form of a press release to appropriate media outlets serving the affected area. Like individual notice, this media notification must be provided without unreasonable delay and in no case later than 60 days following the discovery of a breach and must include the same information required for the individual notice.

- Notice to the Secretary of HHS

In addition to notifying affected individuals and the media (where appropriate), covered entities must notify the Secretary of breaches of unsecured protected health information. Covered entities will notify the Secretary by visiting the HHS web site and filling out and electronically submitting a breach report form. If a breach affects 500 or more individuals, covered entities must notify the Secretary without unreasonable delay and in no case later than 60 days following a breach. If, however, a breach affects fewer than 500 individuals, the covered entity may notify the Secretary of such breaches on an annual basis. Reports of breaches affecting fewer than 500 individuals are due to the Secretary no later than 60 days after the end of the calendar year in which the breaches occurred.

- Notification by a Business Associate

If a breach of unsecured protected health information occurs at or by a business associate, the business associate must notify the covered entity following the discovery of the breach. A business associate must provide notice to the covered entity without unreasonable delay and no later than 60 days from the discovery of the breach. To the extent possible, the business associate should provide the covered entity with the identification of each individual affected by the breach as well as any information required to be provided by the covered entity in its notification to affected individuals.

Burden of Proof

Covered entities and business associates have the burden of proof to demonstrate that all required notifications have been provided or that a use or disclosure of unsecured protected health information did not constitute a breach. This section also requires covered entities to comply

with several other provisions of the Privacy Rule with respect to breach notification. For example, covered entities must have in place written policies and procedures regarding breach notification, must train employees on these policies and procedures, and must develop and apply appropriate sanctions against workforce members who do not comply with these policies and procedures.

All suspected breaches shall be reviewed and investigated promptly by the Compliance Officer. The Privacy Officer, in consultation with legal counsel, shall determine whether a breach has occurred, the appropriate actions to be taken, and whether notification to the Secretary is required. Reports of data breached shall be made to the Audit and Compliance Committee.

RED FLAG RULE

The Federal Trade Commission has promulgated Identity Theft Prevention Red Flag Rules as codified at 16 CFR 681.2. While St. Mary's has determined that it is not subject to these requirements, St. Mary's believes that it is in the best interests of the organization to adopt an Identity Theft Prevention Policy as required by the Red Flag Rules. The policy is as follows:

ST. MARY'S HEALTHCARE SYSTEM FOR CHILDREN Identity Theft Prevention Policy

Objective of this Policy: The objective of this Policy is to provide assurance that neither ST. MARY'S patients nor ST. MARY'S are harmed by ST. MARY'S receipt, creation, use, processing or disclosure of false or inaccurate personal information, including but not limited to protected health information as defined by Health Insurance Portability and Accountability Act of 1996 and its implementing regulations ("HIPAA").

This Policy is intended to help accomplish these objectives by providing guidance to ST. MARY'S Workforce and Contractors, so that they will be able to:

- Recognize events or circumstances which may indicate that that identity theft is occurring or has occurred;
- Know how to report possible identity theft;
- Know who is responsible for and authorized to respond to possible identity theft; and
- Know the procedures which should be followed in responding to possible identity theft.

Recognizing Identity Theft: All members of ST. MARY'S Workforce and Contractors are responsible for knowing how to identify possible identity theft affecting a ST. MARY'S patient.

Definition: Identity theft is the inappropriate or unauthorized misrepresentation of personal information for the purpose of obtaining access to property or services. Identity theft is often committed in order to obtain credit to purchase consumer goods, but may also be committed to obtain medical care, drugs and supplies, or payment for care, services or supplies. Identity theft may result in false or inaccurate information becoming included in medical and billing records, and other patient records, and provided to third parties who may rely upon it in making diagnostic, treatment, credit and other important decisions.

The following are examples of facts and circumstances which may indicate identity theft. These are only examples, and many other facts or circumstances may be identity theft indicators:

- Identification documents which appear to have been altered or forged.
- The patient or responsible party cannot provide documentation of identifying information, such as a health insurance card.
- The patient or responsible party provides inconsistent identifying information, such as a Social Security Number in a range which does not correlate with the reported birth date.
- The Social Security Number or other identification or account number provided is already identified with another patient.
- The patient's medical history, physical appearance or diagnosis is inconsistent with the same information in the medical records.
- A report by the patient or insurance company that coverage for the provision of legitimate products or services has been denied because insurance benefits have been depleted or a lifetime cap has been reached, which is inconsistent with known coverage.
- A patient or responsible party inquires or complains about inappropriate billing or notices, such as:

A bill for another individual, for services the patient denies receiving, or from a health care provider the patient denies receiving services from.

An explanation of benefits or other insurance notification for products or services the patient denies receiving.

A collection notice or credit report for a debt for products or services the patient denies receiving, or from a health care provider the patient denies receiving services from.

-The repeated return of mail sent to the patient's address of record as undeliverable, while products or services continue to be provided to the patient.

-Notification by the patient, an individual claiming to be a victim of identity theft, any law enforcement agency, or any other person that an account or record has been opened or created fraudulently by ST. MARY'S.

-The receipt of identification information associated with known fraudulent activity.

Reporting and Responding to Potential Identity Theft: All members of the Workforce and Contractors are required to report possible or suspected identity theft when they obtain information or observe activities or records which reasonably seem to indicate its occurrence. The Compliance Officer shall provide forms for such reports. Reports may also be made to the COMPLIANCE HOTLINE.

ST. MARY'S shall establish written procedures for reporting and initial investigation of potential identity theft, including identification of accountable investigative staff, expected investigative activities, and expected initial investigation response times. The results of each initial investigation shall be documented in writing. Reports and investigation results documentation shall be retained by ST. MARY'S for one year. The Compliance Officer shall review such documentation annually for internal reporting purposes.

In the event an initial investigation determines that there is a reasonable possibility of identity theft, the matter shall promptly be reported to the Compliance Officer. The Compliance Officer shall document any such report and promptly initiate further investigative action. The results of

any such investigation shall be documented in writing and retained by Compliance Officer for at least one year, and such reports shall be reviewed annually for internal reporting purposes.

Any identity theft confirmed by the Compliance Officer shall be treated as a Security Incident, subject to the Security Incident Response Policy. Where any individual has reason to believe that possible identity theft activity has resulted in the receipt, creation or disclosure of false or inaccurate information which may be used in care or treatment decisions potentially affecting patient health or safety, the potential identity theft shall be reported immediately to the Compliance Officer and Executive Vice President.

CHAPTER SIX

COMPLIANCE OVERSIGHT

The Board of Directors has appointed a Compliance Officer for St. Mary's Healthcare System for Children. Proper execution of compliance responsibilities, and promotion of adherence to the compliance program and this compliance manual, shall be a factor in the annual work evaluation of the Compliance Officer.

The officer selected should be respected and trusted by employees at all levels of the organization. The OIG suggests that chief financial officer or similarly situated financial personnel **not serve** as the Compliance Officer, since much of the compliance program focuses on billing and financial operations. The Administrator, Medical staff and legal counsel also are not recommended.

The Compliance Officer shall:

- Be Adam Waxer, Esq.;
- Receive thorough and regular training in compliance procedures;
- Have direct access to the Board of Directors, and
- Have access to necessary records and documentation, including resident records, billing records, and marketing agreements and records.

It shall be the responsibility of the Compliance Officer to ensure that:

- The Employee Standards and Code of Conduct is distributed to all employees;
- This compliance manual and the Employee Standards and Code of Conduct are revised as needed to reflect changes in state or federal law, private payer requirements, or changes in St. Mary's operations;
- A background check is conducted for all prospective employees, including a criminal background check where applicable, and a determination made of whether the prospective employee is subject to sanctions under or exclusion from the Medicare and/or Medicaid programs;
- Employees are given appropriate compliance program training, including information regarding the duty to report suspected violations or questionable conduct.

Corporate Compliance and the mechanism for reporting;

- An anonymous Compliance Hotline has be instituted for reports of suspected violations or questionable conduct are treated confidentially (unless circumstances dictate to the contrary);
- An appropriate inquiry or investigation is initiated with respect to any report of a suspected violation or questionable conduct, and corrective and/or disciplinary action is taken, where appropriate;
- Reports are periodically filed with the Board of Directors regarding material matters involving suspected violations or questionable conduct, and on an as needed basis;

- Periodic reviews of vulnerable areas are conducted and the findings reported to the Board of Directors;
- At least annually, the Board of Directors is provided a report regarding the operation of the compliance program;
- A compliance filing system is maintained, including a log of all compliance issues raised, the resolution of such issues, and action taken in response. If any specific compliance issues are assigned to individuals outside the organization for review, as appropriate, such as legal counsel, accountants, quality consultants, etc., the Compliance Officer has the authority and responsibility to authorize such reviews;
- Activities of the Audit and Corporate Compliance Committee, are coordinated to assure that all duties are fully performed; and
- St. Mary's compliance program is explained to St. Mary's vendors, suppliers, and other contractors.

Audit and Corporate Compliance Committee

The Board of Directors has appointed an Audit and Corporate Compliance Committee to oversee the Audit and Compliance functions of St. Mary's. The Board has adopted a Committee Charter as follows:

Audit and Compliance Committee Charter

Overall Roles and Responsibilities

The Audit and Compliance Committee recommends policies and processes to the Board of Directors related to:

- The organization's financial statements and other financial information provided to the governmental bodies financial institutions, rating agencies and the public.
- The organization's systems of internal controls for finance, accounting, legal, compliance and ethics, according to policies that management and the Board have established.
- The organization's auditing, accounting financial reporting, and compliance processes.

Consistent with this function, the Audit and Compliance Committee should encourage continuous improvement of, and promote adherence to, the organization's policies, procedures, and practices for corporate accountability, transparency, and integrity.

Throughout its work, the Audit and Compliance Committee will serve as an independent and objective party to monitor the organization's financial reporting process, internal control systems and corporate compliance. The Committee will provide an open avenue of communication among the independent auditor, financial and senior management, the Internal Auditor, Compliance Officer, and the governing body.

Responsibilities: External Audit

External Auditors are accountable to the Audit and Compliance Committee and the Board of Directors (Board). The responsibilities of the Audit and Compliance Committee include:

- Recommending the selection of the external auditor. Periodically reviewing the auditor's performance and recommending either renewal or replacement.

- Meeting with external auditors in an executive session, without management present, at least once per year. Discussing with the auditor the organization's internal controls, and the fullness and accuracy of the organization's financial statements.
- Meeting with the external auditor and management at least annually to review the scope of the proposed financial audit for the current year, procedures to be used, particular areas of potential risk or scrutiny, and appropriate fees.
- Reviewing annual financial statements and other financial information submitted to any governmental body, financial institution, rating agency, or the public, including any certification, report, opinion, or review rendered by the independent Auditor. Evaluating determinations made about the applicability of accounting principles, the reasonableness of significant judgments or estimates, and the clarity of financial disclosures.
- Discussing the results of the annual audit and closely reviewing any significant changes to the financial statements or changes in accounting principles and disclosure practices.
- Reviewing the external Auditor's annual management letter regarding internal control weaknesses, recommendations for improvements, and management's corrective action plans. Monitoring management's implementation of corrective action plans.
- Reviewing any non-audit services provided to the organization by the external Auditor to ensure that the external Auditor is sufficiently independent and that the organization is in compliance with external requirements.
- Reviewing, with the organization's counsel, any legal matter that could have a significant impact on the organization's financial statements.
- Reporting to the Board at least annually and providing the Board with the annual external audit report.

Responsibilities: Internal Audit

The Internal Auditor has a direct reporting line to the CEO. The Internal Auditor reports to the Audit and Compliance Committee at scheduled meetings and whenever the Auditor or the Committee deems a matter should be brought to the Committee's attention. The Committee's specific responsibilities in this area include:

- Overseeing the internal audit program, including approval of the annual internal audit plan and review of the independence and authority of its reporting.
- Reviewing staffing and other resources for internal audit to assess whether sufficient resources are available.
- Reviewing and evaluating findings and recommendations from completed audits, including management response and action plans.
- Meeting with the Internal Auditor in executive session, without the CEO or any other management present, at least once a year.
- Reporting to the Board at least annually on the internal audit program.

Responsibilities: Corporate Compliance

The Corporate Compliance Officer has a direct reporting line to the CEO. The Corporate Compliance Officer reports to the Audit and Compliance Committee at scheduled meetings and whenever the Auditor or the Committee deems a matter should be brought to the Committee's attention. The Committee's specific responsibilities in this area include:

- Overseeing the corporate compliance program, including policies and practices designed to address the organization's compliance with all applicable legal, regulatory, and ethical requirements.
- Recommending approval of the annual corporate compliance plan and reviewing processes and procedures for reports concerns by employees, physicians, vendors, and others.
- Recommending organizational integrity guideline and Code of Conduct. Reviewing and reassessing the guidelines and Code of Conduct at least annually.
- Reviewing resources for corporate compliance with the Corporate Compliance Officer and CEO to assess whether sufficient resources are provided.
- Reviewing and evaluating findings and recommendations from completed compliance activities and audits, including management responses and action plans.
- Meeting with the Corporate Compliance Officer in executive session, without the CEO or any other management present, at least once a year.
- Reporting to the Board at least annually on the corporate compliance program.

Conflict of Interest: The Committee will review the annual conflict of interest disclosure statements completed by directors and officers, as well as supporting documents provided by the Corporate Compliance Officer or General Counsel, in accordance with the organization's conflict of interest policies and procedures. The Committee will make a determination as to the disposition of each conflict, determining whether the conflict disqualifies the individual from continuing to serve on the Board, or if additional actions beyond disclosure are required to comply with the conflict of interest policy (e.g., competitive bidding or ensuring he individual abstain from certain Board votes). The Committee will make a summary report of all declared conflicts and the Committee's recommended disposition to the full Board for approval. The Committee will also review and make a recommendation to the Board chairperson with regard to any potential violations of the conflict of interest policy by the director or officer, including the failure to disclose a potential conflict in a timely manner.

The Committee shall review and reassess the charter at least annually to reflect changes in accounting practices, laws, and regulatory requirements and obtain the approval of the Board.

Meetings

The Audit and Compliance Committee meets at least four times a year or when necessary at the call of the Committee chair. Meeting dates and times should be specified a year in advance. The Committee will maintain written minutes of its meetings and activities. Minutes of each Committee meeting shall be distributed to each member of the Committee. Minutes shall be distributed to the Board following Committee meetings, and as otherwise requested by the Chairman of the Board.

Members

The Committee is composed of 3 or more directors, each of whom is an independent director and free from any relationship that, in the opinion of the Board, would interfere with the exercise of his or her independent judgment as a member of the Committee. The System Chair shall designate one member as Committee Chair. In addition, the System Chair may appoint non-director members. The President and Chief Executive Officer shall be an Ex-Officio member of

the Committee. No member of the Committee may be employed by or have any other direct or indirect financial or compensatory relationship with the organization or its subsidiaries.

All Committee members should have a working familiarity with basic finance and accounting practices. At least one member of the Committee will have accounting or related financial management expertise. Appropriate steps should be taken to enhance members' familiarity with audit and compliance issues through participation in educational programs conducted by the corporation or outside experts.

The Committee shall be staffed by the Corporate Compliance Officer, Internal Auditor, General Counsel, senior-most Vice Presidents for Inpatient and Community programs, the Chief Medical Officer, and the Chief Financial Officer.

Reports

The Committee will receive and review the following reports:

- Annual financial audit plan and report, respectively.
- Annual plan and report, respectively, from the internal Auditor.
- Annual compliance plan and periodic reports from the internal Auditor.
- Updates on important compliance issues that have developed since the previous meeting and management responses.
- Conflict of interest disclosures and pertinent background information developed by the Corporate Compliance Officer or General Counsel.

Annual Committee Goals

The Audit and Compliance Committee will establish annual goals specifying its principal work focus areas for the coming year.

All violations, suspected violations, questionable conduct, or questionable practices shall be reported by employees to St. Mary's either by reporting such conduct to an immediate supervisor or to Compliance Hotline or by reporting such conduct in writing to the Compliance Officer.

An employee making a compliance report should describe the circumstances of the event or practice as fully as possible, and should include any relevant documents related to the reported event or practice. Written reports, and any relevant documents, should be placed in a sealed envelope and marked "For Compliance Officer Only."

Procedures Following a Compliance Report

The policy of St. Mary's prohibits any retaliatory action against an employee for making any verbal or written communication to an immediate supervisor, the Compliance Hotline, the Compliance Officer. Although employees are encouraged to report their own wrongdoing, they may not use any verbal or written report in an effort to insulate themselves from the consequences of their own violations or misconduct. Also, discipline or sanctions shall not be increased because an employee reported his or her own violation or misconduct. On the other hand, prompt and complete disclosure may be considered a mitigating factor in determining an employee's discipline or sanction.

Employees and/or supervisors shall not prevent, or attempt to prevent, an employee from communicating via the Compliance Hotline or to a designated official of St. Mary's. If an employee attempts such action, he or she is subject to disciplinary action up to and including dismissal. When a report of a suspected violation or questionable conduct, including reports of suspected violations of applicable state or federal health or safety standards, is brought to the attention of the Compliance Officer, he/she shall:

Determine whether the report raises compliance issues. If a compliance issue is raised, a compliance report is generated via the Compliance Hotline, a copy of which shall be placed in a prepared file;

Investigate the suspected violation or questionable conduct and/or shall delegate the investigation or analysis of suspected violations or questionable conduct to any individual(s) he/she deems appropriate. A memorandum regarding such inquiry shall be prepared, and copies forwarded, if appropriate, to the CEO, COO, facility Administrator, or Board of Directors, or legal counsel. The memo shall address:

The specific steps and/or methods used in investigating the matter such as people interviewed, records reviewed, analyses performed, etc.;

The specific findings and/or results of the investigation; and

A proposed plan of action such as disciplinary action, policy or procedure changes, in-service training regarding existing policy and/or procedure, or other suggested actions to prevent future noncompliance. A copy of the memo shall be placed in a prepared file;

- Based on the results of the investigation by the Compliance Officer, and taking into consideration any other suggestions by the CEO, COO, facility Administrator, legal counsel, etc., will take corrective and/or disciplinary action or will recommend such action to the Board of Directors.
- Place all files regarding corporate compliance matters in a secure file in the office of the Compliance Officer. Access to files will be provided only to the Compliance Officer, COO, and Administrator and legal counsel.

A Compliance Investigation Committee (CIC) was established to review all investigations to ensure that they are carried out objectively, thoroughly and the dispositions are supported by the findings of each investigation. The CIC reviews compliance investigations to determine trends, review corrective action plans and follow-up activities and make recommendations to mitigate systematic contributors of compliance risks.

Confidentiality of a Report

Supervisors receiving compliance reports or questions will report such information to the Compliance Officer. Supervisors will otherwise keep such information confidential. The Compliance Department will keep the identity of reporting employees and the contents of their reports confidential to the fullest extent permitted by law. However, confidentiality cannot be guaranteed in all situations. Generally, the Compliance Officer will only release information to:

- Third parties such as lawyers and accountants as needed by the Compliance Officer and St. Mary's to fully investigate and evaluate such reports;

- St. Mary’s officers, directors, who are not the subject of a report and whose duties and responsibilities require that they be informed of and respond to compliance issues;
- Appropriate committees of the Board of Directors; and Law enforcement officials as appropriate.

Employees filing reports, either orally or in writing should not disclose the contents of the report to anyone other than their supervisor or the Compliance Officer, or an individual designated by one of them. Anonymous reports will be treated seriously and investigated as thoroughly as those filed by employees who identify themselves.

Medical Records Compliance

It is the policy of St. Mary’s Healthcare System for Children (SMHCS) to provide ongoing monitoring of vulnerable areas of the medical record and financial documentation to ensure a process that would identify matters involving potential areas of violations or questionable conduct in accordance with federal, state, city and other regulatory agencies. Programs under review would include inpatient facilities as well as Home Care and Community programs.

On a quarterly basis, a sample of resident medical records (5% of the current census or 30 whichever is greater) for one program, will be reviewed to ascertain compliance with the following documentation requirements:

- a. Presence of a currently signed physician’s order warranting services and/or treatment;
- b. Provision of services in accordance with physician’s order;
- c. Progress note addresses the specific services/treatment ordered and identifies respective goal/objectives;
- d. Progress note is signed and dated;
- e. Where applicable, time segments are billed in minutes/units and correspond to the billing voucher;
- f. Where applicable, appropriate billing codes are used;
- g. Medical record documentation and financial records match.

The review team will consist of the AVP, Inpatient Services/Quality Management and a minimum of 4 managers/supervisors from the respective program under review. Results of the medical records findings will be coordinated with the Finance Department for the completion of the review. Data will be aggregated and analyzed by the AVP, Inpatient Services and Quality Management and disseminated to the program manager, VP for Community Programs, AVP for Community Programs and members of the Audit and Corporate Compliance Committee. Written action plan will be required for any aspect of review that is less than 95% compliant. All review activities will be incorporated into the program’s quality reports.

Board of Directors Responsibility

The Board of Directors shall ultimately be responsible for supervising the work of the Compliance Officer and adopting and maintaining the standards of conduct in this compliance manual. The Board of Directors shall delegate tasks set forth in this compliance manual. St. Mary’s shall maintain written notes, records, correspondence, or

minutes (as appropriate) of Board of Directors meetings reflecting that compliance activity reports were made to the Board of Directors, and decisions on any issues raised (subject to the attorney/client privilege).

The Board of Directors, shall:

- Oversee all of the compliance efforts of St. Mary's;
- Consult with advisors as necessary;
- Ensure that Compliance Hotline correspondence is treated with the strictest of confidentiality (unless circumstances dictate to the contrary);
- Coordinate with the Compliance Officer to ensure the adequacy of the program;
- Receive periodic reports from the Compliance Officer concerning the compliance program;
- Receive notice of all state or federal survey or inspection reports indicating that St. Mary's is not in substantial compliance with applicable law or standards and a summary of the corrective measures instituted and maintained to address such notices;
- Receive quarterly reports from the Quality Council of St. Mary's;
- Ensure that appropriate corrective measures are instituted and maintained in response to identified quality issues;
- Maintain, and improve as appropriate, the compliance program and this compliance manual;
- Review the performance of St. Mary's and all employees in light of the compliance program and this compliance manual;
- Ensure that St. Mary's meets applicable standards of business, legal, and ethical compliance;
- Ensure that matters related to education, training, and communications in connection with the compliance program and this compliance manual are properly disseminated, understood, and followed;
- Take action as appropriate and necessary to ensure that St. Mary's conducts its activities in compliance with applicable law and regulations and sound business ethics; and
- Ensure that appropriate corrective action is taken, including employee disciplinary action, in response to verified violations of applicable law or this compliance program.

Supervisors Responsibilities

Supervisors should serve as the first line of communication regarding compliance issues for employees. As such, supervisors are required and directed to report concerns, questions, and employee reports of suspect activity immediately to their supervisor or directly to the Compliance Officer.

Supervisors must be available to discuss with each employee under their direct supervision:

- The content and procedures of the Employee Standards and Code of Conduct; that adherence to the Employee Standards and Code of Conduct and the compliance program is a condition of employment;

- That St. Mary's shall take appropriate disciplinary action, including termination of employment, for violation of the principles set forth in the compliance program and applicable laws and regulations;
- That neither St. Mary's nor any of its employees will retaliate against any individual for reporting a suspected violation or questionable conduct or assisting in an investigation; the necessity and importance of participating in ongoing training regarding St. Mary's corporate compliance program; and

Note: Supervisors shall maintain policies and procedures that ensure that functions under their supervision are implemented in compliance with law, and that employees under their supervision perform their duties in compliance with these policies and procedures and applicable law. Supervisors' performance of these responsibilities shall be a factor in their evaluations.

Legal Counsel Responsibilities

The Compliance Officer, Administration and the Board of Directors shall consult legal counsel as necessary on issues raised by reports of suspected violations or questionable conduct.

Legal counsel shall review the compliance program and this compliance manual to ensure that:

- It addresses all applicable federal and state laws and regulations;
- The compliance program is effective in curtailing unethical or illegal conduct; and
- Any necessary amendments or corrections to the compliance program, the Employee Standards and Code of Conduct, and the compliance manual are made accordingly.

Quality and Risk Management Committee Charter:

Overall Roles and Responsibilities

The Quality and Risk Management Committee assists the board in overseeing and ensuring the quality of clinical care, patient safety, and customer service provided throughout the organization. The committee also assists the board in approving and overseeing medical policies and professional staff appointments, reappointments, and clinical privileges. The committee oversees St. Mary's insurance coverage, and legal matters related to active or pending litigation.

Responsibilities

The responsibilities of the Quality and Risk Management Committee include:

- Reviewing and recommending a multi-year Strategic Quality Plan with long term and annual improvement targets.
- Reviewing and recommending quality/safety-related policies and standards.
- Approving and monitoring a dashboard of key performance indicators compared to organizational goals and industry benchmarks. Report in summary fashion to the full board.
- Reviewing sentinel events; if appropriate, recommend corrective action.
- Monitoring summary reports of facility, program, and medical staff quality and patient safety activities.
- Reviewing management's corrective plans with regard to negative variances and serious errors.

- Overseeing compliance with quality- and safety-related accreditation standards.
- Making recommendations to the board on all matters related to the quality of care, patient safety, customer service, and organizational culture.

Additional Responsibilities: Professional Affairs

- Overseeing the effectiveness of the medical staff credentialing process.
- Reviewing and acting on medical staff recommendations to grant medical staff appointments, reappointments, and clinical privileges.
 - o Approving appointments, reappointments, and clinical privileges that fully meet the hospital's criteria, with no issues or major questions.
 - o Making recommendations to the board with regard to all other credentialing applications.
 - o The committee may also, in accordance with bylaws, return a recommendation to the medical staff for further documentation or reconsideration.
- Reviewing medical staff recommendations and recommending to the board disciplinary or corrective actions involving medical staff members, as provided in the bylaws.
- Monitoring physician perceptions and satisfaction and overseeing physician relations activities.
- Serving as a forum for education and discussion of facility-medical staff relationships and concerns.
- Reviewing and making recommendations to the board for approval of medically-related policies developed by the committee or by a medical staff committee, including criteria for medical staff membership and privileges and matters related to professional conduct.

Additional Responsibilities: Insurance, Claims and Litigation

- Overseeing the insurance coverage of the System, including general and professional liability, property, directors and officers, employment practices, automobile, umbrella and workers compensation.
- Periodic evaluation of the insurance broker(s) engaged to procure coverage, and oversight of the request for proposals process as necessary.
- Review and oversight of insurance claims and litigation matters, including case status reports, settlements, and case trends.

Meetings

The committee meets at least four times a year, or when necessary at the call of the committee chair. Meeting dates and times should be specified a year in advance.

Members

The committee shall be comprised of at least 3 directors, appointed by the System Chair. The System Chair shall designate one member as Committee Chair. In addition, the System Chair may appoint non-director members. The President and Chief Executive Officer shall be an Ex-Officio member of the Committee.

At least one member of the Committee will have clinical, risk management, insurance or legal experience. Appropriate steps should be taken to enhance members' familiarity with Quality and Risk Management through participation in educational programs conducted by the corporation or outside experts.

The committee shall be staffed by the Executive Vice President/Chief Medical Officer, senior-most Vice Presidents for Inpatient and Community programs, General Counsel, and Director(s) of Quality Improvement.

Reports

The committee will report to the board at least quarterly, including an in-depth annual quality review. Regular reports will include:

- Quality indicators in dashboard format, including roll-up measures of clinical quality, patient safety, and customer service (quarterly).
- Progress on major performance improvements and patient safety goals (quarterly or twice a year).
- Sentinel event summaries (at least quarterly).
- Patient satisfaction/perceptions (quarterly and annual in-depth report).
- Employee satisfaction/perceptions (annual)
- Patient safety culture (annual in depth report)
- Accreditation
- Audit of credentialing process (at least every two years)
- Schedule of Insurance, pre-expiration/renewal considerations
- Summary of Litigation matters – new, ongoing, and closed matters

Annual Committee Goals

The Quality and Risk Management Committee will establish annual goals specifying its principal focus areas for the coming year.

Executive Review and Compensation

The Board of Directors has appointed an Executive Review and Compensation Committee to oversee the performance review and compensation of St. Mary's executive staff. The Board shall adopt a committee charter in substantially the same form as the following:

Overall Roles and Responsibilities

The Executive Review and Compensation Committee recommends policies and processes to the Board for the regular and orderly review of the performance, compensation, and development of the CEO, other senior executives, and the organization's disqualified individuals.

The Committee is also responsible for conducting annual CEO goal-setting, evaluation, and compensation review, in accordance with Board policy.

Responsibilities

The specific responsibilities of the Executive Review and Compensation Committee include:

- Recommending a CEO evaluation policy to the Board, including annual goals for the CEO and a process for annual CEO performance evaluation. The policy shall include provisions for input from the full Board and a report to the Board on the results of the evaluation and compensation review.

- Conducting the CEO evaluation process, consistent with Board-approved policy, and in a manner that promotes trust and candid communication between the Board and CEO, ensures that the CEO understands the Board’s expectations, and provides constructive feedback to the CEO on his or her performance.
- Assessing whether the organization’s executive compensation program meets IRS requirements and achieves the “rebuttable presumption of reasonableness.”
- Reviewing and understanding all current legal and regulatory requirements with regard to executive compensation.
- Recommending a compensation philosophy and plan to the Board.
- Approving or recommending to the Board an independent compensation consultant to provide comparative market information on compensation and benefits and to advise the Committee on compensation trends and regulatory compliance issues.
- Reviewing and recommending to the Board an incentive compensation program for the CEO and other senior executive managers designed to allow the organization to recruit and retain superior talent.
- Approving annual compensation for the CEO consistent with the compensation philosophy and incentive compensation plan.
- Directing the CEO to prepare and annually update a CEO/management succession and management development plan to be reviewed with the Committee.
- Reporting to the Board in sufficient detail to assure the Board that its responsibilities for executive evaluation and compensation are being fulfilled.

Meetings

The Committee will meet at least three times a year and additionally as needed at the call of the Committee Chair. Meeting dates and times should be specified a year in advance.

Members

The Committee will include a Chair and at least two other Board members, all appointed by the System Chair, who meet the Board’s definition for an “independent director.” All of the members of this Committee, and especially the Committee Chair, shall be independent directors, without any significant economic relationship with the organization.

The CEO shall not be a member of this Committee, but may participate when the Committee discusses the executive compensation plan for other senior executives and the management succession and development plan.

Members of this Committee typically include persons with executive experience in large, complex organizations, business owners, healthcare academics, and/or those with backgrounds in human resources. Committee members must understand and respect the confidential, sensitive nature of discussions on compensation and performance evaluation.

[The Committee shall be staffed by the Director of Human Resources (and the Chief Financial Officer?) and shall consult with the President and Chief Executive Officer as necessary.]

Reports

The Committee will receive and review the following reports:

- Data from independent sources on executive compensation for functionally comparable positions in comparable organizations.
- Compensation philosophy statement.
- Tally sheets summarizing the value of each element of executive compensation, including potential future costs.
- Management succession plan.

Annual Committee Goals

Each year the Executive Review and Compensation Committee will consider whether to set particular goals or focus areas for its work in the coming year, in addition to its ongoing responsibilities.

CHAPTER SEVEN

Employee Education and Documentation

The provisions of the Employee Standards and Code of Conduct should be passed out and communicated to all new employees, in a language they can read and understand. To do this, on the day a new employee begins work, the Human Resources Department will review with the employee the Employee Standards and Code of Conduct and ensure that its provisions are understood. The employee then should sign and date an Employee Affirmation Statement or Supervisor Affirmation Statement, as applicable.

An information and education program will be utilized to assist employees in understanding the compliance program and the Employee Standards and Code of Conduct. Furthermore, all employees will be apprised of applicable federal and state laws, regulations, and standards of ethical conduct, and the consequences that will follow for any violation of those rules or the compliance program.

Communicating Compliance Provisions

Seminars will be conducted at least annually or more often if needed. New employees should be scheduled for compliance program training no more than 30 days after beginning employment. The seminars will be coordinated and led by the AVP, Inpatient Services/Quality Management or his/her designee. Participation should be a condition of employment and ongoing performance evaluations.

In addition:

- All employee training shall include an overview of compliance policies and procedures for implementing the policies, focusing on the policies and procedures applicable to each employee's job responsibilities; procedures for reporting compliance violations, including use of the Compliance Hotline or other available reporting mechanisms; and the disciplinary system;
- All compliance program training documents including, but not limited to, lists of attendees, dates of training, and agendas or program descriptions shall be retained by the Corporate Compliance Officer for no less than six years;
- St. Mary's may provide to employees all relevant fraud alerts and advisory bulletins issued by the OIG, or summaries or relevant points from fraud alerts;
- St. Mary's shall post a notice detailing its commitment to ethical standards and compliance with all applicable laws and regulations in the conduct of its business;
- Employee Education and Communication will be conducted upon hire, during annual orientation and as often as necessary based on the needs of the department or regulatory changes.
- St. Mary's shall use payroll stuffers and electronic communications (as appropriate) to inform employees of changes in applicable federal and state laws and regulations; and employees shall be told that they can obtain additional compliance information from their department director and/or the Compliance Officer. Any questions that the employee's immediate supervisor or the

Compliance Officer cannot answer shall be referred to Administration and/or legal counsel, as applicable.

Monitoring, Enforcement, Discipline and Amendments - Policy Statement

St. Mary's has established an anonymous Compliance Hotline for employees and other people to report all violations, suspected violations, questionable conduct, or questionable practices. All violations, suspected violations, questionable conduct, or questionable practices shall be reported by the employee to his or her immediate supervisor or the anonymous Compliance Hotline and/or in writing to the Compliance Officer.

- St. Mary's prohibits any retaliatory action against an employee for making any verbal or written communication to the anonymous Compliance Hotline, the Compliance Officer;
- Although employees are encouraged to report their own wrongdoing, employees may not use any verbal or written report to insulate themselves from the consequences of their violations or misconduct;
- Employees and/or supervisors shall not prevent, or attempt to prevent, an employee from communicating suspected violations, questionable conduct, or questionable practices. If an employee or supervisor attempts such action, he or she is subject to disciplinary action up to and including dismissal;
- Prompt and complete disclosure may be considered a mitigating factor in determining an employee's discipline or sanction; and
- The discipline or sanction shall not be decreased because an employee reported his or her own violation or misconduct.

When a report of a suspected violation or questionable conduct, including reports of suspected violations of applicable state or federal health or safety standards, is brought to the attention of the Compliance Officer, she shall follow the following procedure:

- Determine whether the report raises compliance issues;
- The Compliance Officer shall investigate the facts regarding the suspected violation or questionable conduct and/or shall delegate the investigation or analysis of suspected violations or questionable conduct to any individual(s) he or she deems appropriate. A memorandum regarding such inquiry shall be prepared, and copies forwarded, if appropriate, to the Chief Executive Officer and Administrator. Such memorandum shall address:
 - The specific steps and/or methods used in investigating the matter (such as people interviewed, records reviewed, analyses performed, etc.);
 - The findings and/or results of the investigation; and
 - A proposed plan of action (such as disciplinary actions, policy or procedure changes, in-service training, or other suggested actions) to prevent future noncompliance. A full report is presented to the Audit and Corporate Compliance Committee. Based on the results of the investigation by the Compliance Officer, and taking into consideration any other suggestions by the Chief Executive Officer, Administrator and/or legal counsel, will take corrective

and/or disciplinary action or will recommend such action to the Board of Directors; and

- All files regarding corporate compliance matters will be placed in a secure file in the office of the Compliance Officer. Access to the file will be provided only to the Compliance Officer, Administrator, Chief Executive Officer and members of the Board of Directors.

Periodic Monitoring

Part of assuring ongoing compliance is utilizing periodic reviews of current conduct and practices. The Compliance Officer, or his designees, shall be responsible for conducting periodic reviews of various areas, such as beneficiary billing, admissions procedures, code assignment, and quality of care and life (including compliance with applicable state and federal health and safety standards), to ensure that applicable laws and regulations are being followed, and that accurate information is being conveyed or submitted. In fulfilling this responsibility, the Compliance Officer:

- Shall develop a plan for conducting such reviews on a regular basis. Such plan shall, at a minimum, include remuneration for referrals, marketing, vendor contracting, and quality of care;
- May utilize the services of employees, consultants, or outside experts as necessary;
- May utilize interviews, questionnaires, and document reviews, as well as sampling for conducting the review;
- Shall prepare a written report detailing the area reviewed and presented to the Audit and Corporate Compliance Committee. He/she shall report to the Board of Directors regarding compliance issues periodically and on an ad hoc basis as needed; and
- Shall include a copy of such reports in relevant files.

Employee Compliance Exit Survey

POLICY

It is the policy of St. Mary's Healthcare System for Children to attempt to survey every employee who separates from the Healthcare System regardless of the terms of the separation. The Compliance Exit Survey allows the departing employee another opportunity and mechanism for reporting potential or actual compliance issues. The Compliance Exit Survey is used to gauge the climate of compliance with the Healthcare System's Code of Conduct by identifying infractions.

The Compliance Exit Survey is a distinct process apart from the Exit Interviews conducted by the Human Resources department.

PROCEDURE

I. IDENTIFYING SEPARATING EMPLOYEES

The Human Resources department will provide the Compliance Officer with a list of all separating employees, every two weeks. The list of separating employees will include:

- A. Employee Name
- B. Employee Type (full-time, part-time, per diem)
- C. Job Type
- D. Department Code
- E. Address (last known)
- F. Date of Hire
- G. Termination Date
- H. Termination Reason

II. THE SURVEY PROCESS

The Compliance Officer or designee will mail the Compliance Exit Survey to the last known address of each terminated employee. A postage paid self-addressed envelope will be enclosed with the Compliance Exit Survey form.

The employee may choose to complete the survey anonymously. The Compliance Officer's contact information is on the survey form for the terminated employee's use, if needed.

III. REPORTED VIOLATIONS

All suspected or potential violations of the Code of Conduct, internal policies and procedures, or State or Federal laws or regulations will be investigated by the Compliance Officer or designee with the cooperation of the appropriate department(s). A report of findings will be written and provided to the department Vice President, and if appropriate the CEO.

If potential liability is discovered, the Healthcare System will develop and implement corrective action.

Filing Systems

The Compliance Officer will establish and maintain a filing system for all compliance related documents. The following files should be established:

1. Compliance Manual, Codes, And Policies

This file will contain this compliance manual and any amendments, the Employee Standards and Code of Conduct, all conflict of interest statements, and any compliance program policy statements issued after the program's initiation.

2. Oversight

This file shall document the appointment of the Compliance Officer, all non-privileged communications to the Compliance Officer, all Board of Directors minutes in which compliance issues are discussed, and any other oversight activity records.

3. Information and Education Campaign

This file will contain employee-training records, educational materials provided to employees, notices and fraud alerts that have been posted or placed in payroll envelopes (and the dates and locations of such notices), and all other written records of training activities.

4. Enforcement

This file shall contain all documents pertaining to the enforcement of the compliance program, such as disciplinary actions taken, and informal and formal reprimands issued.

Note: Files containing information relating to employee sanctions or discipline present special legal issues. As such, access to these files should be controlled. With regard to notices related to an employee's failure to follow the compliance program, access should be limited to the Compliance Officer and others whose access is approved by the Human Resources Department.

5. Response

This file will contain all documents reflecting actions taken after an issue has been detected, as well as efforts to deter and prevent future violations.

This file will include a record of requests for legal assistance or legal opinions in connection with reports received via the anonymous Compliance Hotline or reported to the Compliance Officer, and the response from legal counsel. This file shall be privileged and confidential; its contents shall be kept in a secure location and only the Compliance Officer, Chief Executive Officer, Administrator and legal counsel shall have access. All material in this file shall be treated as subject to the attorney client and/or work product privilege and shall not be disclosed to people outside the privileged relationship.

6. Enforcement and Discipline

The OIG has indicated that employers must take the requirements of its compliance plan seriously for the program to be considered effective. This includes requiring that employees at all levels abide by the program and reinforcing that commitment with disciplinary action when appropriate. Therefore, St. Mary's Compliance plan includes:

1. Any employee who engages in a deliberate or reckless violation of standards established in the compliance program, the Employee Standards and Code of Conduct, or any other laws or regulations, shall be subject to disciplinary action, up to and including termination. St. Mary's shall accord no weight to an employee's claim that any improper conduct was undertaken for the benefit of St. Mary's. Any such conduct is not for the benefit of St. Mary's and is expressly prohibited;
2. Where appropriate, discipline shall be enforced against employees for failing to detect or report wrongdoing. This means that employees must understand that they have an affirmative duty to report wrongdoing; and
3. The standards established in this compliance program and the Employee Standards and Code of Conduct shall be consistently enforced through disciplinary proceedings and sanctions. These shall include informal reprimands, formal reprimands, demotion, financial penalties, suspension, and termination.

In determining the appropriate discipline for any violation of the compliance program and the Employee Standards and Code of Conduct, St. Mary's shall treat all employees equally, without taking into account a particular employee's title, position, or function within St. Mary's organization. The compliance program should be viewed as a living, breathing document, which changes as a provider's policies and procedures change, or as applicable law or interpretations thereof change. St. Mary's shall amend, if appropriate, the compliance program and this compliance manual in an effort to avoid any future recurrence of a violation and to address additional matters as necessary.

CHAPTER EIGHT

Compliance Officer Checklist

St. Mary's will:

- Periodically review and revise the written compliance program and the Employee Standards and Code of Conduct as appropriate. This will occur typically when 1) applicable laws change; 2) it becomes clear that employees do not understand the program; 3) recurring operational problems occur that need to be addressed as part of the compliance program; or 4) other times as needed.
- Ensure that ongoing training of employees is conducted and documented and will make sure that training is frequent enough so that new employees receive training promptly.
- Ensure that systems for routine auditing of billing practices, quality of care, contracts, and related areas are in place and are working. Modify these as needed.
- Make routine, periodic compliance reports to the Audit and Corporate Compliance Committee, Board of Directors, or other management (including at least an annual report) regarding compliance activities, even if no violations are detected.
- Manage and monitor the employee reporting process. Ensure that employee reports are seriously and promptly investigated and addressed, including implementing systems or policy changes as needed, and working with human resources personnel to instigate disciplinary action when needed.

Compliance Checklist for Supervisors

- 1) Supervisors should use the following checklist to ensure that they understand the provider's corporate compliance program and their role and responsibilities relating to it.
- 2) Receive and review the Employee Standards and Code of Conduct. Ensure that you understand the program and the Standards and ask questions of your supervisor if you do not.
- 3) Ensure that all employees you supervise attend compliance training and sign and return the Employee Affirmation Statement. For new employees, this should occur immediately upon hire.
- 4) Ensure that all employees you supervise are familiar with the Employee Standards and Code of Conduct and, in particular, know how and to whom they report suspected violations of applicable statutes or regulations or the facility's compliance program.
- 5) Ensure that all employees you supervise understand that full participation in and compliance with the compliance program and Employee Standards and Code of Conduct is a mandatory condition of employment and that failure to participate fully may subject the employee to disciplinary action. Respond promptly to questions or reports by employees you supervise regarding any aspect of the compliance program. Treat all reports by employees confidentially, and report them immediately to the Compliance Officer.

- 6) Ensure that your employees attend scheduled training regarding the compliance program. New employees should be trained promptly, at least within 30 days of beginning their employment.
- 7) Advise the Human Resources Department or the Compliance Officer whenever you have new employees who have not promptly received training in the compliance program or the Employee Standards and Code of Conduct, or who refuse to participate in any manner requested with the compliance program.
- 8) Be able to answer the following questions:
 - a. What is a compliance program?
 - b. Why have a compliance program?
 - c. What do you hope to prevent?
 - d. What types of quality of care issues are prosecutors reviewing?
 - e. Who should be involved in responding to an investigation?
 - f. What does a compliance program mean for employees who do not participate in it or violate it?
 - g. What is management's role?
 - h. Which employees should be involved and at what levels?
 - i. How should a facility train employees on compliance related issues?
 - j. Which employees should be trained?
 - k. How often do you need to train employees?

St. Mary’s Healthcare System for Children

Employee Affirmation Statement

I have received and reviewed a copy of the Employee Standards and Code of Conduct as part of my compliance training, and I understand, acknowledge, and accept its contents as they relate to my position. I have also had the opportunity to ask questions and discuss any aspects of the Employee Standards and Code of Conduct with [my immediate supervisor], and will forward an original signed copy of this Affirmation Statement to [my immediate supervisor].

Further, except as stated below or on the attached document, as of this date I have no knowledge of any transactions or events that appear to violate the Employee Standards and Code of Conduct. I acknowledge that I must adhere to the principles and standards of the Employee Standards and Code of Conduct and to report any violations or suspected violations of the Employee Standards and Code of Conduct to my immediate supervisor, the Compliance Hotline, or in writing to any of the officers designated to receive such reports. I also acknowledge that the Employee Standards and Code of Conduct does not represent any type of employment agreement or contract and that my employment is on an “at will” basis.

Signature of Employee: _____

Print Name: _____ Date: _____

St. Mary's Healthcare System for Children

Supervisor Affirmation Statement

I have reviewed and received a copy of the Employee Standards and Code of Conduct as part of my compliance training and supervisory responsibilities, and I understand, acknowledge, and accept its contents as they relate to my position. I have also had the opportunity to ask questions and discuss any aspects of the Employee Standards and Code of Conduct with my immediate supervisor, and will forward an original signed copy of this Affirmation Statement to my immediate supervisor.

I have reviewed an executed copy of the "Employee Affirmation Statement" from each of the individuals I supervise. These statements are attached. I have also provided each of those individuals with the opportunity to ask questions and discuss any aspects of the Employee Standards and Code of Conduct; and have answered all questions and discussed the aspects of the Employee Standards and Code of Conduct to the best of my ability.

Except as stated below or on the attached document, as of this date I have no knowledge of any transactions or events that appear to violate the Employee Standards and Code of Conduct. I acknowledge that I must adhere to the principles and standards of the Employee Standards and Code of Conduct and to report any violations or suspected violations of the Employee Standards and Code of Conduct to St. Mary's on the toll free anonymous Compliance Hotline or in writing to any of the officers designated to receive such reports. I also acknowledge that the Employee Standards and Code of Conduct does not represent any type of employment agreement or contract and that my employment is on an "at will" basis.

Signature of Supervisor: _____

Department: _____

Print Name: _____

Date. _____

SUPPLEMENTARY INFORMATION:

I. Background

The Office of Inspector General (OIG) issues Special Fraud Alerts based on information it obtains concerning particular fraudulent and abusive practices within the health care industry. These Special Fraud Alerts provide the OIG with a means of notifying the industry that we have become aware of certain abusive practices, which we plan to pursue and prosecute, or bring civil and administrative action, as appropriate. The Alerts also serve as a powerful tool to encourage industry compliance by giving providers an opportunity to examine their own practices.

The Special Fraud Alerts are intended for extensive distribution directly to the health care provider community, as well as those charged with administering the Medicare and Medicaid programs. On December 19, 1994, the OIG published in the Federal Register the texts of 5 previously issued Special Fraud Alerts (59 FR 65372), and indicated our intention of publishing all future Special Fraud Alerts in this same manner as a regular part of our dissemination of this information. Two additional OIG Special Fraud Alerts addressing home health fraud and fraud and abuse provisions of medical supplies in nursing facilities was published in the Federal Register on August 10, 1995 (60 FR 40847). With regard to the provision of health care services reimbursed by Medicare and Medicaid to nursing facilities, this newly issued Special Fraud Alert highlights such fraudulent practices as (1) making claims for services not rendered or not provided as claimed, Appendix G 171.HHS – Special Fraud Alert Page 2 and (2) the submission of claims falsified to circumvent coverage limitations on medical specialties. A reprint of this Special Fraud Alert follows.

II. Special Fraud Alert: Fraud and Abuse in the Provision of Services in Nursing Facilities (May 1996)

The Office of Inspector General (OIG) was established at the Department of Health and Human Services by Congress in 1976 to identify and eliminate fraud, waste and abuse in Health and Human Services programs and to promote efficiency and economy in departmental operations. The OIG carries out this mission through a nationwide program of audits, investigations and inspections.

To help reduce fraud and abuse in the Medicare and Medicaid programs, the OIG actively investigates schemes to fraudulently obtain money from these programs and, when appropriate, issues Special Fraud Alerts which identify segments of the health care industry that are particularly vulnerable to abuse. This Special Fraud Alert focuses on the provision of medical and other health care services to residents of nursing facilities and identifies some of the illegal practices that the OIG has uncovered.

GLOSSARY OF TERMS

Board of Directors shall be able to delegate tasks set forth in this manual to employees.

Building and/or Equipment Lease shall mean any building, building space, and/or equipment rental agreement to which St. Mary's is a party.

Chief Executive Officer (CEO) shall be able to delegate tasks set forth in this manual to other employees.

Chief Executive Officer/CEO shall be able to delegate tasks set forth in this manual to other employees.

Compliance Officer shall be able to delegate tasks set forth in this manual, including delegating the task of inquiring into or investigating any suspected violation or questionable conduct, to other employees. The Compliance Officer shall also report periodically, and on an ad hoc basis as needed, to the Board of Directors, CEO, and/or other management regarding St. Mary's compliance program.

Corporate Compliance Manual and Code of Conduct (compliance manual) shall mean this manual and all attachments, exhibits, modifications, supplements, or amendments.

Corporate Compliance Program (compliance program) shall mean all aspects of the corporate compliance program undertaken by St. Mary's including, but not limited to, the compliance manual, compliance training seminars, and maintenance of the anonymous Compliance Hotline, etc.

Employee shall mean any and all people employed by St. Mary's, including employees, officers, supervisors, or other people on the payroll of St. Mary's. Agent shall mean agents, physicians, and independent contractors of St. Mary's.

Facility Administrator shall be able to delegate tasks set forth in this compliance manual to other employees.

Health Facility shall mean the skilled nursing facility located at 29-01 216th Street Bayside, New York 11360.

Legal Counsel shall refer to the contract attorney retained by St. Mary's Healthcare System for Children

Office of Inspector General (OIG) shall mean the U. S. Department of Health and Human Services' Office of Inspector General, the agency charged with interpreting and enforcing many of the federal fraud and abuse laws applicable to health care providers.

Resident shall mean a resident of St. Mary's skilled nursing facility (SNF) located in Bayside, NY.

Physician Agreement shall mean any written or oral agreement between St. Mary's and an employed or non-employed physician or physician group, including, but not limited to, agreements relating to acquisitions, employment, consulting, building and/or equipment leases, joint ventures, loans, medical directors, partnerships, physician services, professional services, recruitment, risk sharing, security, service agreements, income guarantees, or promissory notes.

Physician shall mean any group, physician, or physician group with whom St. Mary's has a relationship of any type, including a financial relationship of any type. Physician shall include, but is not limited to, acupuncturists, chiropractors, optometrists, osteopaths, medical doctors, podiatrists, and psychiatrists.

Program shall mean any healthcare or education services provided by any St. Mary's corporation, some of which may be licensed, approved, or contracted by a Federal, State, or local agency.

Provider shall mean St. Mary's Healthcare System for Children and its member corporations..

Provider's Corporate Office shall mean the corporate office and personnel of St. Mary's..

"St. Mary's" shall mean all of the member corporations and program of St. Mary's Healthcare System for Children including St. Mary's Hospital for Children, St. Mary's Home Care, St. Mary's Community Care Professionals Corp., St. Mary's Rehabilitation Center for Children, St. Mary's Foundation for Children and SMH Administrative Services. St. Mary's also operates Extraordinary Pediatrics PC,

Vendor Agreement shall mean any agreement with a seller, supplier, or provider of supplies or services, including, but not limited to, any acquisition, consulting, building and/or equipment lease, joint venture, loan, partnership, professional services, risk sharing, security, or service agreement, with respect to St. Mary's.

Vendor shall mean any seller, supplier, or provider of supplies or services including, but not limited to, consultant services and physical, occupational, speech, and respiratory therapists, to St. Mary's.



ST. MARY'S HEALTHCARE SYSTEM FOR CHILDREN

St. Mary's Hospital for Children, Inc.
St. Mary's Community Care Professionals, Inc.
Extraordinary Home Care, Inc.
SMH Case Management, Inc.

NOTICE OF PRIVACY PRACTICES

Effective Date: April 2003; Revised September 24, 2013; Revised September 4, 2015

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.

We are required by law to protect the privacy of health information that may reveal your identity, and to provide you with a copy of this notice which describes the health information privacy practices of St. Mary's health care professionals who provide treatment or care for St. Mary's patients, and affiliated health care providers that jointly perform payment activities and business operations with St. Mary's. A copy of our current notice will always be available in the reception area of all of our sites. You or your personal representative may also obtain a copy of this notice by requesting a copy from St. Mary's staff or **Dara Goldstein, Privacy Officer at (718) 281-8587**.

Generally, when this notice uses the words, "you" or "your," it is referring to the patient which is the subject of patient information. However, when this Notice discusses rights regarding patient information, including rights to access or authorize the disclosure of patient information, "you" and "your" may refer to a minor-patient's parent(s), legal guardian or other personal representative, or, as applicable, an adult patient's personal representative.

*If you have any questions about this notice or would like further information, please contact **Dara Goldstein, Privacy Officer at (718) 281-8587**.*

IMPORTANT SUMMARY INFORMATION

Requirement for Written Authorization. We will generally obtain your written authorization before using your health information or sharing it with others outside St. Mary's Healthcare System. You may also initiate the transfer of your records to another person by completing an authorization form. Your written authorization is required prior to the use or sharing of psychotherapy notes. We will not sell or receive anything of value in exchange for your medical information without your written authorization. Your information will not be used for marketing purposes without your written authorization. If you provide us with written authorization, you may revoke that authorization at any time, except to the extent that we have already relied upon it. To revoke an authorization, please contact **Dara Goldstein, Privacy Officer at (718) 281-8587**.

Exceptions to Requirement. There are some situations when we do not need your written authorization before using your health information or sharing it with others. They are:

- **Exception for Treatment, Payment, and St. Mary's Operations.** For more information, see page 3-4 of this notice.

- **Exception for Disclosure to Friends and Family Involved in Your Care.** We will ask you whether you have any objection to sharing information about your health with your friends and family involved in your care. For more information, see page 4 of this notice.
- **Exception in Emergencies or Public Need.** We may use or disclose your health information in an emergency or for important public needs. For example, we may share your information with public health officials at the New York State or city health departments who are authorized to investigate and control the spread of diseases. For more examples, see pages 4-6 of this notice.
- **Exception if Information Does Not Identify You.** We may use or disclose your health information if we have removed any information that might reveal who you are.

How to Access Your Health Information. You generally have the right to inspect and to receive a copy your health information. For more information, please see page 6 of this notice.

How to Correct Your Health Information. You have the right to request that we amend your health information if you believe it is inaccurate or incomplete. For more information, please see page 7 of this notice.

How to Keep Track of the Ways Your Health Information Has Been Shared with Others. You have the right to receive a list from us, called an “accounting list,” which provides information about when and how we have disclosed your health information to outside persons or organizations. Many routine disclosures we make will not be included on this list, but the list will identify non-routine disclosures of your information. For more information, please see page 7 of this notice.

How to Request Additional Privacy Protections. You have the right to request further restrictions on the way we use your health information or share it with others. We are not required to agree to the restriction you request, but if we do, we will be bound by our agreement. For more information, please see page 8 of this notice.

How to Request More Confidential Communications. You have the right to request that we contact you in a way that is more confidential for you. We will try to accommodate all reasonable requests. For more information, please see page 8 of this notice.

How Someone May Act on Your Behalf. You have the right to name a personal representative who may act on your behalf to control the privacy of your health information. Parents and guardians will generally have the right to control the privacy of health information about minors unless the minors are permitted by law to act on their own behalf.

How to Learn About Special Protections for HIV, Alcohol and Substance Abuse, Mental Health and Genetic Information. Special privacy protections apply to HIV-related information, alcohol and substance abuse information, mental health information, and genetic information. Some parts of this general Notice of Privacy Practices may not apply to these types of information. If your treatment involves this information, you will be provided with separate notices explaining how the information will be protected. To request copies of these other notices now, please contact **Dara Goldstein, Privacy Officer at (718) 281-8587.**

How to Obtain a Copy of this Notice. You have the right to a paper copy of this notice. You may request a paper copy at any time. To do so, please ask a St. Mary’s staff member or **Dara Goldstein, Privacy Officer at (718) 281-8587.** You or your personal representative may also obtain a copy of this notice by requesting a copy from St. Mary’s staff.

How to Obtain a Copy of Revised Notices. We may change our privacy practices from time to time. If we do, we will revise this notice so you will have an accurate summary of our practices. The revised notice will apply to all of your health information, and we will be required by law to abide by its terms. We will post any revised notice in St. Mary's reception area. You or your personal representative will also be able to obtain your own copy of the revised notice by requesting a copy from a St. Mary's staff member or **Dara Goldstein, Privacy Officer at (718) 281-8587**. The effective date of the notice will always be located in the top right corner of the first page.

How to File a Complaint. If you believe your privacy rights have been violated, you may file a complaint with us or with the Secretary of the Department of Health and Human Services. To file a complaint with us, please contact **Dara Goldstein, Privacy Officer at (718) 281-8587**. *No one will retaliate or take action against you for filing a complaint.*

WHAT HEALTH INFORMATION IS PROTECTED

We are committed to protecting the privacy of information we gather about you while providing health-related services. Some examples of protected health information are:

- information about your health condition (such as a disease you may have);
- information about health care services you have received or may receive in the future (such as an operation);
- information about your health care benefits under an insurance plan (such as whether a prescription is covered);
- geographic information (such as where you used to live or work);
- demographic information (such as your race, gender, ethnicity, or marital status);
- unique numbers that may identify you (such as social security number, phone number, or driver's license number); and
- other types of information that may identify who you are.

HOW WE MAY USE AND DISCLOSE YOUR HEALTH INFORMATION WITHOUT YOUR WRITTEN AUTHORIZATION

1. Treatment, Payment and St. Mary's Business Operations

St. Mary's staff and other health care professionals in the St. Mary's Healthcare System may use your health information or share it with others for the purposes of your treatment or care, obtaining payment for treatment or care, and conducting St. Mary's normal business operations. Your health information may also be shared with affiliated health care facilities and providers so that they may jointly perform certain payment activities and business operations along with St. Mary's. Below are further examples of how your information may be used with your consent.

Treatment. We may share your health information with health care providers at St. Mary's who are involved in taking care of you, and they may in turn use that information to diagnose or treat you. A health care provider at St. Mary's may share your health information with another health care provider inside St. Mary's, or at another health care facility, to determine how to diagnose or treat you. A health care provider may also share your health information with another health care provider to whom you have been referred for further health care.

Payment. We may use your health information or share it with others so that we obtain payment for your health care services. For example, we may share information about you with your health insurance company in order to obtain reimbursement for treatment or care we have provided to you. In some cases, we may share information about you with your health insurance company to determine whether it will cover your future treatment or care.

Business Operations. We may use your health information or share it with others in order to conduct our normal business operations. For example, we may use your health information to evaluate the performance of our staff in caring for you, or to educate our staff on how to improve the care they provide to you. We may also share your health information with another company that performs business services for us, such as a billing company. If so, we will have a written contract to ensure that this company also protects the privacy of your health information.

Treatment Alternatives, Benefits and Services. We may use your health information when we contact you in order to recommend possible treatment alternatives or health-related benefits and services that may be of interest to you.

Fundraising. We may use your information when deciding whether to contact you or your personal representative to raise money to help us operate. We may also share this information with a charitable foundation that will contact you or your personal representative to raise money on our behalf. If you do not want to be contacted for these fundraising efforts, please contact **Dara Goldstein, Privacy Officer at (718) 281-8587.**

2. Friends and Family

We may share your information with friends and family involved in your care, without your written authorization or consent. We will always give you an opportunity to object. We will follow your wishes unless we are required by law to do otherwise.

Friends and Family Involved in Your Care. If you do not object, we may share your health information with a family member, relative, or close personal friend who is involved in your care or payment for that care. We may also notify a family member, personal representative or another person responsible for your care about your location and general condition here at the St. Mary's, or about the unfortunate event of your death. In some cases, we may need to share your information with a disaster relief organization that will help us notify these persons. If you object to sharing your information with your family members, personal representative, or other person responsible for your care, please contact **Dara Goldstein, Privacy Officer (718)281-8587.**

3. Emergencies or Public Need

We may use your health information, and share it with others, in order to treat you in an emergency or to meet important public needs. We will not be required to obtain your written authorization, consent or any other type of permission before using or disclosing your information for these reasons.

Emergencies. We may use or disclose your health information if you need emergency treatment or if we are required by law to treat you but are unable to obtain your consent. If this happens, we will try to obtain your consent as soon as we reasonably can after we treat you.

Communication Barriers. We may use and disclose your health information if we are unable to obtain your consent because of substantial communication barriers, and we believe you would want us to treat you if we could communicate with you.

As Required by Law. We may use or disclose your health information if we are required by law to do so. We also will notify you of these uses and disclosures if notice is required by law.

Public Health Activities. We may disclose your health information to authorized public health officials (or a foreign government agency collaborating with such officials) so they may carry out their public health activities. For example, we may share your health information with government officials that are responsible for controlling disease, injury or disability. We may also disclose your health information to a person who may have been exposed to a communicable disease or be at risk for contracting or spreading the disease if a law permits us to do so.

Victims of Abuse, Neglect or Domestic Violence. We may release your health information to a public health authority that is authorized to receive reports of abuse, neglect or domestic violence. For example, we may report your information to government officials if we reasonably believe that you have been a victim of abuse, neglect or domestic violence. We will make every effort to obtain your permission before releasing this information, but in some cases we may be required or authorized to act without your permission.

Health Oversight Activities. We may release your health information to government agencies authorized to conduct audits, investigations, and inspections of our facility. These government agencies monitor the operation of the health care system, government benefit programs such as Medicare and Medicaid, and compliance with government regulatory programs and civil rights laws.

Product Monitoring, Repair and Recall. We may disclose your health information to a person or company that is required by the Food and Drug Administration to: (1) report or track product defects or problems; (2) repair, replace, or recall defective or dangerous products; or (3) monitor the performance of a product after it has been approved for use by the general public.

Lawsuits and Disputes. We may disclose your health information if we are ordered to do so by a court that is handling a lawsuit or other dispute.

Law Enforcement. We may disclose your health information to law enforcement officials for the following reasons:

- To comply with court orders or laws that we are required to follow;
- To assist law enforcement officers with identifying or locating a suspect, fugitive, witness, or missing person;
- If you have been the victim of a crime and we determine that: (1) we have been unable to obtain your consent because of an emergency or your incapacity; (2) law enforcement officials need this information immediately to carry out their law enforcement duties; and (3) in our professional judgment disclosure to these officers is in your best interests;
- If we suspect that your death resulted from criminal conduct;
- If necessary to report a crime that occurred on our property;

To Avert a Serious Threat to Health or Safety. We may use your health information or share it with others when necessary to prevent a serious threat to your health or safety, or the health or safety of another person or the public. In such cases, we will only share your information with someone able to help prevent the threat. We may also disclose your health information to law enforcement officers if you tell us that you participated in a violent crime that may have caused serious physical harm to another

person (unless you admitted that fact while in counseling), or if we determine that you escaped from lawful custody (such as a prison or mental health institution).

National Security and Intelligence Activities or Protective Services. We may disclose your health information to authorized federal officials who are conducting national security and intelligence activities or providing protective services to the President or other important officials.

Inmates and Correctional Institutions. If you later become incarcerated at a correctional institution or detained by a law enforcement officer, we may disclose your health information to the prison officers or law enforcement officers if necessary to provide you with health care, or to maintain safety, security and good order at the place where you are confined. This includes sharing information that is necessary to protect the health and safety of other inmates or persons involved in supervising or transporting inmates.

Workers' Compensation. We may disclose your health information for workers' compensation or similar programs that provide benefits for work-related injuries.

Coroners, Medical Examiners and Funeral Directors. In the unfortunate event of your death, we may disclose your health information to a coroner or medical examiner. This may be necessary, for example, to determine the cause of death. We may also release this information to funeral directors as necessary to carry out their duties.

Organ and Tissue Donation. In the unfortunate event of your death, we may disclose your health information to organizations that procure or store organs, eyes or other tissues so that these organizations may investigate whether donation or transplantation is possible under applicable laws.

Research. In most cases, we will ask for your written authorization before using your health information or sharing it with others in order to conduct research. However, under some circumstances, we may use and disclose your health information without your authorization if we obtain approval through a special process to ensure that research without your authorization poses minimal risk to your privacy. Under no circumstances, however, would we allow researchers to use your name or identity publicly. We may also release your health information without your authorization to people who are preparing a future research project, so long as any information identifying you does not leave our facility. In the unfortunate event of your death, we may share your health information with people who are conducting research using the information of deceased persons, as long as they agree not to remove from our facility any information that identifies you.

YOUR RIGHTS TO ACCESS AND CONTROL YOUR HEALTH INFORMATION

We want you to know that you have the following rights to access and control your health information. These rights are important because they will help you make sure that the health information we have about you is accurate. They may also help you control the way we use your information and share it with others, or the way we communicate with you about your medical matters.

1. Right to Inspect and Obtain a Copy of Records

You have the right to inspect and obtain a copy of any of your health information that may be used to make decisions about your treatment for as long as we maintain this information in our records. This includes medical and billing records. To inspect or obtain a copy of your health information, please submit your request to **Dara Goldstein, Privacy Officer (718)281-8587**. Upon your request, we will provide you with a copy of your record in the format you request, if it is available. This includes a paper

copy or electronic copy of your record, if it is available. If you request a copy of your record, we may charge a fee for the cost of copying, mailing or other supplies we use to fulfill your request. The standard fee is \$0.75 per page for paper and \$10.00 for an electronic copy. The fee must generally be paid before or at the time we give the copies to you. For St. Mary's Hospital for Children residents, we will respond to your request for inspection of records within twenty-four hours and we ordinarily will respond to requests for copies within two working days. For patients and clients of all other St. Mary's programs, access to your records will be made within ten days of your request.

Under certain very limited circumstances, we may deny your request to inspect or obtain a copy of your information. If we do, we will provide you with a summary of the information instead. We will also provide a written notice that explains our reasons for providing only a summary, and a complete description of your rights to have that decision reviewed and how you can exercise those rights. The notice will also include information on how to file a complaint about these issues with us or with the Secretary of the Department of Health and Human Services. If we have reason to deny only part of your request, we will provide complete access to the remaining parts after excluding the information we cannot let you inspect or copy. You may be charged a fee for the cost of preparing the summary of your record.

2. Right to Amend Records

If you believe that the health information we have about you is incorrect or incomplete, you may ask us to amend the information. You have the right to request an amendment for as long as the information is kept in our records. To request an amendment, please contact **Dara Goldstein, Privacy Officer (718)281-8587**. Your request should include the reasons why you think we should make the amendment. Ordinarily we will respond to your request within 60 days. If we need additional time to respond, we will notify you in writing within 60 days to explain the reason for the delay and when you can expect to have a final answer to your request.

If we deny part or your entire request, we will provide a written notice that explains our reasons for doing so. You will have the right to have certain information related to your requested amendment included in your records. For example, if you disagree with our decision, you will have an opportunity to submit a statement explaining your disagreement which we will include in your records. We will also include information on how to file a complaint with us or with the Secretary of the Department of Health and Human Services. These procedures will be explained in more detail in any written denial notice we send you.

3. Right to an Accounting of Disclosures

After April 14, 2003, you have a right to request an "accounting of disclosures" which is a list with information about how we have shared your information with others. An accounting list, however, will not include:

- Disclosures we made to you;
- Disclosures we made in order to provide you with treatment or care, obtain payment for that treatment or care, or conduct our normal business operations;
- Disclosures made to your friends and family involved in your care;
- Disclosures made to federal officials for national security and intelligence activities;
- Disclosures about inmates to correctional institutions or law enforcement officers; or
- Disclosures made before April 14, 2003.

To request this list, please contact **Dara Goldstein, Privacy Officer at (718) 281-8587**. Your request must state a time period for the disclosures you want us to include. For example, you may request a list of the disclosures that we made between January 1, 2004 and January 1, 2005. You have a right to one list within every twelve-month period for free. However, we may charge you for the cost of providing any additional lists in that same twelve-month period. We will always notify you of any cost involved so that you may choose to withdraw or modify your request before any costs are incurred.

Ordinarily we will respond to your request for an accounting list within 60 days. If we need additional time to prepare the accounting list you have requested, we will notify you in writing about the reason for the delay and the date when you can expect to receive the accounting list. In rare cases, we may have to delay providing you with the accounting list without notifying you because a law enforcement official or government agency has asked us to do so.

4. Right to be Notified in the Event of a Breach.

We will notify you if your medical information has been “breached” which means that the privacy or security of your information has been compromised (used or shared in a way that violates the law).

5. Right to Request Additional Privacy Protections

You have the right to request that we further restrict the way we use and disclose your health information to provide you with treatment or care, collect payment for that treatment or care, or to conduct St. Mary’s normal business operations. You may also request that we limit how we disclose information about you to family or friends involved in your care. For example, you could request that we not disclose information about a surgery you had. If you pay for services or health care items out-of-pocket in full, you can ask us not to share that information for the purpose of payment or our operations with your health insurer. We may agree unless a law requires us to share that information.

To request restrictions, please contact **Dara Goldstein, Privacy Officer at (718) 281-8587**. Your request should include (1) what information you want to limit; (2) whether you want to limit how we use the information, how we share it with others, or both; and (3) to whom you want the limits to apply.

We are not required to agree to your request for a restriction, and in some cases the restriction you request may not be permitted under law. *However, if we do agree, we will be bound by our agreement unless the information is needed to provide you with emergency treatment or comply with the law.* Once we have agreed to a restriction, you have the right to revoke the restriction at any time. Under some circumstances, we will also have the right to revoke the restriction as long as we notify you before doing so; in other cases, we will need your permission before we can revoke the restriction.

6. Right to Request Confidential Communications

You have the right to request that we communicate with you or your personal representative about your medical matters in a more confidential way. To request more confidential communications, please contact **Dara Goldstein, Privacy Officer at (718) 281-8587**. *We will not ask you the reason for your request, and we will try to accommodate all reasonable requests.* Please specify in your request how you or your personal representative wishes to be contacted, and how payment for your health care will be handled if we communicate with your personal representative through this alternative method or location.

**FOR FURTHER INFORMATION, PLEASE CONTACT:
DARA GOLDSTEIN, PRIVACY OFFICER**

**5 DAKOTA DRIVE, SUITE 200
NEW HYDE PARK, NY 11042
(718) 281-8587**



ST. MARY'S HEALTHCARE SYSTEM FOR CHILDREN
St. Mary's Hospital for Children, Inc.
St. Mary's Community Care Professionals, Inc.
Extraordinary Home Care, Inc.
SMH Case Management, Inc.

NOTICE OF PRIVACY PRACTICES ACKNOWLEDGMENT

PATIENT NAME: _____ ID # _____

I have received this NOTICE OF PRIVACY PRACTICES for St. Mary's Healthcare System for Children. I understand that if I have any questions, I may contact Dara Goldstein, the St. Mary's Privacy Officer, by telephone at (718)281-8587 or by mail at St. Mary's Healthcare System for Children, Inc., 5 Dakota Drive, Suite 200, New Hyde Park, NY 11042.

Signature _____ Date _____

Print Name _____

NOTE: Signed acknowledgement by a patient caretaker to be maintained in patient clinical record at St. Mary's Healthcare System for Children.



Healthcare System for Children

INSTITUTIONAL REVIEW AUTHORIZATION

Resident Name: _____ ID Number: _____

Date: _____

We understand that information about you and your health is personal, and we are committed to protecting the privacy of that information. Because of this commitment, we must obtain your written authorization before we may use or disclose your protected health information for the research purposes described below. This form provides that authorization and helps us make sure that you are properly informed of how this information will be used or disclosed. Please read the information below carefully before signing this form.

USE AND DISCLOSURE COVERED BY THIS AUTHORIZATION

A representative of St. Mary's must answer these questions completely before providing this authorization form to you. DO NOT SIGN A BLANK FORM. You or your personal representative should read the descriptions below before signing this form.

The following person(s), class (es) of persons, and/or organization(s) may disclose, use, and receive the information, but they may only use and disclose the information to the other parties on this list, to the research subject or his/her personal representative, or as required by law.

- Every research site for this study, including St. Mary's, and including each sites' research staff and medical staff
Every health care provider who provides services to you in connection with this study
Any laboratories and other individuals and organizations that analyze your health information in connection with this study in accordance with the study's protocol
The following research sponsors:
The United States Food and Drug Administration
The members and staff of St. Mary's affiliated Institutional Review Board (IRB)
Principal Investigator:
Study Coordinator:
Members of the Research Team:
Contract Research Organization (Name:)
Other (as described below):

The appropriate boxes should be checked below and the descriptions should be in enough detail so that you (or any organization that must disclose information pursuant to this authorization) can understand what information may be used or disclosed.

- The entire research record and any medical records held by St. Mary's may be used and disclosed.

HIV-related information, which includes any information indicating that you have had an HIV-related test, or have HIV infection, HIV-related illness or AIDS, or any information which could indicate that you have been potentially exposed to HIV.

• Other Information:

SPECIFIC UNDERSTANDINGS

By signing this research authorization form, you authorize the use and/or disclosure of your protected health information described above. The purpose for the uses and disclosures you are authorizing is to conduct the research project explained to you during the informed consent process and to ensure that the information relating to that research is available to all parties who may need it for research purposes. Your information may also be used as necessary for your research-related treatment, to collect payment for your research-related treatment (when applicable), and to run the business operations of the program. This information may be re-disclosed if the recipient(s) described on this form is not required by law to protect the privacy of the information.

You have a right to refuse to sign this authorization. While your health care outside the study, the payment for your health care, and your health care benefits will not be affected if you do not sign this form, you will not be able to participate in the research described in this authorization and will not receive treatment as a study participant if you do not sign this form.

If you sign this authorization, you will have the right to revoke it at any time, except to the extent that the program has already taken action based upon your authorization or needs the information to complete analysis and reports of data for this research. This authorization will never expire unless and until you revoke it. To revoke this authorization, please write to [insert name of responsible person or department] at the program.

You have a right to see and copy the information described on this authorization form in accordance with St. Mary's policies. You also have a right to receive a copy of this form after you have signed it.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (212) 870-8624 or the New York City Commission of Human Rights at (212) 566-5493. These agencies are responsible for protecting your rights.

CONTACT INFORMATION

The contact information of the subject or personal representative who signed this form should be filled in below.

Address:

Telephone:
_____ (Daytime)
_____ (Evening)

Email Address (optional):

Description of Personal Representative’s Authority _____

SIGNATURE

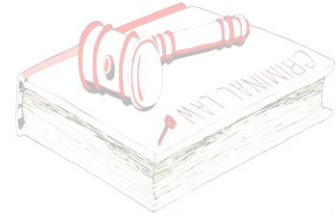
I have read this form and all of my questions about this form have been answered. By signing below, I acknowledge that I have read and accept all of the above.

Print of Subject or Personal Representative

Signature of Subject or Personal Representative

Date

THE SUBJECT OR HIS OR HER PERSONAL REPRESENTATIVE MUST BE PROVIDED WITH A COPY OF THIS FORM AFTER IT HAS BEEN SIGNED.



Corporate Compliance and You

The Corporate Compliance Program

The objective of our Corporate Compliance Program is to ensure that we comply with our Code of Ethical Conduct and all applicable laws, rules and regulations. To achieve this, we must be aware of our legal and ethical responsibilities. Any questions regarding the Corporate Compliance Program should be directed to your immediate Supervisor or the Corporate Compliance Officer.

Our Code of Ethical Conduct provides general guidance for appropriate behavior so we may carry out our mission within appropriate moral, ethical and legal standards.

WHAT TYPE OF COMPLIANCE ISSUES WOULD YOU HAVE TO REPORT?

Generally, you would call to report any activity or behavior you suspect to be inappropriate, unethical or illegal. Some issues or areas of concern may include:

- Theft or any kind in any quantity
- Sexual harassment
- Breach of Confidentiality
- Drug and/or alcohol abuse
- Conflicts of interest
- Accepting gifts or favors for doing your work
- Retrospectively adding/editing documentation
- Documenting services not provided
- Billing for services not rendered
- Billing and/or coding
- Falsifying documents
- Falsifying time sheets or swiping time card for yourself or another employee
- When in doubt, ask before acting!

WHAT SHOULD YOU DO IF YOU THINK AN ETHICAL OR COMPLIANCE BREACH HAS OCCURRED?

Get advice. If you have concerns, speak with your supervisor or the Compliance Officer. We encourage you to talk to your direct line manager first. However, the Corporate Compliance Officer or any member of the Administration is available at all times.

WHAT HAPPENS WHEN I REPORT A POTENTIAL VIOLATION?

St. Mary's Healthcare System for Children takes all reports seriously. St. Mary's will investigate reports and take appropriate action such as education, discipline or termination.

WHAT HAPPENS IF I DO NOT REPORT A POTENTIAL VIOLATION?

You are required to report any potential violation of which you have knowledge. Failure to do so may result in corrective action, including disciplinary action.

WHAT WILL HAPPEN IF I REPORT A VIOLATION IN GOOD FAITH THAT TURNS OUT TO BE INCORRECT?

There will be no reprisals for good faith reporting.

IF A REGULATORY AGENCY CONTACTS ME AND STARTS ASKING QUESTIONS, WHAT SHOULD I DO?

Employees of the Department of Health, JCAHO, FBI, Office of Inspector General or other regulatory agency may approach you with questions about the organization. While you may speak voluntarily with government agents, it is recommended that before doing so, you contact your supervisor.

IF SOMEONE MAKES A FALSE REPORT ABOUT ME, WHAT PROTECTION DO I HAVE?

All reports are fully investigated. You should be assured, however, that the process is open and impartial and no action will be taken until the report is proven to be true. If a report is found to be true, the appropriate action, including disciplinary action, will follow.

WHAT SHOULD I DO IF MY SUPERVISOR ASKS ME TO DO SOMETHING THAT I THINK IS A POTENTIAL VIOLATION OF THE CODE OF ETHICAL CONDUCT?

Discuss the matter first with your supervisor. If you are still uncomfortable, you should immediately report the situation to a level of management above your immediate supervisor or the Corporate Compliance Officer.

WHO IS THE CORPORATE COMPLIANCE OFFICER FOR ST. MARY'S HEALTHCARE SYSTEM FOR CHILDREN?

The Corporate Compliance Officer is Adam Waxer, Esq. He can be reached at 718-281-8585. Messages left on voice mail are confidential and will be treated in the strictest of confidence.

ST. MARY'S COMPLIANCE HOTLINE

St. Mary's has established a Compliance Hotline to assist families, employees, and business associates with reporting known or suspected instances of fraud, waste, neglect, and abuse. If you believe an employee of St. Mary's is acting unethically and/or violating state or federal laws, please call the Compliance Hotline at 888-343-2581. The Compliance Hotline is available 24 hours a day, 7 days a week. For your convenience, you may also make your report online via the website: <https://www.integrity-helpline.com/stmaryskids.jsp>.