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BLANCHARD VALLEY HEALTH SYSTEM

CORPORATE COMPLIANCE SUPPORT MANUAL

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TABLE OF CONTENTS

COMPLIANCE SUPPORT OVERVIEW..... 4

CHAPTER 1: COMPLIANCE STANDARDS AND PROCEDURES..... 7

- 1.1 Claim Development and Submission..... 7
- 1.2 Patient Intake 9
- 1.3 Emergency Patient..... 9
- 1.4 Length of Patient Stay 9
- 1.5 Medical Documentation 9
- 1.6 Confidentiality Policy..... 9
- 1.7 Arrangements with Physicians and Other Sources of Business 10
- 1.8 Quality of Care 11
- 1.9 Inappropriate Relations Between Employees and Patients 11
- 1.10 Reporting of Child and Elder Abuse..... 11
- 1.11 Tax-Exemption Considerations..... 11
- 1.12 Conflicts of Interest 14
- 1.13 Licenses, Permits, Certifications, Accreditations and Other Regulatory Approvals 14
- 1.14 BVHS Property..... 14
- 1.15 Transaction and Financial Records 15
- 1.16 Antitrust and Unfair Competition 15
- 1.17 Confidentiality 17
- 1.18 Political and Lobbying Activities..... 18
- 1.19 Improper Payments and Gifts..... 19
- 1.20 False Statements and Schemes to Defraud 20
- 1.21 Government Contracting 21
- 1.22 Employment and the Workplace..... 21
- 1.23 Intellectual Property 21
- 1.24 Advertising 23
- 1.25 Electronic Mail and Internet Usage..... 23
- 1.26 Wiretapping and Eavesdropping 23
- 1.27 Retaining Outside Consultants 23
- 1.28 Handling Governmental Inquiries, Litigation and Other Legal Matters 23
- 1.29 Care in Communications 24
- 1.30 Communications with the Media and Investment Community..... 25
- 1.31 Environmental Compliance..... 25
- 1.32 Document Retention Policies and Procedures 25

CHAPTER 2: OVERALL PROGRAM OVERSIGHT..... 28

- 2.1 Responsible Officer 28
- 2.2 Supervisor Responsibilities 28
- 2.3 Compliance Committee..... 29
- 2.4 Report to the Board..... 29

CHAPTER 3: DUE CARE IN DELEGATION OF AUTHORITY..... 30

- 3.1 Policy 30
- 3.2 Fraud and Abuse Screening..... 30
- 3.3 Inquiry..... 30
- 3.4 Current Employees and Agents..... 30

CHAPTER 4: EDUCATION AND TRAINING..... 31

- 4.1 General Policy 31
- 4.2 Documentation..... 31
- 4.3 Compliance Support Program 31
- 4.4 Fraud and Abuse Education and Training..... 31

CHAPTER 5: MONITORING AND AUDITING 32

- 5.1 General Policy 32
- 5.2 Monitoring 32
- 5.3 Compliance Certification Forms 32
- 5.4 Asking Questions and Handling Questionable Situations 32
- 5.5 Reporting 33
- 5.6 General Auditing 34
- 5.7 Fraud and Abuse Auditing 34

CHAPTER 6: ENFORCEMENT AND DISCIPLINE 36

- 6.1 Persons Subject to Action..... 36
- 6.2 Consideration..... 36
- 6.3 Legal Actions..... 36

CHAPTER 7: RESPONSES TO PROBLEMS AND CORRECTIVE ACTION..... 37

- 7.1 Investigation 37
- 7.2 General BVHS Response 38
- 7.3 BVHS Response to Medicare/Medicaid Violations 38

BLANCHARD VALLEY HEALTH SYSTEM COMPLIANCE SUPPORT MANUAL SUMMARY

Blanchard Valley Health System has adopted a Compliance Support Program to help our associates understand and comply with state and federal law and the policies of the organization. The Compliance Manual covers the following organizations: Blanchard Valley Health System, and its wholly-owned subsidiaries (collectively “BVHS”). Violations of law and policy can occur even with good intentions. Our Program aims to educate our employees on the laws and policies that apply to them, and to monitor our operations to maintain compliance. The education part of our Compliance Support Program involves familiarizing employees with the Compliance Support Manual. The Manual sets forth the detailed components of our Compliance Support Program.

Why Implement A Compliance Support Program?

First and foremost, BVHS wants to ensure that each of us is aware of and acts according to our duties to patients, to the organization, and to the public. By doing this, we are also reducing the risk of investigation and legal liability.

What Duties Are We Talking About?

BVHS must comply with many different federal, state and local laws, which change from time-to-time. Understanding these laws and their impact is an ongoing process. In addition, BVHS has policies of conduct that may in some cases prohibit activity that is otherwise legal. Violations of policy may also result in legal liabilities.

What Does Compliance Mean To Me?

Health care is a team effort. All of us make decisions, or document actions, that could significantly affect patients, payors, employees, or other providers. For this reason, each of us must be proactively involved in knowing and complying with applicable laws and BVHS policies.

We are also required to be alert for and to report known or suspected problems. Of course, managers and supervisors have an especially important role in ensuring compliance. But each of us has a duty to be vigilant in calling possible

compliance problems to the attention of someone in the organization who can address the issue, even if your supervisor is the person who is engaging in questionable activities. It is your responsibility to raise questions, with persons other than the supervisor if necessary. Any attempts to discourage an employee from raising compliance issues will be viewed as basis for discharge regardless of your position at BVHS.

What Is Our Compliance Support Program?

To be effective, a compliance support program must include ongoing identification of potential problem areas, training to avoid these problems, monitoring to make sure the training is effective, and corrective action where needed. Our Compliance Support Program consists of the following Chapters, which are described in greater detail in the Compliance Support Manual:

1. Standards and Procedures - sets forth the rules, regulations and policies that apply to all employees. They cover such areas as business arrangements, billing practices, patient care issues, documentation, confidentiality, conflicts of interest, records, property, antitrust issues, politics and lobbying, gifts, fraud, government contracts, workplace issues, advertising, handling investigations, and document retention, among other areas.

2. Program Oversight - identifies the

Compliance Officer and the Compliance Committee and describes their roles in overseeing the Compliance Support Program. It also defines the responsibilities of supervisors in ensuring compliance.

3. **Delegation** - establishes a screening process for applicants for employment, and addresses how the organization will handle employees charged with criminal activities.

4. **Education/Training** - sets forth the education and training requirements for employees regarding compliance.

5. **Monitoring/Auditing** - sets forth our policies for monitoring compliance and makes clear each employee's duty to ask questions until they are satisfactorily answered and to report suspected violations. It also creates various channels for reporting suspected problems, including a confidential reporting system.

6. **Enforcement/Discipline** - sets forth the penalties for failing to follow the applicable rules, failing to report suspected problems, or threatening reprisals against those who do make reports.

7. **Corrective Action** - describes the manner in which reported problems will be investigated and addressed. Certain procedures need to be followed in order to protect BVHS and its employees.

Where Do We Start?

Each of us should become familiar with the Manual generally, and with any Standards and Procedures that are relevant to your job duties. Each of us will receive training in areas relevant to our specific functions. After this training, each of us will be asked to sign (including electronically) a verification that we have read and understand this information.

Where Will I Find The Manual?

The Manual will be kept available for reference at all times in the following locations:

1. A hard copy is available in the Compliance Department and the Human Resources Departments.
2. An electronic version is available on BVHS's website: The Core.

A copy will be provided to you upon request; however, only the copies kept at the designated locations will be current at all times. Significant changes in the Manual will be brought to your attention through educational presentations and/or written notices

Are We All Better Off If We Don't Know Exactly What All These Rules Say?

This is a reasonable question. However, the clear answer is "No." You can violate some of these rules without understanding that the conduct is illegal. This can expose you personally as well as the organization to civil and criminal liability.

Can I Really Get In Serious Trouble If I Don't Know All These Complex Rules?

Yes. You can even go to jail in some cases. Contrary to popular belief, some criminal laws do not require that you know the conduct is illegal. In fact, most violations occur because the person did not understand the legal significance of his or her actions. Some important examples:

Clinical/Billing Rules. Any statement or omission of important information can give rise to a fraud claim. Violations can easily occur simply because clinical or clerical personnel who record information do not understand the degree of care that is needed in documenting the record. Medicare authorities (including the FBI) focus on identifying such practices as "upcoding," improper transfers or discharges, improper bundling of services, billing for services without a signed

physician order, and billing for services not actually rendered. They look for inaccurate or incomplete documentation of patient information, inaccurate characterization of diagnosis and procedures/treatments, and other information that is recorded by clinical and clerical personnel outside the billing office. They even look for documentation of the basis for concluding that the services were medically necessary and provided in an appropriate manner. Even inadvertent errors can result in claims under the Civil Money Penalty Law, which is violated whenever a bill is submitted that BVHS's employees "should know" does not meet Medicare's complex requirements.

Referral Laws. Federal and state laws prohibit payments or other consideration to induce referrals or purchases of health care items and services. But it can be easy to overlook the fact that a business arrangement with a physician or other source of business could be viewed as, in part, for the purpose of inducing referrals. In addition, certain other laws (the so-called "Stark Laws") prohibit referrals by physicians who have economic relationships with a provider, regardless of whether the intention is to induce referrals. (Specific exceptions apply in some cases). While you do not need to know all these laws, you do need to know when it is necessary to ask questions.

Tax-Exemption Rules. In order to maintain its tax-exempt status, BVHS must avoid transactions that do not serve its charitable mission or improperly benefit parties that have influence over BVHS, such as Board members, officers, key employees and medical staff members. Failure to appropriately document the fairness of transactions may result in personal tax liability to the parties benefiting from the transaction and the parties who approved the transaction.

Antitrust Laws. Federal and state laws prohibit explicit or implicit agreements between competitors that restrict competition, in some cases even when that is not the intention. Casual discussions that appear legitimate (e.g., discussions

about how to avoid duplication of services) may constitute evidence of serious legal violations. Similarly, any exchange of price information can be evidence of a crime.

These examples show why it is important that each of us has the resources we need to make sure we are in compliance.

How Does The Manual Change My Rights And Duties As An Employee?

The Manual is for the sole and exclusive benefit of the organization, and does not create any contract or other legal rights for its employees. Violation of the provisions of this Manual may result in disciplinary action, such as suspension, monetary penalties, and/or termination.

CHAPTER 1: COMPLIANCE STANDARDS AND PROCEDURES

Set forth below are BVHS's compliance standards and procedures. The standards and procedures are based on the laws and regulations specific to our business. In certain areas BVHS's standards and procedures exceed requirements of applicable laws or regulations.

1.1 Claim Development and Submission.

One of the most common misperceptions among employees is that compliance is simply a billing problem to be handled in the billing office. However, compliance is a much broader concept, pervading all areas of health care operations. Even in the context of claim submission, compliance involves more than just accurate billing, for the underlying data must be accurate in order for the claim to be accurate.

Effective compliance in the claims development and submission process requires participation of all those directly involved in the patient care process as well as many of those whose jobs are related to that process. For example, a claim for health care services may be deemed improper because:

- the admitting or registration personnel failed to give the Medicare beneficiary the notices and information required by the program;
- the patient care staff failed to document the time spent, services provided and materials used in the patient's care;
- an ancillary department misidentified a service;
- data entry personnel applied a charge to the wrong patient account; or
- a medical record department incorrectly applied the HCPC, CPT or other code.

In each of these instances, the person billing the

claim may have performed flawlessly, yet the claim would nevertheless be improper.

There are hundreds of specific rules applicable to the Medicare and Medicaid programs that govern how bills are to be submitted. Some of the laws governing violations of these rules include:

The Federal Criminal False Claims Law prohibits anyone from knowingly causing any bill or other information to be submitted to Medicare or Medicaid that is false or misleading. Violators can be imprisoned for up to five years. A similar law prohibits knowing and willful attempts to defraud in connection with any health care benefits (not merely governmental benefits). Violators can be imprisoned for up to 10 years (20 years if serious bodily injury results). Violators of either law can be fined up to \$250,000 per violation (\$500,000 for corporations) or double the amount of any resulting loss, whichever is greater, and/or excluded from federal programs.

The Federal Civil False Claims Act ("FCA") provides that any person who "knowingly" presents, or causes to be presented" a "false or fraudulent claim for payment or approval" to the United States, its agents or contractors is liable for a civil penalty ranging from \$5,500 to \$11,000 per claim, plus three times the amount of damages sustained by the government. A person is deemed to have acted knowingly if he or she acted in "deliberate ignorance" or "reckless disregard" of the falsity of the claim. If an individual or entity becomes aware that it was paid any amount under the Medicare or Medicaid programs to which it was not entitled under program rules, it must disclose and repay the amount within 60 days; failure to do so violates the FCA. The FCA also empowers and provides incentives to private citizens (commonly referred to as a "qui tam relator" or "whistleblower") to file suit on the government's behalf. Anyone who files a lawsuit under the FCA is protected from being fired,

demoted, threatened or harassed by their employer for filing the suit. If a court finds that the employer retaliated, the court can order the employer to re-hire the employee, and to pay the employee twice the amount of back pay that is owed, plus interest and attorney's fees.

The Program Fraud Civil Remedies Act ("PFCRA") allows the Department of Health and Human Services to impose administrative penalties for false claims relating to federal healthcare programs. Under the PFCRA, "knowingly" filing a false claim triggers fines of up to \$5,000 for each claim and an assessment by the United States for up to twice the amount of the False Claim if the Government has made payment. As under the FCA, "knowingly" includes actual knowledge, deliberate ignorance, or reckless disregard of the falsity of the claim.

The Federal Civil Money Penalty Law imposes substantial monetary penalties for certain actions, including submitting (or causing someone to submit) bills or other information that the person knows or "should know" may result in payments in violation of the many rules of Medicare and Medicaid programs. A person "should know" something if he or she acted with reckless disregard of, or in deliberate ignorance of, its truth or falsity. Such penalties can also be imposed for other conduct, such as financial inducement to patients. Examples of prohibited conduct include:

- Billing for services not rendered.
- Misrepresenting the services actually rendered (such as "upcoding" the level of a service, misrepresenting the qualifications of the person rendering the service or representing that supervision requirements were met when they were not).
- Falsely certifying that certain services were medically necessary. Most CMS Billing Forms (e.g., CMS Form 1500 and the UB-04) contain statements by which the

provider of services affirms that the services provided to the patient were medically necessary.

- Submitting (or causing someone to submit) a claim for payment which is inconsistent with or contrary to Medicare or Medicaid payment requirements.
- Failing to repay an amount received under Medicare or Medicaid programs to which the person is not entitled within 60 days of learning of the overpayment.

BVHS has implemented processes to ensure compliance with these rules. We expect all personnel to accurately bill for services, supplies and equipment provided and to comply with the rules of the applicable payment program. Ongoing written departmental audits should be performed in every department that generates a billable charge to ensure all Medicare and Medicaid payment requirements are met. Any false, misleading or inaccurate statement or omission in any document that may be material to a determination of coverage or the amount of benefits is prohibited. If improprieties are discovered in bills (or claims) that have already been submitted to the payer, the employee who becomes aware of such facts should immediately contact his or her supervisor or the Compliance Department.

The Ohio False Claims Law prohibits any person from knowingly making a false statement to secure payment or other benefit administered by a government agency. Ohio's Medicaid law includes civil penalties for engaging in "deception" with respect to Medicaid claims, and defines "deception" to include acting in deliberate ignorance or reckless disregard of the truth or falsity of facts that make a claim false. Ohio law also imposes criminal penalties for knowingly making (or causing to be made) a false or misleading statement or representation for use in obtaining Medicaid payments or fraudulently obtaining money from third parties for items or

services rendered to Medicaid recipients in violation of program rules or to obtain eligibility for Medicaid benefits. Like the FCA, Ohio provides protections from retaliation by an employer for civil service employees who report Medicaid fraud to the authorities.

1.2 Patient-Resident Intake. Only the admitting physician may provide the preliminary diagnosis on admission. Diagnoses are clinically determined and are never made to suit available insurance benefits. Facility guidelines must be followed in connection with patient intake, including with respect to physician supervision.

1.3 Emergency Patients. The Emergency Medical Treatment and Active Labor Act (“EMTALA”) requires hospitals that accept Medicare to screen and treat emergency patients and women in active labor. Such patients are to be provided a medical screening examination to determine if they have emergency medical conditions, and are to be treated appropriately within the hospital’s capabilities, regardless of their ability to pay for such services. If an emergency patient is to be transferred or discharged, hospital staff must ensure that the patient’s condition is not likely to materially deteriorate as a result of transfer or discharge. There are limited exceptions, such as cases in which the physician documents that the benefits of transfer outweigh the risks. In such cases, appropriate steps must be taken to minimize the risks of transfer. BVHS has adopted separate procedures concerning its obligations under EMTALA, including the mechanism for documenting the appropriateness of transfers and discharges. Associates who become aware of conduct that may violate EMTALA must report the incident to the Compliance Department.

1.4 Length of Patient-Resident Stay. Patients are to be discharged/transferred only when clinically appropriate. Facility staff should not attempt to influence each other or attending physicians regarding the length of a patient’s stay solely for the purpose of improving the facility’s census or reimbursement or any other reason unrelated to clinical considerations. Any exception, for example for failure of the patient to comply with BVHS policies, must be approved in writing in advance by the Director of Nursing of the operational area in consultation with the Compliance Department.

1.5 Medical Documentation. As applicable, medical records documentation must meet the requirements of the Medical Staff Bylaws and Rules and Regulations, facility policies, applicable laws, regulations and accreditation standards (e.g., Joint Commission, Ohio Department of Health, Medicare/Medicaid, etc.). Where appropriate, medical records documentation should reflect the standards or requirements of third-party payors or their outside review agents. It is not appropriate to avoid enforcing documentation requirements for fear of the impact such action might have on census. Late documentation must be clearly labeled as such in the medical records. Any alteration (without appropriate notation) or falsification of medical records is prohibited. If falsifications or inappropriate alterations are discovered, any person who becomes aware of such facts should immediately contact the Compliance Department.

1.6 Confidentiality Policy. Employees have access to confidential information involving the patients we serve and the personnel who provide services to those patients. BVHS is committed to maintaining patients’ and practitioners’ rights of privacy consistent with applicable legal requirements and BVHS’s Privacy Program. All employees are expected to follow the Privacy Program policies and procedures in performing their jobs. You should contact the Privacy Officer or the Compliance Department when any questions arise with respect to releases of such information. Other issues of confidentiality can be raised by personal

information relating to employees, contractors, and outside medical professionals who treat patients at BVHS facilities. Such information must be maintained in confidence and used only for appropriate purposes.

1.7 Arrangements with Physicians and Other Sources of Business. The federal Stark Law regulates financial arrangements with physicians. The federal Anti-kickback Law regulates arrangements with both physicians and other parties who may refer patients to BVHS.

Stark Law. The Stark Law makes it illegal for a physician to refer a Medicare or Medicaid patient to a provider for the furnishing of “designated health services” (which include inpatient and outpatient health care services) in which the physician has a financial interest, *i.e.* a direct or indirect ownership or investment interest or a compensation arrangement. An ownership or investment interest includes any interest by equity, debt or other means. Such an interest in an entity that has an ownership interest in a second entity constitutes an indirect interest in the second entity.

There are several exceptions to this prohibition. If a physician has such a financial interest in the provider, the arrangement must fall within an exception. Failure to fall within an exception makes any referral from an affected physician improper, even if the financial arrangement was not intended to induce referrals. Violators are subject to claims for treble damages, a civil penalty of up to \$15,000 for each prohibited self-referred service and exclusion from participation in federal health care programs. In addition, a party that has participated in a “scheme” to circumvent the operation of the Stark Law is subject to a civil penalty of up to \$100,000.

Anti-kickback Law. The federal Anti-kickback Law prohibits knowingly and willfully offering, paying, soliciting, or receiving, directly or indirectly, anything of value if the purpose is “to induce” the recipient to (1) refer, order, recommend,

or purchase an item or service for which payment may be made under a federal health care program such as Medicare or Medicaid, or (2) arrange for someone else to do so. Unlike the Stark Law, this statute is not limited to physicians. An arrangement that is intended to induce referrals violates this statute even when the payment is not directly related to the volume or value of referrals and there is no agreement to make referrals.

The law contains certain exceptions. One of the exceptions is for payments to bona fide employees for employment in the provision of Medicare and Medicaid-covered items and services.

Anyone convicted of violating the federal anti-kickback law can be imprisoned for up to five years and fined up to \$25,000, as well as lose status as a Medicare/Medicaid provider.

Contracts and Contract Administration. Due to the complex nature of these laws and the specific requirements that must be satisfied, all contracts (including service contracts, leases and joint ventures) with physicians and other parties who are in a position to influence utilization of BVHS services must be approved by either internal or external legal counsel. Any question as to whether a party is a potential source of business should be brought to the attention of the Compliance Department prior to the contract’s execution.

Whenever a physician may receive or be entitled to receive anything of value from BVHS for any reason whatsoever (e.g., investment income, rent payments, compensation for services, debt repayments, etc.), you must either have legal counsel approved or document which Stark Law exception applies. If neither legal counsel nor a legally-approved template contract is used, then the Stark Law Compliance Checklist (Exhibit 1.7) must be used. A copy of this checklist should be placed in the contract file.

No payments may be made to a physician or other outside party who is in a position to influence

utilization of BVHS services until the following items are obtained: (i) a valid contract executed by the physician and applicable department head (or his designee); (ii) an accurate time sheet for the applicable pay period; and (iii) evidence that the contract has been reviewed and approved by legal counsel.

Every payment or other benefit provided to physicians and referral sources must be for the services specified and at the rates called for in the written agreement. Every payment must also be supported by proper documentation that the services contracted for were in fact provided. None of the documentation submitted by physicians or referral sources should make reference to referrals that may be made or may have been made to BVHS, since no compensation may or is to be given or received for referrals. Financial officers are prohibited from issuing checks if these requirements are not met.

Employees/agents have the responsibility to comply in a timely fashion with the BVHS's policy regarding contract preparation, review and execution and payments to physicians. Any uncertainties about contract appropriateness or legality must immediately be brought to the attention of the Compliance Department.

Referrals to Other Providers. Any recommendation, referral or order of health care items or services provided by outside parties must be based on quality of care factors and the needs and preferences of the individual patient. The fact that individual physicians or other practitioners may refer patients does not disqualify them, legally or ethically, from receiving referral of patients from a BVHS facility. Nonetheless, the volume or value of a physician's or other practitioner's referrals in and of itself may not be considered in making a decision to refer a particular patient to that physician or practitioner.

In any discussion with a physician or other practitioner regarding referrals, it should be made clear that referrals to BVHS are not a prerequisite

for receiving referrals.

1.8 Quality of Care. To deliver high-quality care and in a cost-effective manner, all personnel shall ensure the following:

- all personnel practice within the scope of their licensure and training;
- regulatory requirements related to license certification are met;
- needed services are determined in a timely manner;
- any concerns about quality of care are addressed promptly and efficiently;
- patient or family complaints are addressed promptly and efficiently.
- all BVHS policies and procedures related to patient care are followed.

1.9 Inappropriate Relations Between Employees and Patients. All employees and agents of BVHS shall conduct themselves in an ethical and legal manner in relation to their patients. Inappropriate relationships between employees/agents and patients are strictly prohibited and may result in disciplinary action, including termination where appropriate.

1.10 Reporting of Child and Elder Abuse. All incidents of suspected child or elder abuse, both physical and financial, shall be reported as required by applicable state law. If you suspect elder or child abuse you must immediately report the matter to your supervisor.

1.11 Tax-Exemption Considerations. Internal Revenue Code Section 501(c)(3) provides exemption for an organization organized and operated exclusively for charitable purposes if no part of its net earnings inure to the benefit of any private shareholder or individual. The organization

must engage primarily in activities that accomplish the exempt purpose for which it was organized. The promotion of health has long been recognized as an exempt charitable purpose.

The prohibition against inurement of net earnings to private individuals is absolute and applies to any activities involving individuals whose relationship with the organization offers them an opportunity to make use of the organization's income or assets for personal gain ("insiders"). This can include not only directors and officers but also key employees and medical staff members. Such "private inurement" can involve, among other things, the payment of excessive compensation to insiders, the provision of goods and services to insiders without adequate consideration to the organization, paying the personal expenses of insiders, or granting low-interest loans.

An organization will not be considered exempt under Code Section 501(c)(3) even if it operates for exempt purposes unless it serves a public rather than a private interest. The organization also may not devote more than an insubstantial part of its activities to attempting to influence legislation and may not directly or indirectly participate in any political campaign on behalf of or in opposition to any candidate to public office.

A health care delivery system also must promote the health of a sufficiently broad class of persons to be considered benefiting the community as a whole (the "community benefit" test). "Incidental" private benefit will not jeopardize the organization's exemption. A private benefit is incidental if it is clear that the benefit to the public cannot be achieved without some private benefit to individuals, and if the private benefit is not substantial when compared to the overall public benefit generated by the activity. The restriction against private benefit affects not only transactions with insiders but can also include activities involving unrelated third parties.

Personnel should consult with the Compliance Department or BVHS's legal counsel to ensure that each transaction under consideration with individuals who can influence the organization or with physicians be compared with IRS published guidelines to ensure that the transaction does not involve private inurement and satisfies the community benefit test.

Intermediate Sanctions. The IRS can impose excise taxes on "disqualified persons" who receive "excess benefits" through compensation arrangements or property transactions with exempt organizations that are not reasonable or at fair market value. Excise taxes may also apply to the organization's "managers" (including officers, directors and persons with similar powers and duties) if they knowingly permit the organization to participate in the excess benefit transaction. These taxes, which do not apply to the organization, are usually referred to as "intermediate sanctions" because they are less harsh than revocation of the organization's tax-exempt status. While they may be imposed by the IRS as an alternative to revoking the organization's exemption, the IRS could pursue both intermediate sanctions and exemption revocation in certain cases.

A "disqualified person" is anyone in a position to exercise substantial influence over the affairs of the organization within a five year period ending on the date of the transaction at issue. These persons include, but are not limited to, individuals serving as voting members on the governing body of the organization, individuals who have the power or responsibilities of the organization's president, chief executive officer or chief operating officer, individuals who have the power or responsibilities of treasurer or chief financial officer of the organization, and individuals who have a material financial interest in certain provider-sponsored organizations in which an exempt organization participates.

An “excess benefit transaction” is any transaction involving an economic benefit to a disqualified person exceeding the fair market value of the services or goods that the organization receives in return. These transactions can include compensation arrangements, purchases, sales and leases of assets, loans, physician practice acquisitions, physician practice support, and revenue-sharing arrangements between disqualified persons and the organization. A revenue-sharing transaction may constitute an excess benefit transaction regardless of whether the economic benefit provided to the disqualified person exceeds the fair market value of the consideration provided in return if the transaction permits a disqualified person to receive additional compensation without providing proportional benefits that contribute to the organization’s accomplishment of its exempt purpose.

An excess benefit cannot be justified as part of a disqualified person’s compensation unless the benefit is treated as part of that person’s compensation when it is provided. This means that the organization will have to show that the benefit was reported on any required Form 1099 or Form W-2.

The organization can establish a rebuttable presumption that a compensation arrangement is reasonable or that a transaction is entered into at fair market value if the arrangement or the transaction is approved in advance by the organization’s governing board or a board-authorized committee that:

1. is composed entirely of individuals who do not have a conflict of interest with respect to the arrangement;
2. obtains and relies on appropriate data or valuations as to comparability prior to making its determination; and
3. adequately documents the basis for its determination concurrently with the

determination.

To be adequate, documentation must note the terms of the transaction that was approved, the date it was approved, the members of the governing body or committee who were present during the discussion regarding the transaction and those who voted on it, the comparability data obtained and how the data was obtained, and the actions taken with respect to consideration of the transaction by anyone other than a member of the governing body or committee who had a conflict of interest with respect to the transaction or arrangement. If a specific compensation arrangement is determined to be reasonable or the fair market value in a specific transaction is determined to be higher or lower than the comparable data, the governing body or committee must record the basis for this conclusion.

Transactions with Physicians. All transactions with physicians should be analyzed under tax-exemption standards to maintain the organization’s continued exempt status in addition to analysis under Federal and state anti-kickback statutes and federal and state self-referral or Stark Law legislation discussed in other sections of this chapter. Transactions with physicians also have intermediate sanction implications.

The payment of compensation for services performed for the organization by physicians raises both the private inurement prohibition and private benefit restriction. Both issues can be avoided if the compensation is “reasonable” and the organization can establish a community benefit connected with entering into the arrangement with the physician.

Incentive compensation arrangements may be used by the organization provided the total compensation package is reasonable and not a disguised distribution of profits. Incentive compensation arrangements should include caps or ceilings and reasonable maximums on the total amount of compensation that can be paid. All

incentive compensation arrangements should be reviewed by legal counsel.

Any compensation or other financial arrangement with physicians should be evaluated and approved by the organization's board or a board-designated committee. Community benefits derived from the compensation arrangement should be reflected in the minutes of the Board or committee.

Physician Practice Acquisitions. The IRS requires that a physician's practice be purchased for a price not exceeding fair market value, i.e. the price at which a willing buyer and a willing seller agree to the transaction, neither being under any compulsion to buy or sell. The IRS has issued guidance recognizing three types of physician practice valuation methods - the income approach, the market approach and the cost approach. The IRS views the income approach as the most relevant to valuing a physician practice. Under this approach, an acquisition price would be based on after-tax earnings using realistic assumptions for revenue growth and taking any future physician compensation into consideration.

It is BVHS's policy to appraise any practice to be acquired to ensure that the purchase price is within fair market value. The reasonableness of amounts paid to the selling physician as compensation must also be documented.

Physician Recruiting & Retention. The IRS will focus on a recruited physician's entire financial package in determining if it is reasonable. The IRS has accepted income guarantees and other arrangements involving physician recruitment, but not physician retention. All physician recruitment arrangements should be prepared utilizing the approved template that has been reviewed by legal counsel.

1.12 Conflicts of Interest. Blanchard Valley Health System (BVHS) has instituted a corporate compliance program to ensure that all of

its business practices are in compliance with applicable civil and criminal laws, rules and regulations. As part of the program, a guide for the Board of Directors and Designated Persons who might find themselves in a position where their personal interests could conflict with the interests of BVHS. It is vitally important that both the fact and the appearance of conflicting interests and improper conduct be avoided.

BVHS has defined its conflict of interest requirements in its Code of Regulations. Additionally, it is available for reference in the Conflict of Interest Policy, Policy No. 90.13.

1.13 Licenses, Permits, Certifications, Accreditations and Other Regulatory Approvals.

BVHS will obtain and maintain all required certificates of need (if applicable), operating and business licenses and permits, and Medicare and Medicaid certifications. BVHS also obtains and maintains certain accreditations such as accreditations from The Joint Commission, the Ohio Department of Health, and other accreditory bodies. If you become aware of any violations or failure to obtain a required certificate of need, a license or permit, or a Medicare or Medicaid certification, immediately contact the Compliance Department. If you become aware that a BVHS facility does not meet Joint Commission or Ohio Department of Health standards applicable to an accredited facility or service, immediately notify the Quality Department and/or the Compliance Department.

1.14 BVHS Property.

Proprietary Information. In the course of work, you may come into contact with confidential information concerning BVHS or its business or other activities. Such information may take many forms and includes information concerning financial performance, operating results, business plans, marketing and sales programs, health care charges, expansion or acquisition plans, processes or business methods, current or prospective suppliers or customers, past transactions and other

information relating to the conduct of BVHS's business and other activities. All such confidential information generated, used or acquired in connection with (or concerning) BVHS's business and other activities is proprietary to the organization ("Proprietary Information") -- that is, it belongs to BVHS -- and may be used only for company purposes and may not be used in any way for the personal purposes or gain of any employee, agent, or third party. You may not disclose Proprietary Information to any person inside or outside of BVHS who is not authorized to receive such information. Your obligations with respect to Proprietary Information continue even after you leave BVHS, regardless of the reason. Employees/agents leaving BVHS for any reason are required to promptly turn over to the organization all such information (and other materials or property) belonging to the company which are in the person's possession, custody or control.

Use of BVHS Property. BVHS property is to be used for the conduct of BVHS's legitimate business and other activities. You may not use company property for personal reasons except as permitted by BVHS policies and procedures or otherwise approved in advance by your supervisor. BVHS's assets, such as office supplies, production equipment and products, must not be taken out of BVHS facilities, unless necessary to perform an employees' job responsibilities. If removed from BVHS's facilities for business purposes, employees must return the property to the facility when it is no longer needed for business purposes. These policies encompass the unauthorized use of BVHS's communications equipment, computers, related facilities or other BVHS assets, including Proprietary Information and trade secrets.

1.15 Transaction and Financial Records.

Financial Records. BVHS personnel shall ensure that financial and other records and accounts, as well as supporting documentation, for which they are responsible accurately and completely reflect

BVHS's actual operations, transactions and other activities. Falsification or deception in connection with the creation and maintenance of BVHS books, records, accounts or entries therein, whether by alteration, destruction, omission, or false or misleading recording, is strictly prohibited.

BVHS's transactions and other activities must be documented as necessary and appropriate to permit preparation of financial statements in conformity with generally accepted accounting principles and other applicable rules, regulations and criteria and to ensure full accountability for all assets, liabilities and transactions of BVHS. All assets, liabilities, receipts and disbursements must be accurately and completely recorded in the regular books, records and accounts of BVHS. No undisclosed or unrecorded funds, assets or accounts may be created or maintained, nor any undisclosed or unrecorded payments received or made, regardless of the purpose.

Transaction Records. All transactions and other BVHS activities must be properly authorized by management in writing. All payments made on behalf of BVHS must be in accordance with applicable legal and regulatory requirements and BVHS policies and procedures, and accompanied by appropriate and accurate supporting documentation. No payment on behalf of BVHS may be approved or made with the intention, understanding or knowledge that any part of the payment is to be used for any purpose that is inconsistent with the purpose(s) described in the supporting documentation.

Audit Procedure. All employees with responsibility for preparing and maintaining BVHS's financial records must strictly comply with BVHS's internal accounting policies and procedures.

1.16 Antitrust and Unfair Competition The antitrust laws prohibit agreements, understandings and other concerted activities that unreasonably restrain trade. The antitrust laws draw an important

distinction between arrangements with competitors as opposed to customers or suppliers. Most restrictive arrangements with competitors are deemed unreasonable “per se” and generally prohibited, while most types of arrangements with customers or suppliers are permissible under certain circumstances.

Price Fixing and Other “Per Se” Violations.

Price fixing is a formal or informal agreement to “fix” or “stabilize” prices or any terms or conditions of sale affecting prices, such as discounts, credit terms, the timing or announcement of pricing changes, the use of pricing formulas, and other similar terms. It is also improper for competitors to agree to (i) divide markets, customers or lines of business, (ii) set or limit capacity levels, (iii) standardize products or services, (iv) coordinate bidding, or (v) boycott or refuse to do business with certain suppliers or customers, or (vi) deal with suppliers or customers.

Employees/agents generally shall not discuss, exchange or otherwise communicate with any employee, representative or agent of a competitor any information concerning BVHS’s or the competitor’s past, present or future prices, pricing policies, other terms or conditions of sale or other matters of competitive significance. While prices of competitors obviously may be considered in making pricing decisions, information as to competitors’ prices should only be obtained from the field -- e.g., from published lists, other public sources or customers to whom the prices have been quoted -- and not from competitors, even if only to verify an offer that a customer claims to have received.

It is BVHS’s policy that business decisions -- including any decisions about prices, terms and conditions of sale terms of BVHS’s products and services, the markets or lines of business to compete in and the customers and suppliers with whom BVHS does business -- shall be made on an independent basis, taking into account all relevant factors, including BVHS’s costs and profit objectives, prevailing market conditions,

competitive prices and other relevant factors and information. Employees/agents are prohibited from entering into any kind of agreement, understanding or arrangement or even discussing or exchanging information with competitors either directly or indirectly, concerning prices, pricing policies, other terms or conditions of sales or purchases, the markets or lines of business in which BVHS will compete, the customers and suppliers with which BVHS will do business or other matters of competitive significance. It is BVHS’s policy never to invite competitors to participate in collusive activities. Any employee/agent receiving an invitation from a competitor to participate in a collusive arrangement or who is drawn into a discussion of prohibited subjects should state in terms that cannot be misconstrued that it is against BVHS policy to engage in such activities or even to discuss such matters with competitors, terminate the discussion and withdraw from the discussion if the discussion continues and immediately report the matter to the Compliance Officer.

Trade and Industry Associations.

Employees/agents must obtain approval of the Compliance Officer or the Executive Committee of the Board of Directors prior to joining or participating in the activities of trade associations (or other industry groups) in which competitors are members or otherwise involved. Personnel participating in trade association activities (or, indeed, in any outside professional or social gathering) should be sensitive to, and avoid participation in, any activity or discussion that might be construed as improper concerted action. Some examples of activities that may be legitimate, but which can raise antitrust concerns under certain circumstances, include:

- expulsion or exclusion of actual or potential members;
- “industry standard” setting activities;
- the collection, dissemination and/or exchange of industry data or other

information of competitive significance;

- presenting “industry” views to legislative bodies or to governmental or regulatory agencies.

Employees/agents shall not participate in these or any other trade association (or other industry group) activities that raise potential antitrust concerns. Employees/agents should not assume that trade association (or other industry group) activities are permissible under the antitrust laws simply because a lawyer is present at a meeting or other gathering. In addition, trade associations (or other industry groups) are generally not an appropriate forum for raising complaints against competitors, and the Compliance Department should be consulted on the appropriate manner of handling any such grievances.

Unfair Competition. Federal and state laws also prohibit unfair methods of competition and unfair or deceptive acts and practices. Some examples include: (i) commercial bribery, or payoffs to induce business or breaches of contracts by others; (ii) acquiring a competitor’s trade secrets through bribery or theft; (iii) making false, deceptive or disparaging claims or comparisons regarding competitors or their products; (iv) mislabeling products; and (v) making affirmative claims concerning one’s own products without a reasonable basis for doing so. Employees should avoid these and any other unethical, unfair or deceptive business practices. In particular, all public statements by or on behalf of BVHS, including advertising statements, promotional materials, sales representations, warranties and guarantees, should always be truthful and have a reasonable basis in fact, and should not be misleading or purposefully made easily susceptible of misinterpretation. You should not create, approve or disseminate any advertising or other materials for BVHS’s products or services which are false, misleading or deceptive or not in compliance with applicable laws and regulations.

Violations by Others. If you have reason to believe that BVHS is being injured by a potential violation of the antitrust or competition laws, you should immediately report the matter to the Compliance Officer. You should not take any retaliatory steps or measures on your own, as such conduct itself might constitute a violation of the antitrust or competition laws.

EMPLOYEES MUST:

1. Familiarize themselves with the restrictions on communication and prohibited topics of discussion.
2. Seek approval of legal counsel prior to entering into any contracts with customers and suppliers as appropriate.
3. Withdraw from (and note for the record, if any) participating in conversations or meetings involving prohibited activities.
4. Consult the Compliance Department with any questions or issues in this area.

EMPLOYEES MUST NOT:

1. Discuss matters of competitive significance with competitors.
2. Participate in collusive arrangements with competitors.

1.17 Confidentiality.

Security of Discussions. BVHS personnel should make efforts to ensure the security of discussions concerning BVHS business. As a general matter, efforts should be made to hold such discussions in secure locations out of hearing range of unauthorized persons - for example, friends, relatives or BVHS personnel not authorized to receive such information. Whenever practicable, such discussions should not be held in public areas at BVHS’s offices or other facilities, such as reception or waiting areas, hallways or elevators.

Whenever practicable, discussions concerning BVHS business taking place in offices or conference rooms should be held with the doors closed. Persons using speaker phones also should exercise care to see that sensitive conversations are not overheard by unauthorized persons.

It is particularly important to exercise care in, and generally refrain from, discussing confidential transaction-related information in public places, such as elevators, trains, taxis, airplanes, lavatories, restaurants, on international or cellular telephone calls and in other places or circumstances where the discussions might be overheard by unauthorized persons. When doing so, appropriate precautions should be taken to avoid revealing the nature of the business and/or the involved parties, such as by using code names whenever practicable and otherwise structuring conversations so as to minimize the chances that someone overhearing the conversation could determine the nature of and/or parties to the transaction.

Document Control. BVHS personnel using confidential documents should make efforts to protect against unauthorized disclosures. Such documents should be provided only to persons who have a need to use them in the course of their work. Such documents generally should be marked as “confidential.” In addition, efforts should be made to avoid making copies of such documents except as necessary.

When not in use, efforts should be made to keep such documents out of general public view, such as by storing them in file cabinets or drawers, turning documents face down or closing an office or conference room door. When in use, efforts should be made to avoid leaving such materials unattended unless appropriate precautions are taken, such as closing an office or conference room door and/or turning the documents face down. BVHS personnel using such materials should check the areas where they are working prior to bringing persons not authorized to receive such materials into those areas, and should remove such documents from work

areas when they vacate them.

BVHS may be under express obligations pursuant to one or more confidentiality agreements governing the handling of confidential documents/information received or which contain or are derived from information obtained from such companies or other parties. The Compliance Department will implement appropriate measures, as necessary, to help implement compliance with any confidentiality obligations pursuant to such an agreement.

1.18 Political and Lobbying Activities.

Political Contributions and Activities. All employees/agents must comply with all applicable campaign finance and ethics laws, as well as tax-exemption laws which require that no substantial part of the activities of BVHS shall consist of carrying on propaganda or otherwise attempting to influence legislation. The tax-exemption laws prohibit BVHS from participating in or intervening in (including the publishing or distributing of statements) any political campaign on behalf of any candidate for public office. Accordingly, BVHS’s assets may not be used to make any contribution or otherwise provide assistance for or on behalf of BVHS to any political party, candidate for public office, political fund raising, campaign committee or other such BVHS in connection with any federal, state or local election (or other political activities). This policy applies not only to direct money contributions, but also to indirect assistance, such as the furnishing of goods, services, equipment, facilities or other assistance, including use of BVHS e-mail for such activities. This policy also applies to the purchase of tickets for dinners or other political fund raising events or advertising space in political publications.

Use of BVHS funds or assets to support or oppose public referenda or similar ballot issues must be reviewed and approved in advance by the Compliance Officer, or by the Executive Committee or the Board of Directors.

These policies are not intended to discourage or prohibit you from making personal political contributions or otherwise engaging in personal political activities of your choice as permitted by law. You may use your own assets to make personal political contributions to the parties, candidates or health care organizations of your choice or otherwise engage in political activities of your choosing. You should not, however, use your personal assets to make political contributions or otherwise undertake political activities for or on behalf of BVHS. It should be clearly understood that any persons making a political contribution or expending funds or other assets for other political activities bears the entire responsibility for such contribution or activity, and will not be compensated or reimbursed by BVHS for any funds or other assets expended or used for such purposes.

Lobbying Activities. The lobbying laws contain complex requirements, including registration of lobbyists and periodic reporting of lobbying activities. You may not engage the services of or consult with lobbyists, or engage in lobbying activities for or on behalf of BVHS, without the prior approval of the Compliance Department.

1.19 Improper Payments and Gifts.

Use of BVHS Funds or Assets for Improper Payments. The use of BVHS funds or assets for any unlawful or improper purpose or payment, such as bribes, kickbacks, payoffs or any other payment made in violation of applicable laws or regulations or for an improper purpose (“Improper Payments”), is strictly prohibited. In addition to payments prohibited by applicable laws or regulations, any payment which is falsified or intentionally not reported in BVHS’s books and records shall be deemed to be an Improper Payment.

You should not make, offer or authorize the making or offering of any payment to any official, employee or representative of any governmental or regulatory body, agency or instrumentality, any actual or potential supplier, customer or competitor

(or any other person or entity having an actual or potential business or other relationship with BVHS) for the purpose of obtaining or retaining influence, assistance, business or other favored treatment, action or inaction for or on behalf of BVHS. Such payments are considered Improper Payments whether made or offered directly or indirectly (for example, through an intermediary), and whether or not such payments may be commonplace or accepted as a way of doing business in certain locations. In addition, any arrangement which assists another party in making or offering such a payment is also improper. Improper Payments need not be in the form of money, but may include the giving of any other thing of value, including goods or services.

With respect to governmental or regulatory officials, employees and representatives, it may not be necessary that a payment be given with the intent to secure influence or favored treatment for the payment to constitute a violation of law. Accordingly, no payment of any kind may be made directly or indirectly to such persons unless the payment is (i) permitted by applicable law, and (ii) approved in advance by the Compliance Officer.

You should promptly report any request for an Improper Payment (or any other payment as to which a question exists) or any action or threat of action for the purpose of obtaining such a payment to the President.

Use of BVHS Funds or Assets for Business Gifts and Entertainment. Gifts and entertainment may be extended to others at BVHS’s expense provided they:

- are reasonable, and not excessive, in nature, frequency and/or value;
- are made in connection with the conduct of legitimate business or other activities for or on behalf of BVHS;
- are in accordance with applicable laws or

regulations and customary business practices in the governing jurisdictions, as well as BVHS policies and procedures;

- are properly authorized (if necessary) and properly reported and recorded;
- would not embarrass BVHS or be construed as a bribe or other Improper Payment should they be made public;
- do not involve the giving of cash or cash equivalents;
- are approved in advance by an officer of BVHS for any gift or expenditure in excess of \$100.00; and
- are approved in advance by the Compliance Department for any gift or expenditure involving any Governmental or regulatory official, employee or representative.

These policies and procedures apply even if a gift would not otherwise constitute an “Improper Payment” as described above.

Receipt of Improper Payments or Gifts by Employees/Agents. You may not solicit, accept or receive, directly or indirectly, any Improper Payment for yourself or others. You may not profit outside of BVHS’s regular compensation scheme from the performance of your responsibilities on behalf of BVHS (with the exception of the receipt of gifts permitted by BVHS policy). You should promptly report any offer of an Improper Payment (or questionable payment) to the President.

The receipt of gifts, loans or special favors from actual or potential competitors or third parties having actual or potential business or other dealings with BVHS can create the appearance of impropriety. Accordingly, you should not solicit, directly or indirectly, gifts or special favors from such parties for themselves or others. You may accept gifts, entertainment or other favors in

connection with the legitimate conduct of BVHS’s business or other activities provided that they are of a type for which BVHS funds might properly be used and the guidelines set forth in the prior section are strictly followed. You must promptly report the offer or receipt of any gifts or other favors inconsistent with these policies to your supervisor.

The policies and procedures set forth in this section do not apply to the arrangement of a personal loan provided that the following conditions are met: (i) the loan is arranged with a recognized lending institution that regularly lends money or extends consumer credit to individuals; (ii) the loan is made in the ordinary course of business and on usual and customary terms for such.

1.20 False Statements and Schemes to Defraud.

Employees/agents are expected to conduct all of BVHS’s business and other activities with honesty, fairness and integrity, and an absence of deception or fraud. Employees shall not knowingly and willfully (i) make or cause to be made a false statement, orally or in writing, to a government official, or (ii) conceal or cause to be concealed a material fact called for in a governmental report, application or other submission. These policies extend to all communications with any federal, state, local or foreign government official or agency.

You can violate this policy even if you do not personally make the false statement or conceal the material fact. For example, you should not provide false or materially incomplete information to any other employee, agent, or third party knowing that, or under circumstances making it likely that, such information will later be used in providing information to a governmental agency. The above-described conduct may also constitute a civil or criminal offense punishable by fines and/or imprisonment.

It is also improper to make false statements or conceal material facts in any communication with BVHS in connection with the conduct of BVHS’s

business or other activities, including employment or employee benefit applications and any other reports or filings. Similarly, you should not engage in any scheme to defraud BVHS or any person or entity with whom BVHS has a business or other relationship out of money, property, or services or to wrongfully withhold or misappropriate the property of others in the course of BVHS's business or other activities.

1.21 Government Contracting. From time to time, BVHS may bid on and/or enter into contracts with governmental entities or instrumentalities. BVHS is committed to strict compliance with all applicable laws and regulations relating to the bidding, pricing, negotiation and performance of government contracts, and expects employees/agents to strictly adhere to all such requirements. A number of fundamental principles should be followed in business dealings with governmental bodies and representatives:

- any estimate must be clearly labeled as such, and any certification of fact should be made only upon a good faith inquiry and informed and good faith belief that such fact is accurate.
- strictly follow the terms, including in particular pricing terms, established for any government contract.
- employ only legitimate and honest methods of securing government contracts. You should not seek or receive, whether directly or indirectly, any information that BVHS is not authorized to possess. Such information may include (i) confidential governmental information relating to the bidding or selection process on a particular contract, or (ii) confidential and proprietary information concerning a competitor's bid on a particular contract.
- do not offer, give, solicit or receive any form of bribe, kickback, payoff or other Improper Payment (as defined in the first paragraph of

1.19 above) in connection with any government contract. You should promptly report any incident which is reasonably suspected to involve an Improper Payment in connection with a government contract to the President.

Any questions relating to government contracts involving BVHS should be directed to the Compliance Officer.

1.22 Employment and the Workplace. BVHS is committed to maintaining a professional and safe work environment in each of its facilities. Consistent with this goal, the organization is dedicated to full compliance with all applicable laws and regulations concerning employment and the workplace. While you are expected to abide by applicable legal requirements and BVHS policies and procedures in this area, supervisors have particular responsibility for seeing that such standards are met.

BVHS's employment policies and procedures are set forth in the Employee Handbook. Any questions regarding an employment-related issue should be directed to the Human Resource Department or to the Compliance Department.

1.23 Intellectual Property. Various laws govern the use of material and/or information that may be the subject of trademark, patent or copyright protection or that may be treated as a trade secret. To protect BVHS's rights in intellectual property belonging to BVHS, use of all such intellectual property must be in accordance with all applicable laws. Absent prior approval by the Compliance Officer, BVHS's copyrighted material, trademarks, patents and other intellectual property may only be used for legitimate and authorized BVHS other activities. You should also be alert to possible violations by others of organization's copyrighted materials, trademarks or other intellectual property rights and promptly report such matters to the Compliance Officer.

In addition, the BVHS is committed to respecting the legitimate rights of third parties with respect to trademarks, patents, copyrighted works and trade secrets belonging to them. You are expected to be familiar with the intellectual property laws that may apply to your activities and to seek guidance from the Compliance Officer before taking any action which might infringe on intellectual property rights belonging to third parties.

Copyrights. Reproduction and other uses of copyrighted materials such as books, articles, magazines, newsletters, drawings, computer software, photographs, videotapes, films, and advertising are governed by the copyright laws of the U.S. and certain foreign countries, as well as various multinational pacts. Subject to certain exceptions, principally for educational, research, news reporting or similar purposes, unauthorized copying of copyrighted material constitutes copyright infringement. Even copying for purposes of creating a personal “archive” or “library” may constitute copyright infringement in certain circumstances.

You should observe the legal protections afforded to copyrighted materials belonging to others, and refrain from any activity which would constitute copyright infringement, including unauthorized copying or dissemination. In particular, photocopying and distribution of multiple copies of substantial portions of copyrighted works and copying for direct commercial purposes are prohibited absent prior approval from the Compliance Officer.

An area of particular concern is the improper duplication of computer software, which may be governed by software licenses in addition to the copyright laws. Persons seeking to make copies of software must strictly comply with any such restrictions well as those imposed under the copyright laws and must obtain prior approval from BVHS’s Security Officer (or an authorized designee.)

Trademarks. A trademark is a word, symbol, name, device or combination of these used to identify and distinguish a product or line or products or services as belonging to a particular company. BVHS utilizes trademarks which are well recognized by the public. You should be vigilant to use BVHS’s trademarks correctly and should notify the Compliance Officer if you become aware of any unauthorized use of BVHS’s trademarks or of confusingly similar trademarks by a third party. Similarly, avoid the use of trademarks belonging to or potentially confusingly similar to those of other companies absent prior approval from the Compliance Officer.

Trade Secrets Belonging to Others. A trade secret may be confidential information belonging to a third party that provides a competitive advantage or is otherwise important in the conduct of that party’s business. BVHS is committed to respecting the legitimate rights of third parties to protect their trade secrets and other confidential and proprietary information (“Third-Party Confidential Information”). You should not engage in efforts to wrongfully obtain or use such information. Persons who believe that they may have inadvertently or otherwise come into possession of Third-Party Confidential Information should promptly contact the Compliance Officer before making any use or further disclosure of such information.

In addition, you should ensure that Third-Party Confidential Information provided to you is properly handled, including observing the terms and conditions of any confidentiality agreement entered into in connection with the receipt of such information. In this regard, be particularly careful not to make any unauthorized use or disclosure of Third-Party Confidential Information. Persons may not enter into any type of confidentiality arrangement with a third party absent prior consultation with the Compliance Department.

BVHS considers it important to limit the distribution of copyrightable material within the organization and such material should not be copied

and disseminated to third parties outside BVHS without the approval of the Compliance Officer.

1.24 Advertising. BVHS's products, services and facilities will be represented fairly and honestly. Advertising, marketing and promotional materials may not contain any unfair, inaccurate, or deceptive statements or any exaggerated or unwarranted representations. You should not use any advertising, promotional, or other tactics or materials that unfairly undermine the facilities or services of a competitor. This includes disparaging comments or innuendo. If you have any questions, please contact BVHS's Corporate Public Relations and Marketing Department.

1.25 Electronic Mail and Internet Usage
BVHS has developed a policy governing electronic mail and internet usage policy. This policy is the titled BVHS "Computer System Access and Usage", Policy No. 40.04. As technology is continually evolving, this policy is subject to change. Please refer to the BVHS Administrative Policy 40.04. If you have any questions, please contact BVHS's Security Officer.

1.26 Wiretapping and Eavesdropping.
Various state and federal laws regulate wiretapping, eavesdropping and other forms of electronic surveillance. It is a violation of the law to use any electronic, mechanical or other device to intercept the contents of any telegraphic, telephonic, facsimile, modem-transmitted electronic mail or other electronic communication, unless one (or in certain jurisdictions all) of the parties to the communication consent to the interception. Accordingly, you should not engage or participate in any electronic surveillance as described above unless you have first received clearance from the Compliance Department.

The law may be violated merely by a person's listening in on a conversation, even if no notes are taken and no recordings are made. Accordingly, absent prior approval from the Compliance Officer, any person who engages a telephone extension

while another individual is using that extension must: (i) have received express permission from all of the people on the line, or be aware that all individuals on the line have given blanket permission to listen to their telephone calls; or (ii) identify themselves so that the participants in the conversation are made aware that someone is listening to the conversation; or (iii) hang up immediately.

1.27 Retaining Outside Consultants.
From time to time in the conduct of BVHS's business, it may be necessary or desirable to retain the services of an outside consultant, broker or other similar party (collectively "Outside Consultants"). To ensure that all such arrangements satisfy legal requirements and BVHS policies, all arrangements must be pursuant to a written agreement setting forth all terms and conditions and including a clear statement of the services to be performed; and all arrangements must be approved in advance by the the appropriate Vice President and the Compliance Department must be notified prior to the engagement.

Persons retaining the services of Outside Consultants are responsible in the first instance for supervising their activities. Persons may not knowingly request, authorize or permit an Outside Consultant to perform any activity which violates applicable legal or regulatory requirements or BVHS's policies and procedures, and must promptly report any such conduct to Compliance Department.

1.28 Handling Governmental Inquiries, Litigation and Other Legal Matters.

Governmental Inquiries and Investigations.
The Compliance Officer is responsible for supervising handling of all inquiries and investigations by any federal, state, local or other governmental or regulatory authority. If you receive an inquiry for information or documents pertaining to BVHS or its activities from a governmental or regulatory representative, whether formal or

informal, whether in writing, over the telephone or by way of a personal visit to an BVHS facility, you should (i) inform the governmental or regulatory representative that the matter must be referred to the Compliance Officer, which has responsibility for handling such inquires, and (ii) immediately thereafter advise the Compliance Officer of the receipt of such inquiry. While governmental or regulatory representatives should be treated in a courteous and straightforward manner, no one should provide (or agree to provide) documents, testimony or other information or assistance in response to a request by a governmental or regulatory representative without the prior approval of the Compliance Officer. (Regularly scheduled JCAHO/state surveys, OSHA visits, audits by third-party payors, tax audits and ordinary medically-related requests for medical records are excepted from the above policy.) In such cases, however, the Compliance Officer should be advised promptly.

No employee may on behalf of BVHS complain to, or facilitate or cooperate in the initiation of conduct of any investigation or proceeding by, any governmental or regulatory authority against any other party without the prior approval of the Compliance Officer.

Litigation and Other Legal or Administrative Proceedings. The Compliance Officer [Legal Department] is also responsible for supervising the conduct of any litigation or other legal or administrative proceedings involving BVHS. You should promptly inform the Legal Services Department of the threatened or actual initiation of any legal or administrative proceeding against BVHS, as well as the receipt of any legal documents, including a claim letter, summons, complaint or subpoena or other request for documents, testimony or other information in connection with such a proceeding.

You should not appear (or agree to appear) as a witness, provide testimony or other information, or otherwise take any action in connection with any legal or administrative proceeding involving BVHS,

including attempting to settle or settling any matter or claim, without the prior approval of the Compliance Officer. You should not agree to appear or otherwise provide assistance (for example, as an expert witness or consultant) in connection with a legal or administrative proceeding not involving BVHS (other than a personal legal matter) unless expressly required by applicable law, in which event the person must still promptly consult with the Legal Services Department upon receipt of any such request.

No person may threaten to initiate or initiate any legal or administrative proceeding on behalf of BVHS against any other person or entity without the prior approval of the Compliance Officer.

Retention of Outside Legal Counsel. As with other legal matters, the Vice President of the affected area and/or the Legal Services Department is responsible for retaining and overseeing the work of outside counsel on behalf of BVHS. Accordingly, BVHS personnel may not retain or otherwise seek advice with respect to BVHS's business or other activities from outside lawyers without the prior approval of the Vice President of the affected area and/or the Legal Services Department. This policy applies whether the contact with outside counsel is formal or informal, and whether the outside lawyer is one regularly engaged by BVHS or a friend or relative of any BVHS employee/agent. This policy also applies with equal force to litigation, corporate, regulatory and other legal matters.

1.29 Care in Communications. You should exercise care and common sense in connection with communications, whether written or oral, and records made in the course of conducting BVHS's business and other activities. Be aware that the organization may be required to disclose company records and other documents, including notes, internal memoranda, handwritten drafts, and other documents written by employees/agents, in connection with a governmental investigation or private litigation. Serious consequences may result

when entirely lawful conduct is mischaracterized (or subject to misinterpretation) as a result of the careless choice of words in a written or oral communication.

Accordingly, you should avoid creating an appearance of impropriety even though the conduct is completely lawful and consistent with BVHS's policies and procedures. Communications and records should be in accordance with BVHS's policies and positions and accurately reflect the facts of a given situation. Avoid speculation and exaggeration. All written materials including email messages should be reviewed before delivery or use to help ensure that such documents cannot be misinterpreted to suggest improper conduct. The same care should be used with less formal and more permanent methods of communication, such as electronic mail.

1.30 Communications with the Media and Investment Community. Only BVHS personnel specifically authorized to communicate with the various news or financial press or other media or the investment community (the "Media and Investment Community") on behalf of BVHS may do so. Examples include requests for information from (i) cable or broadcast networks, (ii) information services, (iii) newspapers, magazines or other print media, (iv) advocacy groups or other types of health care organizations, or (v) securities analysts. All requests for information about BVHS from any member of the Media and Investment Community should be promptly referred to the BVHS Public Relations Department. With the exception of the Executive Officers of BVHS, absent approval, employees/agents may not respond to any such inquiries or contacts on their own. This restriction applies to all Media and Investment Community contacts, whether "on" or "off" the record, for "deep" background purposes, a "no comment" reply or a "disclaimer" of information. Any grant of approval for Media and Investment Community contacts applies only to the specific contact for which approval was sought.

Requests for proposed speeches, articles, interviews or comments with or by any BVHS employee/agent by the Media and Investment Community or other organizations, and the issuance of any press releases by any BVHS employee/agent, must also be reviewed and approved in advance by the BVHS Public Relations Department. BVHS-initiated interviews similarly must be approved before they may be scheduled with the Media.

1.31 Environmental Compliance. BVHS is committed to full compliance with all applicable environmental laws and regulations. This includes obtaining necessary approvals and permits and operating within their requirements. All personnel are required to familiarize themselves with the environmental impact of their jobs and the rules that govern the performance of their jobs.

Each BVHS facility is responsible for evaluating environmental standards applicable to the various types of activities conducted and equipment operating at such facility and for implementing compliance with the applicable standards. In connection with such efforts, facilities should: (i) identify cost-effective approaches to environmental compliance; and (ii) make efforts whenever practicable to minimize waste by using nonrenewable resources wisely, recycling when practicable rather than disposing of materials, and planning for future waste handling needs.

1.32 Document Retention Policies and Procedures. Document retention policies and procedures ensure that records are retained for a uniform time period throughout BVHS and avoid the unnecessary accumulation of documents unlikely to be required for future business operations. These policies and procedures apply to documents and records maintained in computer storage (or other electronic form) as well as written documents and materials. All employees/agents have a responsibility to adhere to BVHS's record retention policies and procedures.

Retention Periods. Employees/agents should

refer to the Document Retention Schedule for information concerning the retention period for specific types of documents.

Records shall be destroyed upon the expiration of the prescribed retention period, but not before. Records shall not be retained for longer than the prescribed period without first contacting the applicable Department Head. Retention periods are specified for original documents only unless otherwise specified.

Employees/agents should not selectively discharge records or other documents that would normally be retained for a longer period of time because they believe that the documents might be harmful to any employee or to BVHS.

Exceptions. Any exceptions to BVHS's document retention policies and procedures may be made only after consultation with the Compliance Officer. Any employee/agent who believes that circumstances warrant such a deviation should promptly contact the Compliance Officer.

Investigations, Legal and Administrative Proceedings. All document destruction procedures shall immediately cease in the following circumstances:

- the records may be covered by a subpoena that has been issued (or other existing request) or there is reason to believe that the records may be subpoenaed (or otherwise requested) in a current or impending matter;
- there is an existing or impending internal or governmental investigation, civil litigation or other legal or administrative proceeding that may reasonably require production of the records; or
- BVHS is voluntarily cooperating with governmental authorities or other outside parties in a legal or administrative proceeding that may reasonably require

production of the records.

The Compliance Officer has primary responsibility to promptly notify appropriate BVHS employees/agents of the occurrence of any of the above events to ensure that a proper "HOLD" is placed on record destruction. Specific instructions regarding the "HOLD" will be appropriately disseminated. If there is any question whether a particular document is, or should be, subject to a "HOLD" designation, the Compliance Officer's approval must be obtained prior to the destruction of such documents.

Any employee/agent who has reason to believe that the above-described or any other circumstances warrant retention of BVHS records beyond the required periods should preserve the records in question and immediately contact the Compliance Officer.

Privileged and Otherwise Protected Documents. BVHS is entitled by law to keep certain documents confidential, even when sought by an opposing party in a legal proceeding. Such documents are commonly referred to as privileged. BVHS's policy is to maintain the confidentiality of privileged documents.

There are several types of protection against disclosure, including the attorney-client privilege, the work product doctrine and, in some circumstances, the self-evaluation privilege. In order to maintain the privileged nature of a document, the rules defining the privilege must be strictly observed. One rule common to all privileges is that the privileged document must be kept confidential from third parties. If an otherwise privileged document is shared with a third party, the privilege is lost forever. If you are custodian of documents that might be privileged, please (i) notify the Compliance Officer and (ii) ensure that the documents are segregated in your files and marked "privileged and confidential."

Work Files. Personal work files may be

maintained so long as a matter is pending. Once a matter is concluded, records contained in a work file should be categorized and retained or discarded in accordance with the prescribed periods set forth.

For specific document retention questions, please refer BVHS Record Retention Policy, Policy No. 80.43. If you have additional questions, please contact the Legal Services Department.

CHAPTER 2: OVERALL PROGRAM OVERSIGHT

2.1 Responsible Officer. BVHS has a designated Corporate Compliance Officer responsible for overall implementation and operation of the Compliance Support Program. The Compliance Officer is responsible for ensuring that:

- This Manual is available to all employees, officers, directors, and agents.
- All employees, officers, directors and agents certify annually in electronically or writing that they have received, read, and understood the Manual.
- All supervisors certify annually in writing that they have reviewed the Manual and made it available to each person supervised, including new employees/agents hired since the date of their last certification, and all new employees/agents required to be audited have been the subject of a new employee/agent audit.
- Standards and manuals are reviewed and updated in response to specific audit results and to conform to changes in the law, the regulatory environment, and BVHS's business.
- Employee/agent and vendor screening mechanisms are in place and are operating properly.
- Employees/agents are receiving adequate education and training and such education and training are documented.
- Audit procedures are implemented in accordance with BVHS policies.
- Complaints and other concerns regarding compliance are promptly investigated.

- Steps are taken to correct any identified problems and prevent their recurrence.
- Participation in training and compliance with laws and BVHS policies is a significant part of evaluations of job performance.

2.2 Supervisor Responsibilities. Supervisors are responsible for ensuring that:

- Each person under their supervision is notified of how to access this Manual (and other BVHS policies that may be issued) and is advised of BVHS's fundamental policy of compliance with applicable laws and BVHS policies.
- Each employee and agent under their supervision receives the appropriate training on the applicable laws affecting their job duties.
- New employees and agents undergo appropriate audits of their work.
- They monitor the compliance of the persons under their supervision or direction.
- They make clear their strong commitment to compliance as an example for employees and agents.
- They encourage open communication among employees and agents under their supervision regarding compliance matters.

Each supervisor's performance of these duties, as well as the overall compliance performance of persons under their supervision will be taken into account in periodic performance reviews.

2.3 Compliance Committee. The Compliance Officer shall have direct access to the Compliance and Audit Committee of the BVHS Board. The Compliance Committee performs any duties delegated to it by the President or the Board of Trustees.

2.4 Report to the Board. The Compliance Officer shall report to the Board of Trustees as appropriate, but not less than quarterly, on the activity and effectiveness of the Compliance Support Program, including a written annual report on the status of compliance within BVHS that addresses any recommendations resulting from the prior year's audit work and any other information requested by the Board.

CHAPTER 3: DUE CARE IN DELEGATION OF AUTHORITY

3.1 Policy. BVHS shall make reasonable inquiry into the background of prospective employees and agents who exercise substantial supervisory authority or who exercise substantial discretion within BVHS.

3.2 Fraud and Abuse Screening. BVHS shall make reasonable inquiry into the background of prospective employees/agents and vendors whose job function or activities may materially impact the Medicare/Medicaid claim development and submission process, BVHS's relationship with physicians, or referral patterns between providers.

Staff. The following categories of prospective employees/agents shall be screened to determine whether they have been (a) convicted of a criminal offense related to health care; or (b) listed by a federal agency as debarred, excluded or otherwise ineligible for federal program participation.

- Any person occupying a management position in BVHS.
- Providers who do or will possess an individual Medicare provider number.
- All billing office supervisors and managers.

Vendors. BVHS shall not knowingly contract with or retain on its behalf any person or entity which has been (a) convicted of a criminal offense related to health care (unless such person or entity has implemented a compliance program as part of an agreement with the federal government); or (b) listed by a federal agency as debarred, excluded or otherwise ineligible for federal program participation. The screening process applicable to vendors must be applied to vendors before contracts are entered into with such vendors and in connection with the renewal of such contracts.

Non-Employees. All non-employed agents,

vendors and contractors who provide items or services to BVHS shall be given a Notice to Agents, Vendors and Contractors in the Form of Exhibit 3.2 attached hereto before providing items or services to BVHS.

3.3 Inquiry. BVHS shall review the following sources:

- the U.S. Department of Health and Human Services List of Excluded Individuals/Entities (see <http://exclusions.oig.hhs.gov>).
- The Ohio Department of Job and Family Services List of Terminated Providers and Excluded Providers (see <http://jfs.ohio.gov/OHP/providers/-TerminatedProviders.stm>)
- Appropriate sources for state or local background check (e.g., State Bureau of Criminal Apprehension, Bureau of Investigation, local Sheriff's Department, etc.).

3.4 Current Employees and Agents.

Employees or agents who are charged with criminal activity that relates to their suitability as employees or agents shall be handled as set forth in BVHS's Corporate Compliance's Background Screening Administrative Policy.

CHAPTER 4: EDUCATION AND TRAINING

4.1 General Policy BVHS shall provide employees/agents with such training as is necessary and appropriate, depending on the person's duties, to ensure compliance with applicable laws and regulations.

4.2 Documentation. BVHS shall document the training provided to each employee/agent, including the name and position of the employee/agent, the date and duration of the educational activity or program, and a brief description of the subject matter of the education.

4.3 Compliance Support Program. Education about BVHS's Compliance Support Program shall include information about the organization's commitment to full compliance with law and policy, the procedures for reporting suspected wrongdoing or concerns, the procedures for asking and having answered any questions the employees/agents may have, and the monitoring and auditing of the employee's/agent's work to assure full compliance with law and policy. All employees shall receive at least 1 hour annually relating to the Compliance Support Program.

4.4 Fraud and Abuse Education and Training.

Claim Development and Submission Process. BVHS shall provide education to employees/agents involved in the claim development and submission process, including BVHS -sponsored educational sessions, educational videos, department meetings in which compliance and the claim development and submission process issues are specifically addressed, attendance at carrier, intermediary or state-sponsored educational sessions, and attendance at seminars.

- **Patient Registration Personnel.** At least 1 hour annually relating to one or more of the following subjects: The Compliance Support Program, an overview of the fraud and abuse

laws as they relate to the claim development and submission process, a review of Medicare requirements applicable to the registration process, and the consequences to both individuals and BVHS of failing to comply with applicable laws.

- **Physician and Other Patient Care Personnel.** At least 1 hour annually relating to one or more of the following subjects: The Compliance Support Program, an overview of the fraud and abuse laws as they relate to the claim development and submission process, a review of Medicare requirements relating to documentation, charge entry and coding (as applicable), and the consequences to both individuals and BVHS of failing to comply with applicable laws.
- **Coding/Billing Personnel.** At least 1 hour annually relating to one or more of the following subjects: The Compliance Support Program, an overview of the fraud and abuse laws as they relate to the claim development and submission process, a review of Medicare requirements applicable to the coding of claims or preparation of claims for services, as applicable, and the consequences to both individuals and BVHS of failing to comply with applicable laws.

Payments for Referrals and Related Issues. BVHS will provide education to employees/agents involved in negotiating relationships with physicians, providers, and vendors, including at least 1 hour annually of training relating to: The Compliance Support Program; an overview of the fraud and abuse laws, and the consequences to both individuals and BVHS of failing to comply with applicable laws.

CHAPTER 5: MONITORING AND AUDITING

5.1 General Policy. It is BVHS's policy to assure compliance with law and policy by:

- Monitoring employee/agent performance.
- Encouraging questions and answering questions.
- Requiring the reporting of suspected violations.
- Auditing employee/agent performance.

5.2 Monitoring. Supervisors are responsible for monitoring the compliance of the persons under their supervision. Each supervisor shall evaluate, in connection with periodic performance reviews and other evaluations, the compliance sensitivity and performance of the persons under their supervision.

All contracts (including service contracts, leases and joint ventures) with physicians and other referral sources must be approved as required by the Section entitled "Contracts and Contract Administration" in 1.7.

5.3 Compliance Certification Forms. To underscore the importance of BVHS's commitment to full compliance with law and policy, all current employees and agents are required to sign the Compliance Certificate after the completion of their annual mandatory education session. All new employees and agents are also required to execute the Compliance Certificate. In addition, employees and agents shall sign such a certificate on an annual basis. On an annual basis, supervisors will be required to execute a certificate indicating, among other things, that they have received this Handbook and made it available to each person under their supervision (including employees and agents hired from the time of the last certification) and that all such new employees and agents required to be audited have been the subject of a new employee/agent audit. The form of certificate is

attached as Exhibit 5.3B.

5.4 Asking Questions and Handling Questionable Situations. No set of policies and procedures can be crafted to cover every potential situation that employees and agents might face in the day-to-day conduct of BVHS operations. The policies set forth in the Manual and elsewhere are written in broad terms and are intended to serve as guidelines for situations that employees and agents may encounter. Nonetheless, situations may arise that are not addressed by this Handbook or which raise questions as to the appropriate application of legal or regulatory requirements or BVHS policies to proposed conduct.

Employees and agents are encouraged to ask any questions they may have and, in fact, have a duty to keep asking questions until they are satisfactorily answered. An employee or agent may ask questions of his or her supervisor or directly to the Compliance Department, 1900 South Main Street, Findlay, OH 45840, or by calling 419-423-5580.

Employees and agents may not engage in conduct that violates applicable legal requirements or BVHS policies even if instructed to do so by their superiors, and will be deemed in violation of BVHS policy and subject to discipline if they do so. If an employee or agent ever questions whether a superior's orders violate applicable laws or policies, the Compliance Officer should be contacted immediately.

Employees and agents who have a question whether certain conduct might violate legal requirements or BVHS's policies should refrain from taking any questionable action and promptly consult with their supervisor.

Employees and agents are not expected to have expert knowledge of all of the various legal and regulatory requirements that may apply to their

activities. However, they should be sensitive to legal and ethical issues and the application of BVHS's policies to their conduct and to know enough to ask questions before engaging in any questionable conduct. When in doubt, the right course is to raise questions with appropriate senior personnel before taking any questionable action.

Because this Handbook is broadly worded to cover a wide variety of situations that may arise, employees and agents may face situations in which completely legal and ethical conduct could technically be interpreted to be a violation of BVHS policies and procedures. Employees and agents who believe that they are faced with such a situation should nevertheless refrain from taking any questionable action and promptly consult with the Compliance Officer, which will review the situation and issue appropriate guidance.

5.5 Reporting. All employees and agents are required to report any information that leads them to suspect any violation of BVHS policy or applicable laws and any situations where proposed conduct may constitute such a violation (collectively, a "Compliance Incident"). Failure to report a Compliance Incident is itself a violation of BVHS policy and will subject an employee or agent to disciplinary action, including termination when appropriate. Complaints regarding patient care issues should be directed to the Patient Relations Department. If such complaints give rise to a compliance incident, they will be reported to the Compliance Department.

Reporting Procedures. A report may be made by 1) explaining the suspected violation in person or in writing to the person's supervisor (or any other person in the chain of authority); 2) mailing any written concern to the Compliance Department; or 3) contacting the anonymous reporting service by calling (419)423-5580; 4) or sending an electronic mail to compliance@bvhealthsystem.org. Supervisors shall immediately forward written reports to the Compliance Department and call the Compliance Department to inform it of oral reports.

The reporting service number shall be posted in common work areas.

Identity of Reporter. Persons making a report shall not be required to provide their identity as part of their report. BVHS will thoroughly investigate both identified and anonymous reports.

Confidentiality. Persons making a report should maintain all information related to the report in strict confidence and should not discuss such information except with BVHS officials addressing the matter. BVHS will maintain the identity of the reporting individual in strict confidence. The person's identity may be disclosed only to the President, legal counsel, and the auditors (and to their collective support personnel to the extent necessary to type and file documents related to the report). Additionally, disclosures will be made consistent with BVHS's legal and fiduciary obligations, for example disclosures to the government. However, depending on the nature of the issue, the identity of the reporting individual may become obvious to others upon investigation.

Response to Reporting. The reporting individual shall receive an oral response within 3 days of receipt of the report. Depending upon the nature of the issue, the response may be that the questioned practice is proper, that the questioned practice is improper and has been corrected by implementation of a new procedure, or that the questioned practice is being currently investigated. If the questioned practice is still under investigation, or has not yet been resolved, the reporting individual shall be informed of the expected time needed to resolve the issue. At the end of this time period the reporting individual should be informed of the issue's resolution, or if the issue is not yet resolved, of its progress. This procedure shall continue until the reporting individual is informed of the issue's final resolution.

Handling Compliance Reports. All reports must be investigated and appropriate action taken in coordination with the Compliance Officer.

Responding to a report can involve complex legal or policy questions that are appropriately handled at senior levels, typically with guidance from counsel. If the result of the investigation indicates that corrective action is required, BVHS will determine and implement those steps to be taken. Employees and agents should not attempt to investigate or otherwise take remedial action to respond to a Compliance Incident on their own, whether with respect to their own or someone else's conduct. Such "self-help" efforts by employees and agents may adversely affect BVHS's ability to investigate or otherwise address the matter and take the best responsive action. Of course, in the case of an emergency (e.g., a discharge of hazardous waste) employees and agents should take appropriate steps to promptly halt any violation and report the matter as required pursuant to the Manual.

Cooperation. Employees and agents are expected to cooperate in any investigation or other effort by BVHS to respond to a report. BVHS will not tolerate any direct or indirect efforts by an employee or agent to cover up a violation of law, regulations, or BVHS policy or otherwise impede an investigation or corrective action, for example by withholding information, fabricating an inaccurate or misleading version of the facts, creating misleading documents, altering or destroying records or other such deceptive conduct. Any such conduct is itself a violation of BVHS policy.

No Reprisals. No employee or agent who in good faith makes a report will be subject to disciplinary action or otherwise penalized for making such report. Any employee or agent involved in reprisals or other action against an individual who in good faith reports a suspected violation of law or BVHS policy will be subject to disciplinary action, including termination when appropriate. However, submission of a report that is known (or should reasonably be known) to be false or misleading at the time made constitutes a violation of BVHS policy and will subject the employee or agent to disciplinary action, including termination when appropriate.

5.6 General Auditing. To assure compliance with law and policy BVHS shall perform periodic audits as directed by BVHS's President. The audits will be executed in accordance with the policies and procedures contained in the applicable auditing tool or protocol utilized by BVHS. Generally, the audits shall include a factual investigation conducted through interviews with key personnel and a random review of preselected documents and files. In addition to periodic audits, BVHS shall conduct a complaint audit which is a review of any matter for which it receives a credible allegation or complaint alleging improper conduct or a violation of any policy or law. All audits shall be performed in accordance with reasonable methods for selecting random samples. BVHS will devote such resources as are reasonably necessary to ensure that the audits are (1) adequately staffed (2) by persons with appropriate knowledge and experience to conduct the audits (3) utilizing audit tools and protocol that are periodically updated to reflect changes in applicable laws and policies.

A final, written copy of all audit reports shall be approved by the Compliance Department and legal counsel. The Vice President, or designee, of the operational area shall be responsible to revise applicable educational training materials and procedure manuals to correct the problems found during audit. The Vice President, or designee, of the operational area shall also be responsible for assuring that the information on how to correct the problem is promptly disseminated to the employees/agents and supervisors involved in the problem. Depending on the circumstances, the Compliance Department may order a follow-up audit on the facility or specific persons to ascertain that a specific concern has, in fact, been corrected.

5.7 Fraud and Abuse Auditing. Representative claims from all of BVHS's individual and institutional providers shall be periodically reviewed to promptly identify deficiencies in the claim development and submission process that may result in inaccurate

claims or other violations of law or policies. Exhibit 5.7 entitled “Auditing BVHS Claims” outlines the auditing procedures and contains a billing audit tool. BVHS will conduct audits in accordance with the schedule set forth below. All audits shall be performed on current billings, except when an audit indicates a possible problem retrospectively, then the retrospective problem shall be investigated and addressed.

New Employee/Agent Audits. It is the policy of BVHS and the responsibility of each department manager to ensure that persons who are new to a position which has a direct impact on the claim development and submission process are provided adequate and appropriate training, and are audited as follows:

- **Billers and coders.** Each person whose principal function includes the billing or coding of claims shall have all claim-related work reviewed by a supervisor or an experienced co-worker for a period of not less than 90 days following the commencement date, and/or until the supervisor is satisfied that the accuracy of the person’s claims justify cessation of the reviews.
- **Admission.** The work of every person new to admission shall be reviewed for a period of not less than 90 days, and/or until the supervisor is satisfied that the accuracy of the person’s work is adequate to justify cessation of the review.
- **Patient Care Providers.** Patient care providers shall be provided guidelines with respect to documentation of services rendered by such providers. The providers’ work shall be reviewed for a period of not less than 90 days, and/or until the supervisor is satisfied that the accuracy of the person’s work is adequate to justify cessation of the review.

The term “provider” includes physicians, nurses, other clinical personnel, and other persons who may document the delivery of services in the provider’s records (including medical records).

Periodic Audits. BVHS will conduct periodic audits of claims submitted to governmental programs. At a minimum, BVHS’s audit activities shall consist of individual provider audits. The audit shall consist of not less than 20 claims annually (e.g., 5 claims/provider/quarter) of every provider with an individual provider number.

CHAPTER 6: ENFORCEMENT AND DISCIPLINE

6.1 Persons Subject to Action. Disciplinary action, including suspension, imposition of monetary penalties or termination, may be taken against any person who:

- authorizes or participates, directly or indirectly, in any action that constitutes a violation of applicable laws or BVHS policies;
- fails promptly to report a Compliance Incident (as defined in 5.5); or withholds information concerning a violation of which the employee or agent becomes aware;
- supervises a person involved in a compliance violation to the extent that the circumstances reflect inadequate supervision or lack of appropriate diligence by the supervisor;
- attempts to retaliate or participates in retaliation, directly or indirectly, against a person who in good faith reports a Compliance Incident or encourages others to do so;
- makes a report of a Compliance Incident which is known (or should reasonably be known) by the reporting person to be false or misleading; or
- fails to cooperate fully with BVHS's efforts to investigate or otherwise address a Compliance Incident.

6.2 Consideration. Imposition of disciplinary action is within the sole discretion of BVHS and will be made based on consideration of all of the relevant facts and circumstances of a particular situation, including whether a person involved in a Compliance Incident promptly reported the matter, the degree of the person's cooperation and the nature of the person's conduct. However,

employees and agents are required to promptly report Compliance Incidents and to cooperate with BVHS in addressing such matters, and the fact that a person fulfills these obligations will not insulate the person from potential disciplinary action.

6.3 Legal Actions. In addition to disciplinary action, violations of applicable legal requirements or BVHS policies may result in the referral of such misconduct to appropriate governmental authorities for criminal or civil prosecution or in legal action by BVHS to recover losses or damages caused by such misconduct.

CHAPTER 7: RESPONSES TO PROBLEMS AND CORRECTIVE ACTION

7.1 Investigation:

General. BVHS shall investigate evidence of possible violations of law or policy, to identify whether a violation has occurred, to identify the individuals involved, to identify appropriate corrective action, to implement those procedures necessary to ensure future compliance, to protect BVHS in the event of civil or criminal enforcement actions, and to preserve and protect BVHS's assets.

Control of Investigations. All Compliance Incident reports received shall be forwarded to the Legal Department. The Legal Department will direct the investigation of the alleged problem or incident. In undertaking an investigation, the Legal Department may solicit the support of internal auditors, external counsel and auditors, and other internal and external resources as appropriate. Such persons shall function under the direction of the Legal Department and shall be required to submit relevant evidence, notes, findings and conclusions to the Legal Department.

Investigative Process. Upon receipt of a complaint or other information (including audit results) that suggests a violation of law or policy, the Legal Department shall commence an investigation as soon as reasonably possible and in any event within 5 business days following the receipt of the complaint or report. The investigation shall include:

- Notification of the Compliance Department of the nature of the matter and obtaining a memorandum from management authorizing an investigation.
- An interview of the complainant if known and other persons who may have knowledge of the alleged facts to determine if there is reason to suspect that the alleged facts may be true, and a review of the applicable laws

and regulations to determine whether or not the alleged facts would, if true, be a problem. If the review results in conclusions or findings that the alleged conduct is permitted under applicable laws and policies or that there is no reason to suspect that the facts may be as alleged, the investigation shall be closed. If the initial investigation concludes that there is reason to suspect the occurrence of an event that violates law or policy (including the submission of inaccurate claims or improper billing) or that additional evidence is necessary to determine this, the investigation shall proceed to the next step.

- The identification and review of applicable documents (including representative bills or claims submitted to the Medicare/Medicaid programs) to determine the nature of the alleged problem, the scope of the problem, the frequency of the problem, the duration of the problem, and the potential financial magnitude of the problem.
- Interviews of the person or persons in the departments and institutions who appeared to play a role in the process in which the alleged problem exists with relation to:
 - the individual's understanding of the applicable law and policy;
 - the identification of persons with supervisory or managerial responsibility in the process;
 - the adequacy of the training of the individuals performing the functions with the process;
 - the extent to which any person acted contrary to law or policy;

- any facts relating to potential civil or criminal liability of individuals or BVHS; and
- any other relevant matter.
- A review of the applicable laws and regulations to determine whether or not the alleged facts would, if true, be a problem.

If the initial investigation results in conclusions or findings that the alleged conduct is permitted under applicable laws and policies or that there is no reason to suspect that the facts may be as alleged, the investigation shall be closed. If the initial investigation concludes that there is reason to suspect the occurrence of an event that violates law or policy (including the submission of inaccurate claims or improper billing) or that additional evidence is necessary to determine this, the investigation shall proceed to obtain the necessary information to determine whether a violation has occurred.

At the conclusion of the investigation, the Legal Department shall prepare a summary report that (1) identifies any apparent violation (including, if possible, estimates of the resulting overpayment by the government, if any), (2) summarizes the investigation process, (3) identifies the persons' responsible for the problem, and (4) identifies any person who appears to have either acted willfully or with reckless disregard or deliberate ignorance toward law or policy.

7.2 General BVHS Response. If the violation is of a law or policy other than the Medicare/Medicaid rules the Compliance Officer shall recommend how to:

- Correct the practice as soon as possible.
- Initiate such disciplinary action, if any, as may be appropriate.

- Promptly undertake a program of education at the appropriate business unit to prevent future similar problems.
- Inform the Board of Directors at their next meeting.

7.3 BVHS Response to Medicare/Medicaid Violations.

Willful Activity. If BVHS uncovers apparent criminal violation of the Medicare/Medicaid rules, it shall:

- Immediately stop all billing related to the problem in the unit(s) where the problem exists until the offending practices are corrected.
- Initiate appropriate disciplinary action. Appropriate disciplinary action shall include, at a minimum, the removal of the person who appeared to have acted willfully with reckless disregard or deliberate ignorance of law or policy from any position with oversight for or impact upon the claims submission or billing process.
- If only Medicaid is involved, the appropriate state agency and/or the state Attorney General shall be notified. If Medicare and Medicaid claims are involved, BVHS shall notify the programs through the local United States Attorney's Office or the local office of the United States Department of Health and Human Services Office of the Inspector General Division, as counsel for BVHS deems appropriate. Notification, if required, shall be made within a reasonable time period but no longer than thirty (30) days after completing the internal investigation. BVHS, through its counsel, may attempt to negotiate a voluntary disclosure agreement prior to the disclosure.

Other Noncompliance. If the investigation

reveals billing or other problems which do not appear to be the result of conduct which is willful or with reckless disregard or deliberate ignorance for the Medicare and Medicaid rules, BVHS shall calculate and repay to the appropriate governmental entity any duplicate payments or improper payments resulting from the act or omission within 60 days of the identification of the duplicate or improper payment, and take the actions set forth in 7.2.

EXHIBIT 1.7

Federal Stark Law Compliance Checklist

For providers of “designated health services” (including hospitals and physician group practices).

The federal Stark Law, 42 U.S.C. §1395nn, prohibits physicians from ordering the “designated health services” listed on Appendix 1 (“DHS”) that are covered by Medicare or a state Medicaid program* if they are provided by a DHS Provider (as defined in Appendix 2) with which the physician or a member of his or her immediate family has a direct or indirect “compensation arrangement” or “ownership or investment interest,” unless an exception applies. This prohibition is absolute—it does not matter whether the financial arrangement is intended to induce referrals.

The term “physician” includes doctors of medicine, osteopathy, podiatry, chiropractic, dental surgery, dental medicine, and optometry, as to items or services within their scope of practice. (A professional corporation of which a physician is the sole owner is deemed equivalent to the physician for all purposes.) A physician’s “immediate family” includes a spouse, natural or adoptive parent, child, sister, brother, stepparent, stepchild, stepbrother, stepsister, father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, sister-in-law, grandparent or grandchild, or spouse of a grandparent or grandchild.

This Checklist provides a step-by-step procedure to determine whether any exception applies to a given arrangement. There are exceptions for compensation arrangements and different exceptions for ownership interests. A few exceptions apply to both. Payments or other items of value received because of an ownership or investment interest are addressed in Part 1. For compensation arrangements, go to Part 2 (page 13).

This Checklist is not intended to be a substitute for legal advice. It is intended to supplement other steps taken by providers and physicians, in conjunction with their counsel, to identify issues that require further review, and to provide a mechanism to document the basis for an exception.

* The Checklist was prepared by Shumaker, Loop & Kendrick, LLP, a law firm with offices in Ohio, Florida and North Carolina, and cannot be duplicated without its written consent. The prohibition affects Medicaid referrals only in states that have adopted legislation to implement the federal law.

Part 1. Ownership and Investment Interests—Any arrangement under which a physician or immediate family member is entitled to receive profit distributions, dividends or interest on secured obligations described below from the DHS Provider (including the physician’s own group) by virtue of holding equity or secured debt obligations, including cases in which the physician or family member has an ownership or investment interest in an entity that has an ownership or investment interest in the DHS Provider, if there is an unbroken chain of ownership or investment interests between the physician and the DHS Provider. This includes any debt obligations of the DHS Provider that are secured by an interest in the entity’s assets (e.g., a mortgage) or revenues (e.g., a collateral pledge of accounts receivable) except for a physician’s security interest in equipment sold by the physician to a hospital. It does not include stock options or convertible debt securities until they are exercised or converted to equity. Purchases and sales of ownership and investment interests, including repurchases of such interests by the DHS Provider, constitute “compensation arrangements,” which are addressed under Part 2 below. Receipt of stock options or convertible securities also constitute “compensation arrangements.”

Y N A. Does the physician order DHS that are covered by Medicare or a state Medicaid program (“Federal DHS”) and furnished by the DHS Provider (excluding services personally performed by that physician, but including DHS that are supervised by that physician)? Include cases in which the physician (i) controls or influences orders by non-physicians for Federal DHS (e.g. nurse practitioners and physician assistants), (ii) directs another party (including another physician) to order the Federal DHS, or (iii) consults with another physician who orders the Federal DHS. (A “consultation” involves a request by a physician for the advice of another physician, which is provided to the first physician.) Exclude orders by radiologists (for radiology services other than interventional radiology services), by pathologists (for clinical laboratory services) and by radiation oncologists (for radiation oncology services), if such services are performed or supervised by them or by another such physician in the same “group practice” (which meets the requirements of AA. and CC. below) pursuant to a consultation initiated by another physician, but do not exclude the other physicians who consult them.

If no, you need not go further. If yes, go to B.

Y N B. Are the DHS furnished only to enrollees of a prepaid health plan?

If yes, go to C. If no, go to D.

Y N C. Is the prepaid health plan one of the following:

— A health maintenance organization (“HMO”) or competitive medical plan (“CMP”) in accordance with a contract with the Centers for Medicare and Medicaid Services (“CMS”) under 42 U.S.C. §1395mm; or

— A health care prepayment plan in accordance with an agreement with CMS under 42 U.S.C. §1395(a)(1)(A); or

- An organization that is receiving payment on a prepaid basis for Medicare enrollees under 42 U.S.C. §1395b-1; or
- A qualified HMO as defined in 42 U.S.C. §300e-9(d); or
- A coordinated care plan as defined in 42 U.S.C. §1395w-2 offered by an organization in accordance with a contract with CMS; or
- A managed care organization contracting with a State Medicaid program under 42 U.S.C. §1396b(m); or
- A health insuring organization, prepaid inpatient health plan, or prepaid ambulance health plan contracting with a State Medicaid program under 42 C.F.R. Part 438; or
- A provider operating under a demonstration project pursuant to 42 U.S.C. §§ 1315, 1396n(a), 1396n(b) or 1396u-2(a).

If yes to any, you need not go further. If no to all, go to D.

Y N D. Are the DHS limited to one or more of the following:

- Implanted items (prosthetics, prosthetic devices or durable medical equipment) that are implanted by the referring physician or a member of his group practice (which meets the requirements of AA. and CC. below) and furnished by a Medicare-certified ambulatory surgical center (“ASC”), during a surgical procedure performed in the same ASC.
- Erythropoietin (“EPO”) or other dialysis-related prescription drugs identified by CMS that are furnished by an end-stage renal disease (“ESRD”) facility to the patient at the facility or, in the case of EPO or Aranesp (or equivalent drugs as determined by CMS), for use in the patient’s home.
- Preventive screening tests, immunizations or vaccines identified at http://www.cms.hhs.gov/PhysicianSelfReferral/11_List_of_Codes.asp that are subject to CMS-mandated frequency limits and reimbursed by Medicare based on a fee schedule.
- Eyeglasses or contact lenses furnished to a patient following cataract surgery that are provided in accordance with 42 C.F.R. §§410.36(a)(2)(ii) and 414.228.

If yes, go to E. If no, go to F.

Y N E. Do the DHS meet both of the following requirements:

- The arrangement for the furnishing of the DHS does not violate the federal

anti-kickback statute, 42 U.S.C. §1320a-7b; and

___ Billing and claims submission for the DHS comply with all federal and state laws and regulations.

If yes, you need not go further. If no, go to F.

Y N F. Is the provider a hospital (the term “hospital” includes the legal entity that operates a hospital and any subsidiary, related entity, or other entities that perform services for the hospital’s patients and for which the hospital bills, but excluding entities that perform services “under arrangements” with the hospital as defined in Medicare regulations)?

If yes, go to G. If no, go to I.

Y N G. Is the hospital located in Puerto Rico?

If yes, you need not go further. If no, go to H.

Y N H. If the referral is made on or after September 23, 2011, does the hospital meet all the following requirements?

___ Its Medicare provider agreement has been continuously in effect since before December 1, 2010.

___ It requires members of its medical staff to provide written disclosure of any ownership or investment interest in the hospital to patients by a time that permits the patient to make a meaningful decision regarding the receipt of care.

___ If it does not have a physician available on the premises to provide services at all times, it discloses this fact to the patient at the time of the provision of a package of information regarding scheduled preadmission testing and regulations for a planned inpatient admission or outpatient visit, and receives a signed acknowledgement from the patient that he or she understands this fact before providing services to the patient.

___ It publicizes its physician ownership and investment interests on any website and in any public advertising.

___ It has the capacity to provide assessment and initial treatment of patients and to refer and transfer patients to other hospitals with the capacity to treat the patients’ needs.

___ The percentage of the total aggregate value of the ownership or investment interests held in the hospital, or in an entity whose assets include the hospital entity, by physician owners or investors (or their family members) does not exceed the percentage that existed as of March 23, 2010.

- It does not condition physician ownership or investment on the physician making or influencing referrals.
- Neither it nor any owner or investor has provided any financing (including a loan or loan guarantee) or made a payment toward or subsidized any financing that is related to a physician's ownership or investment interest, directly or indirectly.
- All returns to owners and investors are proportional to their investment.
- It submits an annual report to the Secretary of Health and Human Services detailing the identity of its physician owners and investors and the nature and extent of all ownership and investment interests.
- Physician owners and investors do not receive, directly or indirectly, any guaranteed receipt of or right to purchase other business interests related to the hospital, including the purchase or lease of any property under the control of other owners or investors in the hospital or located near the premises of the hospital.
- It does not offer a physician owner or investor the opportunity to purchase or lease any property under the control of the hospital or of any other owner or investor on more favorable terms than other parties
- The aggregate number of operating rooms, procedure rooms and beds has not increased from the number the hospital was operating and legally permitted to operate as of March 23, 2010 or, if the hospital did not have a provider agreement on that date, the date of the provider agreement. (A "procedure room" is one in which catheterizations, angiographies, angiograms, or endoscopies are performed.)

If yes to all, go to I. If no to any, go to O.

Y N I. Is the provider located in a rural area, i.e. not located in a metropolitan area, as defined by the U.S. Office of Management and Budget?

If yes, go to J. If no, go to M.

Y N J. Are the referrals to an immediate family member of the referring physician or a provider with which an immediate family member has a direct or indirect ownership interest or compensation arrangement?

If yes, go to K. If no, go to L.

Y N K. Are all the following requirements met?

- The referred patient resides in the rural area; and

No other party is available to furnish the services in a timely manner within 25 miles or 45 minutes transportation time of the patient's residence (if the services are furnished at the patient's home, this requirement does not apply); and

 The financial relationship does not violate the federal anti-kickback law or any Federal or State law or regulation governing billing and claims submission.

If yes, you need not go further. If no, go to L.

Y N L. Are 75% or more of the provider's DHS furnished to individuals residing in the rural area?

If yes, you need not go further. If no, go to M.

Y N M. Is the physician authorized to perform services at the hospital?

If yes, go to N. If no, go to O.

Y N N. Is the ownership or investment interest in the hospital itself (and not merely a subdivision of the hospital)?

If yes, you need not go further. If no, go to O.

Y N O. Is the ownership interest an investment security which may be purchased on the open market?

If yes, go to P. If no, go to Q.

Y N P. Are both of the following requirements met?

 The security is listed on the New York Stock Exchange, the American Stock Exchange, any regional exchange in which quotations are published on a daily basis, or (as to foreign securities) on a recognized foreign, national or regional exchange on which quotations are published on a daily basis, or is traded under an automated interdealer quotation system operated by the National Association of Security Dealers; and

 The security is in a corporation that had, at the end of the corporation's most recent fiscal year, or on average during the previous three fiscal years, stockholder equity (assets less liabilities) exceeding \$75,000,000.

If yes to both, you need not go further. If no to either, go to Q.

Y N Q. Is the ownership interest in shares of a regulated investment company as defined in Internal Revenue Code §851(a) (i.e. a mutual fund) that had, at the end of its most recent fiscal year, or on average during the previous three fiscal years, total assets

exceeding \$75,000,000?

If yes, you need not go further. If no, go to R.

Y N R. Does the ownership or investment interest in the DHS Provider arise from a retirement plan offered by the DHS Provider to the physician (or family member) through the physician's (or family member's) employment with the DHS Provider.

If yes, you need not go further. If no, go to S.

Y N S. Do the Federal DHS constitute "physician services" as defined in 42 C.F.R. §410.20(a) that are personally performed or supervised by another physician who is an employee or "qualifying independent contractor" of the ordering physician's group practice (which meets the requirements of AA. and CC. below)? A "qualifying independent contractor" is a physician who is performing services pursuant to a direct contract to provide services to a group practice's patients in the group practice's facilities, which contract allows the group practice to bill for the services, consistent with Medicare billing rules, and either (i) compensates the physician in a manner that meets the requirements of CC. below or (ii) meets the requirements of Part 2, item W. below. "Supervision" means the level of supervision required to comply with Medicare payment and coverage rules.

If yes, you need not go further. If no, go to T.

Y N T. **Do the Federal DHS include parenteral or enteral nutrients ("PEN") or PEN equipment or supplies (including infusion pumps used for PEN)?**

If yes, go to EE. If no, go to U.

Y N U. **Do the DHS include durable medical equipment ("DME"), including infusion pumps that are DME other than infusion pumps used for PEN?**

If yes, go to V. If no, go to W.

Y N V. **Is the DME limited to canes, crutches, walkers, folding manual wheelchairs, and blood glucose monitors as to which all the following are true?**

In the case of a blood glucose monitor, the physician or group practice also furnishes outpatient diabetes self-management training to the patient, and the monitor includes one starter set of test strips and lancets consisting of no more than 100 of each; and

For all other cases, the patient needs the item in order to ambulate and uses it to leave the physician's office; and

They are furnished as part of the treatment for the specific condition for which the patient-physician encounter occurred; and

They are furnished in the same building (i.e. structures with a common post office street address) in

which the ordering physician or his or her “group practice” (which meets the requirements of AA. and CC. below) owns or rents an office as to which any of the following applies:

- (1) The office is normally open to patients at least 35 hours per week; and the ordering physician or one of the group physicians furnishes patient care services in the office at least 30 hours per week (including some services that are unrelated to the furnishing of DHS); or
- (2) The office is normally open to patients at least 8 hours per week and the ordering physician furnishes patient care services in the office at least 6 hours per week (including some services that are unrelated to the furnishing of DHS) and the patient usually receives physician services from that office; or
- (3) The office is normally open to patients at least 8 hours per week and the ordering physician or one of the group physicians furnishes patient care services in the office at least 6 hours per week (including some series that are unrelated to the furnishing of DHS) and if the ordering physician does not order the DHS during a patient visit at the office, then the ordering physician or a group physician is present when the DHS is furnished during such occupancy of the premises.

(If the physician’s practice primarily consists of treating patients in their homes—not including nursing, long-term care or other facilities or institutions—the DHS are furnished in the patient’s home by the physician or a qualified person accompanying the physician contemporaneously with a physician service that does not constitute DHS); and

— The item is furnished personally by (i) the ordering physician, (ii) another physician who is an owner, employee or “qualifying independent contractor” (see S. above) of the group practice of which the ordering physician is an owner, employee or “qualifying independent contractor” or (iii) a non-physician employee of the ordering physician or group practice; and

— The physician or group practice that furnishes the DME meets all Medicare DME supplier standards set forth in 42 C.F.R. §424.57(c); and

— The arrangement does not violate the federal anti-kickback statute, 42 U.S.C. §1320a-7b, or any Federal or State law or regulation governing billing or claims submission.

If yes to all, go to W. If no to any, go to EE.

Y N W. Do the DHS include magnetic resonance imaging (“MRI”), computed tomography (“CT”) or positron emission tomography (“PET”) services, or interpretations of such services?

If yes, go to W. If no, go to Y.

Y N X. Has the ordering physician informed the patient in writing at the time of the order that the patient may obtain such MRI, CT or PET services, as the case may be, from other parties, and provided the patient with a written list of suppliers (as defined in 42 U.S.C. §1395x(d))?

If yes, go to Y. If no, go to EE.

Y N Y. Does the written list contain the names, addresses and telephone numbers of at least 5 suppliers of services being ordered that are located within 25 miles of the ordering physician's office, or all of such suppliers if there are less than 5 within 25 miles? (Hospitals and other institutional providers may be listed but do not count toward the maximum number.)

If yes, go to Z. If no, go to EE.

Y N Z. Do the Federal DHS meet all the following requirements?

They are furnished personally by the ordering physician or an individual who is supervised by the ordering physician. "Supervision" means the level of supervision required to comply with Medicare payment and coverage rules.

They are furnished in the same building (i.e. structures with a common post office street address) in which the ordering physician has an office as to which either of the following applies:

(1) The office is normally open to patients at least 35 hours per week and the physician furnishes patient care service in the office at least 30 hours per week (including some services that are unrelated to the furnishing of DHS); or

(2) The office is normally open to patients at least 8 hours per week and the physician furnishes patient care services in the office at least 6 hours per week (including some services that are unrelated to DHS) and one of the following applies: (i) the patient usually receives physician services from that office, (ii) the physician ordered the DHS during a patient visit at that office or (iii) the physician is present when DHS is furnished during such occupancy of the premises.

(If the physician's practice primarily consists of treating patients in their homes—not including nursing, long-term care or other facilities or institutions—the DHS are furnished in the patient's home by the physician or a qualified person accompanying the physician contemporaneously with a physician service that does not constitute DHS); and

They are billed by the physician who performed or supervised the services or an entity that is wholly owned by such physician.

If yes to all, you need not go further. If no to any, go to AA.

Y N AA. Is the DHS Provider a group practice as to which all the following are true?

- It is a single legal entity recognized as such under the law of the state in which it achieved its legal status, and not merely an affiliation of physicians or other legal entities under common ownership, control or management. (A group practice that operates in separate states under separate legal entities will be deemed to meet this requirement if the states are contiguous, the entities have identical ownership, governance and operations, and the use of separate entities is legally required); and
- It is not owned in whole or in part by another medical practice that is an operating physician practice; and
- It was formed primarily for the purpose of being a physician group practice; and
- It has no other substantial business purpose; and
- At least two physicians are either owners (directly or indirectly through another entity) or employees of the entity; and
- Each physician owner or employed physician provides, in the group's facilities, substantially the full range of patient care services that such physician routinely provides in any location; and
- At least 75% of all time spent by all physician owners and employed physicians (in the aggregate) providing medical services at any location outside a Health Professional Shortage Area ("HPSA") is billed through the group practice, and this is supported by documentation. Measures other than "time spent" can be used in some cases. (This requirement does not apply to a group practice located in a HPSA); and
- At least 75% of the group's patient encounters are conducted personally by physician owners or employed physicians; and
- The method for allocating income and overhead expenses to the physicians is determined before the receipt of payment for the services giving rise to the overhead expense or producing the income; and
- It has consolidated billing, accounting and financial reporting; and
- It has centralized decision-making by a body representative of the group practice that maintains effective control over the group's assets and liabilities (including budgets, compensation and salaries); and
- If the ordering physician is required to make referrals to a particular party, the requirement is set forth in a written agreement signed by the parties that sets the compensation in advance in sufficient detail to be objectively verified; is related to the physician's services that are covered by the agreement; is reasonably necessary to effectuate the purposes of the arrangement; and does not apply if (i) the patient expresses a preference, (ii) the patient's insurer prohibits or penalizes referrals to the required provider or (iii) the referral is not in the patient's best medical interests, in the

physician's judgment.

If yes to all, go to BB. If no to any, go to EE.

Y N BB. Is the amount of compensation paid to any of the physician owners or physician employees (directly or indirectly) based on the volume or value of Federal DHS ordered by the physician?

If yes, go to CC. If no, go to DD.

Y N CC. Do all portions of compensation that are based on the volume or value of Federal DHS constitute one of the following?

A fixed "per unit of service" fee for services rendered by the physician that does not exceed fair market value for those services in transactions with parties who do not make referrals; or

A share of the overall profits of the group (or any component of the group that includes 5 or more physicians) derived from DHS, which profits are either distributed on a basis unrelated to the volume or value of DHS (whether or not Federal DHS and whether or not personally performed by the physician) that are ordered by the physician (e.g., distributions in proportion to non-DHS revenues) or constitute less than 5% of the total revenues of the group and of each physician's total compensation; or

A productivity bonus based on services personally performed by the physician or services and supplies that are furnished "incident to" personally performed services as defined in 42 C.F.R. §410.26 (see Appendix 3).

If yes to any, go to DD. If no to all, go to EE.

Y N DD. Do the Federal DHS meet all the following requirements?

They are ordered by a physician who is an owner, employee, or "qualifying independent contractor" (see S. above) of the group practice; and

They are furnished personally by an owner of the group, a physician employee of the group, the "qualifying independent contractor" who ordered the services or a nonphysician who is "supervised" by a physician who is an owner, employee, or "qualifying independent contractor" of the group; and

They are furnished in either (i) space (including a portion of a building or a mobile vehicle) that is never used by any party other than the group, or (ii) the same building (i.e. structures with a common post office street address) in which the ordering physician, or the group practice of which he is an owner or employee, owns or rents an office, and as to which any of the following applies:

- (1) The office is normally open to patients at least 35 hours per week and the ordering physician or one of the group’s owner or employee physicians furnishes patient care services in the office at least 30 hours per week (including some services that are unrelated to the furnishing of DHS); or
- (2) The office is normally open to patients at least 8 hours per week and the ordering physician furnishes patient care services in the office at least 6 hours per week (including some services that are unrelated to the furnishing of DHS) and the patient usually receives physician services from that office; or
- (3) The office is normally open to patients at least 8 hours per week and the ordering physician or one of the group’s owner or employee physicians furnishes patient care services in the office at least 6 hours per week (including some services that are unrelated to the furnishing of DHS) and, if the ordering physician does not order the DHS during a patient visit at the office, then the ordering physician or a group physician is present when the DHS is furnished during such occupancy of the premises.

(If the physician’s practice primarily consists of treating patients in their homes—not including nursing, long-term care or other facilities or institutions—the DHS are furnished in the patient’s home by the physician or a qualified person accompanying the physician contemporaneously with a physician service that does not constitute DHS); and

- They are billed by one of the following: (i) the physician performing or supervising the services, (ii) the group practice of which the performing or supervising physician is an owner or employee, under a billing number assigned to the group, (iii) the group practice as to which the supervising physician is a “qualifying independent contractor” (see S. above), under a billing number assigned to the group, or (iv) an entity wholly owned by (i) or (ii) under a billing number assigned to it or to one of those entities.

If yes to all, you need not go further. If no to any, go to EE.

Y N EE. Is the ownership or investment interest directly between the physician or family member and the DHS Provider?

If yes, go to HH. If no, go to FF.

Y N FF. Does the DHS Provider have actual knowledge that the physician or family member has an indirect ownership or investment interest in the DHS Provider?

If yes, go to HH. If no, go to GG.

Y N GG. Is the DHS Provider acting in reckless disregard or deliberate ignorance of the fact

that the physician or family member has such an indirect interest?

If no, you need not go further. If yes, go to HH.

Y N HH. Did the arrangement cease to comply with an exception to the Stark Law for reasons beyond the control of the DHS Provider?

If yes, go to II. If no, go to JJ.

Y N II. Are all of the following requirements met?

For the immediately prior 180 consecutive calendar days, the arrangement complied with an applicable exception; and

Less than 91 days have passed since the arrangement ceased to meet an exception; and

The provider promptly took steps to rectify the non-compliance; and

The arrangement does not violate the federal anti-kickback statute; and

The provider has not relied on this exception for any arrangement with the same physician (or a member of his or her family) in the prior 3 years; and

The claim or bill for the referred services satisfies all Federal and State law and regulations.

If yes to all, you need not go further. If no to any, go to JJ.

Y N JJ. For at least some Federal DHS, the arrangement may not qualify for any exception, and the physician may be prohibited from ordering such DHS provided by the DHS Provider. CONTACT THE COMPLIANCE OFFICER IF THERE IS ANY DOUBT AS TO WHETHER THE ARRANGEMENT IS PERMISSIBLE.

Part 2. Compensation arrangements—Any arrangement under which a physician or immediate family member—or any entity that is owned directly or indirectly by the physician or a family member—receives or pays anything of value (including discounts, forgiveness of debt, and ownership or investment interests) directly or indirectly, to or from a DHS Provider (including the physician’s own group), except for the following:

- (1) payments or other items of value received due to rights held under an ownership or investment interest in the DHS Provider (such as dividends and interest on debt instruments that are secured by the DHS Provider facilities) addressed under Part 1 above;
- (2) forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors;
- (3) items, devices, or supplies (not including surgical items, devices, or supplies) that are used solely to collect, transport, process, or store specimens for the entity furnishing the items, devices, or supplies or are used solely to order or communicate the results of tests or procedures for the entity, and
- (4) payment made by an insurer or a self-insured plan (or a subcontractor of the insurer or self-insured plan) to a physician to satisfy a claim, submitted on a fee-for-service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer or by the self-insured plan, if (i) the health services are not furnished, and the payment is not made, under a contract or other arrangement between the insurer or the self-insured plan (or a subcontractor of the insurer or self-insured plan) and the physician; (ii) the payment is made to the physician on behalf of the covered individual and would otherwise be made directly to the individual; and (iii) the amount of the payment is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account directly or indirectly the volume or value of any DHS referrals.

A physician has an “indirect” compensation arrangement with a DHS Provider if he or a member of his immediate family (or an entity in which they have an ownership or investment interest) receives or pays compensation to or from any entity that is linked with a DHS Provider by a “chain” of entities that have either a compensation arrangement or an ownership or investment interest between each adjacent pair of links in the chain. For this purpose, an ownership or investment interest in either direction is a link in the chain. If a physician has more than one compensation arrangement with a DHS Provider, each must be analyzed separately.

Y N A. Does the physician order DHS that are covered by Medicare or a state Medicaid program (“Federal DHS”) and furnished by the DHS Provider (excluding services personally performed by that physician, but including DHS that are supervised by that physician)?

Include cases in which the physician (i) controls or influences orders by non-physicians for Federal DHS (e.g. nurse practitioners and physician assistants), (ii) directs another party (including another physician) to order the Federal DHS, or (iii) consults with another physician who orders the Federal DHS. (A “consultation” involves a request by a physician for the advice of another physician, which is provided to the first physician.)

Exclude orders by radiologists (for radiology services other than interventional radiology services), by pathologists (for clinical laboratory services) and by radiation oncologists (for radiation oncology services), if such services are performed or supervised by them or by another such physician in the same “group practice” (which meets the requirements of EE. and GG. below) pursuant to a consultation initiated by another physician, but do not exclude the other physicians who consult them.

If no, you need not go further. If yes, go to B.

Y N B. Is the compensation arrangement directly between the DHS Provider and any of the following:

- the physician or family member;
- a professional corporation solely owned by the physician; or
- a physician practice organization in which the physician (or family member) has an ownership or investment interest as defined above.
- a physician practice organization with which the physician has an employment arrangement if the DHS Provider has elected to treat the physician as standing in the shoes of the physician practice organization.

If yes to any, go to K. If no to all, go to C.

1 2 C. Is the link in the chain of financial arrangements that is closest to a party B. (1) a direct compensation arrangement with that party (“Type 1”) or (2) an ownership interest in an entity that is not described in B. (“Type 2”)? Note that in some cases, a physician may have both a Type 1 and a Type 2 indirect compensation arrangement with a DHS Provider arising from the same compensation arrangement. This would occur if a physician has both an ownership interest in and a compensation arrangement with an entity not described in B. that, in turn, has a compensation arrangement with a DHS Provider.

If it is Type 1, go to D. and continue as to that compensation arrangement. If it is Type 2, go to D. and continue as to the compensation arrangement that is closest to the party described in B.

Y N D. Does the aggregate compensation under that compensation arrangement vary with or take into account the volume or value of referrals to the DHS Provider or other business generated for the DHS Provider? If the physician has a direct or indirect ownership or investment interest in a physician practice organization, include all referrals or other business generated by other physicians who are owners, employees or independent contractors of the practice entity while they are working for the entity.

If no, you need not go further. If yes, go to E.

Y N E. Does the compensation arrangement meet all the following requirements?

- The arrangement is for identifiable services and is commercially reasonable even if no DHS referrals are made; and
- There is a signed written agreement specifying the items or services covered by the arrangement or the physician or family member is an employee of the DHS Provider; and
- Any compensation paid either to or from the party described in C. is consistent with the fair market value of the services or items actually provided; and
- Any compensation paid to the party described in C. is not determined in a manner that takes into account the volume or value of DHS referrals or other business generated by the physician or any physician practice organization in which the physician has an ownership or investment interest, except that a fixed “per use” or “per unit of service” fee is permitted for items or services actually provided by the physician other than use of space or equipment (except for equipment furnished as an integral part of a service or package of services), even if the number of uses or units of service increases with the physician’s or practice organization’s referrals, if the fee does not exceed fair market value for the items or services provided in transactions with parties who do not make referrals and does not change during the term of the agreement; and
- If the arrangement is for use of space or equipment (other than equipment furnished as an integral part of a service or package of services), the compensation is not determined using a formula based on either (i) percentage of the revenue raised, earned, billed, collected or otherwise attributable to the services performed or business generated in the space or by use of the equipment, or (ii) per-unit-of-service rental charges, to the extent such charges reflect services provided to patients referred between the parties; and
- The compensation arrangement complies with the Federal anti-kickback law, 42 U.S.C. §1320a-7b, and all Federal and State laws and regulations relating to billing and claims submission.

If yes to all, go to F. If no to any, go to H.

Y N F. Is a physician required to refer patients to specific providers.

If no, you need not go further. If yes, go to G.

Y N G. Does the arrangement meet all the following requirements:

- It is set forth in a written agreement signed by the parties that sets the compensation in advance in sufficient detail to be objectively verified; and

— It is related to the physician’s services that are covered by the agreement referred to in C.; and

— It does not apply if (i) the patient expresses a preference, (ii) the patient’s insurer prohibits or penalizes referrals to the required provider, or (iii) the referral is not in the patient’s best interest, in the physician’s judgment.

If yes to all, you need not go further. If no to any, go to H.

Y N H. Does the DHS Provider have actual knowledge that the aggregate compensation referred to in C. varies with or takes into account the volume or value of DHS referrals or other business generated by the physician or any physician practice organization in which the physician has an ownership or investment interest (regardless of whether it constitutes permissible “per use” or “per unit of service” fees)?

If yes, go to J. If no, go to I.

Y N I. Has the DHS Provider taken reasonable steps to confirm that the aggregate compensation referred to in C. does not vary with or take into account the volume or value of DHS referrals or other business generated by the physician or any physician practice organization in which the physician has an ownership or investment interest (regardless of whether it constitutes permissible “per use” or “per unit of service” fees)?

If yes, you need not go further. If no, go to J.

Y N J. Is the compensation arrangement with a physician practice organization with which the physician has a compensation arrangement but not an ownership or investment interest?

If yes, go to K. If no, go to YYY.

Y N K. Does the consideration constitute “compliance training” by a hospital that is held in the local community or service area? “Compliance training” means training regarding the basic elements of a compliance program (e.g. establishing policies and procedures, training of staff, internal monitoring and reporting) or specific training regarding the requirements of federal and state health care programs (e.g. billing, coding, reasonable and necessary services, documentation, and unlawful referral arrangements); and training regarding other legal requirements (including programs that offer continuing medical education credit only if compliance training is the primary purpose of the program).

If yes, you need not go further. If no, go to L.

Y N L. Do the Federal DHS constitute “physician services” as defined in 42 C.F.R. §410.20(a) that are personally performed or supervised by another physician who is an employee or “qualifying independent contractor” of the ordering physician’s group

practice (which meets the requirements of EE. and GG. below)? A “qualifying independent contractor” is a physician who is performing services pursuant to a direct contract to provide services to a group practice’s patients in the group practice’s facilities, which contract allows the group practice to bill for the services, consistent with Medicare billing rules, and either (i) compensates the physician in a manner that meets the requirements of GG. below or (ii) meets the requirements of W. below. “Supervision” means the level of supervision required to comply with Medicare payment and coverage rules.

If yes, you need not go further. If no, go to M.

Y N M. Is the compensation a malpractice insurance subsidy to an obstetrician in a HPSA that falls within the safe harbor regulations under the federal anti-kickback law, or meets all the following requirements:

- ___ It is paid by a hospital, a federally qualified health center or a rural health clinic; and
- ___ The physician engages in obstetrical practice as a routine part of his or her medical practice; and
- ___ The physician’s practice is located in a rural area (as defined in 42 C.F.R. §411.351), a health professional shortage area (“HPSA”) that is a primary care HPSA, or an area with a demonstrated need for the physician’s obstetrical services as determined by the Secretary of HHS in an advisory opinion (collectively, an “Area of Need”); and
- ___ At least 75% of the physician’s obstetrical patients reside in a medically underserved area or are members of a medically underserved population; and
- ___ The arrangement is in a writing, signed by the physician and the party making the payments; and
- ___ The arrangement is not conditioned on the physician’s referral of patients to the party making the payments; and
- ___ The amount of the payments is not determined (directly or indirectly) based on a volume or value of any actual or anticipated DHS referrals by the physician or other business generated between the parties; and
- ___ The physician is allowed to establish staff privileges at any hospital, federally qualified health center, or rural health clinic; and
- ___ The physician is not restricted from making referrals to any party except for any restriction in an employment agreement that meets the requirements of item V. or a service agreement that meets the requirements of item W.; and

- ___ The payment is made to a person or organization (other than the physician) that is providing the malpractice insurance (including a self-funded organization); and
- ___ The physician treats obstetrical patients who receive medical benefits or assistance under any Federal health care program in a nondiscriminatory manner; and
- ___ The insurer is a bona fide malpractice insurance policy or program, and the premium, if any, is calculated based on a bona fide assessment of the liability risk covered; and
- ___ For each coverage period (not to exceed one year), at least 75% of the physician's obstetrical patients treated under the coverage of the insurance during the prior period (not to exceed one year) resided in an Area of Need as defined above or a medically underserved area or were part of a medically underserved population (For the initial coverage period, this requirement will be met if the physician certifies that he or she has a reasonable expectation that it will be met during such period); and
- ___ The arrangement does not violate the Federal anti-kickback law or any Federal or state law or regulation governing billing or claims submission; and
- ___ The payments do not exceed the costs attributable to malpractice insurance; and
- ___ If the physician engages in obstetrical practice on a part-time or sporadic basis, the payments do not exceed the costs that are both attributable exclusively to the obstetrical portion of the physician's malpractice insurance and are related exclusively to services provided in (1) an Area of Need as defined above or (2) any area provided that at least 75% of the physician's obstetrical patients treated in the coverage period (not to exceed one year) resided in a rural area or a medically underserved area or were part of a medically underserved population.

If yes, you need not go further. If no, go to N.

Y N N. Is the compensation a payment for referral services that falls within the safe harbor regulations under the federal anti-kickback law?

If yes, you need not go further. If no, go to O.

Y N O. Are the DHS furnished only to enrollees of one of the following?

- ___ A health maintenance organization (HMO) or competitive medical plan (CMP) in accordance with a contract with the Health Care Financing Administration (HCFA) under 42 U.S.C. §1395mm; or
- ___ A health care prepayment plan in accordance with an agreement with CMS

under 42 U.S.C. §1395(a)(1)(A); or

___ An organization that is receiving payment on a prepaid basis for Medicare enrollees under 42 U.S.C. §1395b-1; or

___ A qualified HMO as defined in 42 U.S.C. §300e-9(d); or

___ A coordinated care plan as defined in 42 U.S.C. §1395w-2 offered by an organization in accordance with a contract with CMS under 42 U.S.C. §1395w-27; or

___ A managed care organization contracting with a State Medicaid program under 42 U.S.C. 1396b(m); or

___ A health insuring organization, prepaid inpatient health plan, or prepaid ambulance health plan contracting with a State Medicaid program under 42 C.F.R. Part 438; or

___ A provider operating under a demonstration project pursuant to 42 U.S.C. §§ 1315, 1396n(a), 1396n(b) or 1396u-2(a).

If yes to any, you need not go further. If no to all, go to P.

Y N P. Does the compensation satisfy all the following requirements?

___ It is paid by a hospital; and

___ It is not related to the furnishing of hospital services or other designated health services; and

___ It cannot be allocated in whole or in part to Medicare or Medicaid under cost reporting principles; and

___ It is not furnished, directly or indirectly, explicitly or implicitly, in a selective, targeted preferential or conditioned manner to medical staff or other persons in a position to make or influence referrals; and

___ It does not in any way take into account the volume or value of referrals or other business generated by the physician.

If yes to all, you need not go further. If no to any, go to Q.

Y N Q. Is the arrangement an isolated financial transaction, such as a one-time sale of property or practice, that meets all the following requirements:

___ The transaction involves a single payment or integrated related installment payments; and

- The total aggregate payment is fixed before the first payment is made; and
- The payments are immediately negotiable or are guaranteed by a third party, secured by a negotiable promissory note, or subject to a similar mechanism to ensure payment even in the event of default by the purchaser or obligated party.

If yes, go to R. If no, go to S.

Y N R. Does the arrangement meet all the following requirements?

- The amount of remuneration is consistent with fair market value and is not determined in a manner that takes into account (directly or indirectly) the volume or value of referrals or other business generated between the parties; and
- The arrangement would be commercially reasonable even if no referrals were made; and
- There are no other transactions between the parties during the subsequent 6 months (unless the transaction falls under another exception), except for commercially reasonable post-closing adjustments that do not take into account the volume or value of referrals or other business generated by the physicians.

If yes to all, you need not go further. If no to any, go to S.

Y N S. Are the DHS limited to one or more of the following?

- Implanted items (prosthetics, prosthetic devices or durable medical equipment) that are implanted by the referring physician or a member of his group practice (which meets the requirements of EE. and GG. below) and furnished by a Medicare-certified ambulatory surgical center (“ASC”), during a surgical procedure performed in the same ASC; and
- Erythropoietin (“EPO”) or other dialysis-related prescription drugs identified by CMS that are furnished by an end-stage renal disease (“ESRD”) facility to the patient at the facility or, in the case of EPS or Aranesp (or equivalent drugs determined by CMS) for use in the patient’s home; and
- Preventive screening tests, immunizations or vaccines identified at http://www.cms.hhs.gov/PhysicianSelfReferral/11_List_of_Codes.asp that are subject to CMS-mandated frequency limits and reimbursed by Medicare based on a fee schedule; and
- Eyeglasses or contact lenses furnished to a patient following cataract surgery that are provided in accordance with 42 C.F.R. §§410.36(a)(2)(ii) and 414.228.

If yes, go to T. If no, go to U.

Y N T. Do the DHS meet both of the following requirements?

The arrangement for the furnishing of the DHS does not violate the federal anti-kickback statute, 42 U.S.C. §1320a-7b; and

Billing and claims submission for the DHS comply with all federal and state laws and regulations.

If yes to both, you need not go further. If no to either, go to U.

Y N U. Does the arrangement constitute employment compensation to a W-2 employee of the provider?

If yes, go to V. If no, go to W.

Y N V. Does the employment arrangement meet all the following requirements?

The arrangement is a bona fide employment relationship; and

The employment is for identifiable services; and

The compensation to be paid over the term of the arrangement:

(1) is consistent with the fair market value of the services, and

(2) is not determined in a manner that takes into account (directly or indirectly) the volume or value of DHS referrals that the physician does not perform personally, except that a “per use” or “per unit of service” fee for items or services actually provided by the physician is permitted, even if the number of uses or units of service increases with the physician’s referrals, if the fee does not exceed fair market value for the items or services provided in transactions with parties who do not make referrals; and

If the ordering physician is required to make referrals to any party, the requirement is set forth in a written agreement signed by the parties that sets the compensation in advance in sufficient detail to be objectively verified, is related to the physician’s services that are covered by the agreement; is reasonably necessary to effectuate the legitimate purposes of the agreement; and does not apply if (i) the patient expressed a different preference, (ii) the patient’s insurer prohibits or penalizes referrals to the required provider, or (iii) the referral is not in the patient’s best medical interests, in the physician’s judgment; and

The arrangement would be commercially reasonable even if no referrals were made.

If yes to all, you need not go further. If no to any, go to W.

Y N W. **Does the arrangement meet all the following requirements?**

- The arrangement compensates the physician or family member for services rendered by the recipient; and
- The arrangement is set forth in a writing signed by the parties that specifies the services covered (a holdover agreement for up to 6 months following the expiration of an agreement of at least 1 year, on the same terms and conditions, will meet this requirement); and
- The arrangement covers all the services to be provided by the physician (or any family member) to the provider or, if there are multiple agreements, each cross-references the others or a master list of contracts that is maintained and updated centrally and available for review by the Secretary; and
- The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement; and
- The initial term of the arrangement is at least one year. If the arrangement is terminable during the year with or without cause, the parties may not enter substantially the same agreement during the first year of the original term; and
- The compensation to be paid over the term of the arrangement:
 - (1) is set in advance in sufficient detail to be objectively verified; and
 - (2) cannot be changed during the course of the arrangement in a manner that in anyway reflects the volume or value of referrals or other business generated by the physician; and
 - (3) does not exceed the fair market value of the services; and
 - (4) is not determined in a manner that takes into account the volume or value of DHS referrals or other business generated between the parties that the physician does not perform personally, except that a “per use” or “per unit of service” fee for items or services actually provided by the physician is permitted, even if the number of uses or units of services increases with the physician’s referrals, if the fee does not exceed fair market value for the items or services provided in transactions with parties who do not make referrals. (This requirement does not apply to incentive plans, such as a withhold, capitation, bonus or other arrangement, that may directly or indirectly have the effect of reducing or limiting services with respect to individuals enrolled with the provider; however, no specific payment can be made directly or indirectly to

a physician or physician group as an inducement to reduce or limit medically necessary services provided with respect to a specific individual and, if the physician or group is placed at substantial financial risk, the arrangement must comply with regulations under Soc. Sec. Act §1876(i)(8)(A)(ii); and

— If the ordering physician is required to make referrals to a particular party provider, the requirement is set forth in a written agreement signed by the parties, is related to the physician’s services that are covered by the agreement; is reasonably necessary to effectuate the purposes of the arrangement; and does not apply if (i) the patient expresses a different preference, (ii) the patient’s insurer prohibits or penalizes referrals to the required provider, or (iii) the referral is not in the patient’s best medical interests, in the physician’s judgment; and

— The services do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law.

If yes to all, you need not go further. If no to any, go to X.

Y N X. Do the Federal DHS include parenteral or enteral nutrients (“PEN”) or PEN equipment or supplies (including infusion pumps used for PEN)?

If yes, go to FF. If no, go to Y.

Y N Y. Does the DHS include durable medical equipment (“DME”) including infusion pumps that are DME other than infusion pumps used for PEN?

If yes, go to Z. If no, go to AA.

Y N Z. Is the DME limited to canes, crutches, walkers, folding manual wheelchairs, and blood glucose monitors as to which all the following are true?

— In the case of a blood glucose monitor, the physician or group practice also furnishes outpatient diabetes self-management training to the patient, and the monitor includes one starter set of test strips and lancets consisting of no more than 100 of each; and

— For all other cases, the patient needs the item in order to ambulate and uses it to leave the physician’s office; and

— They are furnished in the same building (i.e. structures with a common post office street address) in which the ordering physician or his or her “group practice” (which meets the requirements of EE. and GG. below) owns or rents an office as to which any of the following applies:

— (1) The office is normally open to patients at least 35 hours per week; and the ordering physician or one of the group physicians furnishes patient care services in the office at least 30 hours per week (including some services that are unrelated to the furnishing of

DHS); or

- ___ (2) The office is normally open to patients at least 8 hours per week and the ordering physician furnishes patient care services in the office at least 6 hours per week (including some services that are unrelated to the furnishing of DHS) and the patient usually receives physician services from that office; or
- ___ (3) The office is normally open to patients at least 8 hours per week and the ordering physician or one of the group physicians furnishes patient care services in the office at least 6 hours per week (including some series that are unrelated to the furnishing of DHS) and if the ordering physician does not order the DHS during a patient visit at the office, then the ordering physician or a group physician is present when the DHS is furnished during such occupancy of the premises.

(If the physician’s practice primarily consists of treating patients in their homes—not including nursing, long-term care or other facilities or institutions—the DHS are furnished in the patient’s home by the physician or a qualified person accompanying the physician contemporaneously with a physician service that does not constitute DHS); and

___ The item is furnished personally by (i) the ordering physician, (ii) another physician who is an owner, employee or “qualifying independent contractor” (see L. above) of the group practice of which the ordering physician is an owner or employee, or (iii) a non-physician employee of the ordering physician or group practice; and

___ The physician or group practice that furnishes the DME meets all Medicare DME supplier standards set forth in 42 C.F.R. §424.57(c); and

___ The arrangement does not violate the Federal anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.

If yes to all, go to AA. If no to any, go to II.

Y N AA. Do the DHS include magnetic resonance imaging (“MRI”), computed tomography (“CT”) or positron emission tomography (“PET”) services, or interpretations of such services?

If yes, go to BB. If no, go to DD.

Y N BB. Has the ordering physician informed the patient in writing at the time of the order that the patient may obtain such MRI, CT or PET services, as the case may be, from other parties, and provided the patient with a written list of suppliers (as defined in 42 U.S.C. §1395x(d))?

If yes, go to CC. If no, go to II.

Y N CC. Does the written list contain the names, addresses and telephone numbers of at least 5 suppliers of services being ordered that are located within 25 miles of the ordering physician’s office, or all of such suppliers if there are less than 5 within 25 miles? (Hospitals and other institutional providers may be listed but do not count toward the maximum number.)

If yes, go to DD. If no, go to II.

Y N DD. Do the Federal DHS meet all the following requirements?

— They are furnished personally by the ordering physician or an individual who is “supervised” by the ordering physician. “Supervision” means the level of supervision required to comply with Medicare payment and coverage rules.

— They are furnished in the same building (i.e. structures with a common post office street address) in which the ordering physician has an office as to which either of the following applies:

— (1) The office is normally open to patients at least 35 hours per week and the physician furnishes patient care service in the office at least 30 hours per week (including some services that are unrelated to the furnishing of DHS); or

— (2) The office is normally open to patients at least 8 hours per week and the physician furnishes patient care services in the office at least 6 hours per week (including some services that are unrelated to the furnishing of DHS); and one of the following applies: (i) the patient usually receives physician services from that office; (ii) the physician ordered the DHS during a patient visit at that office or (iii) the physician is present when DHS is furnished during such occupancy of the premises.

(If the physician’s practice primarily consists of treating patients in their homes—not including nursing, long-term care or other facilities or institutions—the DHS are furnished in the patient’s home by the physician or a qualified person accompanying the physician contemporaneously with a physician service that does not constitute DHS); and

— They are billed by the physician who performed or supervised the services or an entity that is wholly owned by such physician.

If yes to all, you need not go further. If no to any, go to EE.

Y N EE. Is the DHS Provider a “group practice” as to which all the following are true?

— It is a single legal entity recognized as such under the law of the state in which it achieved its legal status, and not merely an affiliation of physicians or other legal entities under common ownership,

control or management. (A group practice that operates in separate states under separate legal entities will be deemed to meet this requirement if the states are contiguous, the entities have identical ownership, governance and operations, and the use of separate entities is legally required); and

___ It is not owned in whole or in part by another medical practice that is an operating physician practice; and

___ It was formed primarily for the purpose of being a physician group practice; and

___ It has no other substantial business purpose; and

___ At least two physicians are either owners (directly or indirectly through another entity) or employees of the entity; and

___ Each owner or employed physician provides, in the group's facilities, substantially the full range of patient care services that such physician routinely provides in any location; and

___ At least 75% of all time spent by all owners and employed physicians (in the aggregate) providing medical services at any location outside a HPSA is billed through the group practice, and this is supported by documentation. Measures other than "time spent" can be used in some cases. (This requirement does not apply to a group practice located in a HPSA); and

___ At least 75% of the group's patient encounters are conducted personally by owners or employed physicians; and

___ The method for allocating income and overhead expenses to the physicians is determined before the receipt of payment for the services giving rise to the overhead expense or producing the income; and

___ It has consolidated billing, accounting and financial reporting; and

___ It has centralized decision-making by a body representative of the group practice that maintains effective control over the group's assets and liabilities (including budgets, compensation and salaries); and

___ If the ordering physician is required to make referrals to a particular party, the requirement is set forth in a written agreement signed by the parties that sets the compensation in advance in sufficient detail to be objectively verified; is related to the physician's services that are covered by the agreement; is reasonably necessary to effectuate the purposes of the arrangement; and does not apply if (i) the patient expresses a preference, (ii) the patient's insurer prohibits or penalizes referrals to the required provider, or (iii) the referral is not in the patient's best medical interests, in the physician's judgment.

If yes to all, go to FF. If no to any, go to KK.

Y N FF. Is the amount of compensation paid to any of the owners or physician employees (directly or indirectly) based on the volume or value of Federal DHS ordered by

the physician?

If yes, go to GG. If no, go to HH.

Y N GG. Do all portions of compensation that are based on the volume or value of Federal DHS constitute one of the following?

___ A fixed “per unit of service” fee for services rendered by the physician that does not exceed fair market value for those services in transactions with parties who do not make referrals; or

___ A share of the overall profits of the group (or any component of the group that includes 5 or more physicians) derived from DHS, which profits are either distributed on a basis unrelated to the volume or value of DHS (whether or not Federal DHS and whether or not personally performed by the physician) that are ordered by the physician (e.g., distributions proportional to non-DHS revenues) or constitute less than 5% of the total revenues of the group and of each physician’s total compensation; or

___ A productivity bonus based on services personally performed by the physician or services and supplies that are furnished “incident to” personally performed services as that term is defined in 42 C.F.R. §410.26 (see Appendix 3).

If yes to any, go to HH. If no to all, go to KK.

Y N HH. Do the Federal DHS meet all the following requirements?

___ They are ordered by a physician who is an owner or employee, or “qualifying independent contractor” (see L. above) of the group practice; and

___ They are furnished personally by an owner of the group, a physician employee of the group, the “qualifying independent contractor” who ordered the services or a nonphysician who is “supervised” by a physician who is an owner, employee, or “qualifying independent contractor” of the group; and

___ They are furnished in (i) space (including a portion of a building or a mobile vehicle) that is never used by any party other than the group, or (ii) the same building (i.e. structures with a common post office street address) in which the ordering physician, or the group practice of which he is an owner or employee, owns or rents an office, and as to which any of the following applies:

___ (1) The office is normally open to patients at least 35 hours per week; and the ordering physician or one of the group’s owner or employee physicians furnishes patient care services in the office at least 30 hours per week (including some services that are unrelated to the furnishing of DHS); or

- ___ (2) The office is normally open to patients at least 8 hours per week and the ordering physician furnishes patient care services in the office at least 6 hours pr week (including some services that are unrelated to the furnishing of DHS) and the patient usually receives physician services from that office; or
- ___ (3) The office is normally open to patients at least 8 hours per week and the ordering physician or one of the group’s owner or employee physicians furnishes patient care services in the office at least 6 hours per week (including some services that are unrelated to the furnishing of DHS) and if the ordering physician does not order the DHS during a patient visit at the office, then the ordering physician or a group physician is present when the DHS is furnished during such occupancy of the premises; and

(If the physician’s practice primarily consists of treating patients in their homes—not including nursing, long-term care or other facilities or institutions—the DHS are furnished in the patient’s home by the physician or a qualified person accompanying the physician contemporaneously with a physician service that does not constitute DHS); and

- ___ They are billed by (i) the physician performing or supervising the services, (ii) the group practice of which the performing or supervising physician is an owner or employee, under a billing number assigned to the group, (iii) the group practice as to which the supervising physician is a “qualifying independent contractor” (see L. above), under a billing number assigned to the group, or (iv) an entity wholly owned by (i) or (ii) under a billing number assigned to it or to one of those entities.

If yes to all, you need not go further. If no to any, go to II.

Y N II. Is the compensation for DHS that are performed by a “group practice” (which meets the requirements of EE. and GG. above) and billed by a hospital under an arrangement that has been continuously in effect since at least December 18, 1989, without interruption?

If yes, go to JJ. If no, go to KK.

Y N JJ. Does the arrangement meet all the following requirements?

- ___ With respect to inpatient services the arrangement is pursuant to the provision of inpatient hospital services under 42 U.S.C. §1395x(b)(3); and
- ___ Substantially all such services furnished to hospital patients are furnished by the group under the arrangement; and
- ___ The arrangement is in a writing that specifies the services to be provided and the compensation for such services; and

___ The amount of compensation to be paid over the term of the agreement:

- (1) is set in advance in sufficient detail to be objectively verified; and
- (2) cannot be changed during the course of the arrangement in a manner that in any way reflects the volume or value of referrals or other business generated by the physician; and
- (3) does not exceed fair market value; and
- (4) it not determined in a manner that takes into account the volume or value of any DHS referrals or other business generated between the parties that the physician does not perform personally, except that a “per use” or “per unit of service” fee for items or services actually provided by the physician is permitted, even if the number of uses or units of service increases with the physician’s referrals, if the fee does not exceed fair market value for the items or services provided in transactions with parties who do not make referrals; and

The arrangement would be commercially reasonable even if no referrals were made; and

If the ordering physician is required to make referrals to a particular party, the requirement is set forth in a written agreement signed by the parties that sets the compensation in advance in sufficient detail to be objectively verified; is related to the physician’s services that are covered by the agreement; is reasonably necessary to effectuate the legitimate purposes of the arrangement; and does not apply if (i) the patient expresses a different preference, (ii) the patient’s insurer prohibits or penalizes referrals to the required party, or (iii) the referral is not in the patient’s best medical interests, in the physician’s judgment.

If yes to all, you need not go further. If no to any, go to KK.

Y N KK. Does the arrangement include the right to use office space or equipment (other than equipment furnished as an integral part of a service or package of services)?

If yes, go to LL. If no, go to MM.

Y N LL. Does the arrangement meet all the following requirements?

It is in a writing signed by the parties specifying the premises or equipment covered (a holdover month-to-month rental for up to 6 months following an agreement of at least 1 year, on the same terms and conditions, will meet this requirement); and

The space or equipment does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease; and

The space or equipment is used exclusively by the provider when being used by the provider, except for space consisting of common areas the payments for which do not exceed the provider’s pro rata

share of expenses for such common space based on the ratio of space used exclusively by the provider to the total non-common space occupied by persons using the common areas; and

___ The term of the arrangement is at least one year. If the arrangement is terminable during the term with or without cause, the parties may not enter into a new arrangement during the first year of the original term unless the material terms are unchanged; and

___ The rent over the term of the arrangement:

- ___ (1) is set in advance in sufficient detail to be objectively verified; and
- ___ (2) cannot be changed during the course of the arrangement in a manner that in any way reflects the volume or value of referrals or other business generated between the parties; and
- ___ (3) is consistent with fair market value; and
- ___ (4) is not determined in a manner that takes into account the volume or value of referrals or other business generated by the physician; and
- ___ (5) is not determined using a formula based on either (i) a percentage of the revenue raised, earned, billed, collected or otherwise attributable to the services performed or business generated in the space or by use of the equipment, or (ii) per-unit-of-service rental charges, to the extent such charges reflect services provided to patients referred between the parties.

___ The arrangement would be commercially reasonable even if no Federal DHS referrals were made.

If yes to all, you need not go further. If no to any, go to MM.

Y N MM. Does the arrangement constitute compensation paid by the physician or family member to a laboratory for clinical laboratory services? *

If yes, you need not go further. If no, go to NN.

Y N NN. Is the compensation in the form of donated software or information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records, i.e. consumer health status information in computer processable form used for clinical diagnosis and

* The statute provides an exception for payments by a physician to a DHS Provider for other items and services if the payment is fair market value for those items or services. The regulations adopted by CMS add a requirement that no other exception is potentially applicable to such payments. Since all payments by a physician to a DHS Provider are potentially able to meet another exception, this requirement effectively eliminates this exception. CMS takes the position that it has the authority to add this requirement; however, this is at best unclear.

treatment for a broad array of clinical conditions?

If yes, go to OO. If no, go to PP.

Y N OO. Does the arrangement meet all of the following requirements?

___ The items and services are provided to a party engaged in the delivery of health care and are provided by either a Health Plan or a party that provides services covered by a Federal health care program that submits claims or requests for payment, either directly or through reassignment, to the Federal health care program; and

___ At the time it is provided to the recipient, the software is able to (i) communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings, and (ii) exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered; and

___ Before receipt of the items and services, the recipient pays 15 percent of the donor's cost for the items and services; and

___ Neither the donor nor any party affiliated with the donor finances the recipient's payment or loans funds to be used by the recipient to pay for the items and services; and

___ The arrangement is in writing, is signed by the parties, and specifies the items and services being provided, the cost to the donor of the items and services, and the amount of the recipient's contribution; and

___ The written agreement covers all of the electronic health records items and services to be provided by the donor, or, if there are multiple agreements between the donor (and affiliated parties) and the recipient, each references the others or a master list of agreements that is maintained and updated centrally, available for review by the Secretary, and maintained in a manner that preserves the historical record of agreements; and

___ The items and services do not include staffing of the recipient's office and are not used primarily to conduct personal business or business unrelated to the recipient's medical practice; and

___ Any electronic health records software contains electronic prescribing capability, either through an electronic prescribing component or the ability to interface with the recipient's existing electronic prescribing system, that meets the applicable standards under Medicare Part D at the time the items and services are provided; and

___ The donor does not shift the costs of the items or services to any Federal health

care program; and

The transfer of the items or services occurs on or before December 31, 2013.

If yes to all, go to QQ. If no to any, go to PP.

Y N PP. Is the compensation in the form of hardware, software, or information technology and training services that are necessary and used solely to receive and transmit electronic prescription information?

If yes, go to QQ. If no, go to TT.

Y N QQ. Are the items and services provided by one of the following?

By a hospital to a physician who is a member of its medical staff; or

By a group practice (which meets the requirements of EE. and GG. above) to a prescribing health care professional who is an owner or employee of the group; or

By a prescription drug plan sponsor or Medicare Advantage organization to pharmacists and pharmacies participating in the network of such sponsor or organization and to prescribing health care professionals.

If yes to any, go to RR. If no to all, go to TT.

Y N RR. Does the arrangement meet all the following requirements?

The items and services are provided as part of, or are used to access, an electronic prescription drug program that meets the applicable standards under Medicare Part D at the time the items and services are provided; and

The arrangement is in writing, is signed by the parties, specifies the items and services being provided, and identifies the cost to the donor of the items and services; and

The written agreement covers all of the electronic prescribing items and services to be provided by the donor (and affiliated parties) and the recipient, or, if there are multiple agreements between the donor and the recipient, each cross-references the others or a master list of agreements that is maintained and updated centrally, available for review by the Secretary, and maintained in a manner that preserves the historical record of agreements.

If yes to all, go to SS. If no to any, go to TT.

Y N SS. Does the arrangement meet all the following requirements?

The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use or compatibility of the items or services with other electronic prescribing or electronic health records systems; and

For items or services that are of the type that can be used for any patient without regard to payor status, the donor does not restrict, or take any action to limit, the recipient's right or ability to use the items or services for any patient; and

Neither the recipient nor the recipient's practice (or any affiliated party) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor; and

Neither the eligibility of a recipient for the items and services, nor the amount or nature of the items or services, is determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.

If yes to all, you need not go further. If no to any, go to TT.

Y N TT. Does the compensation arrangement comply with both of the following:

The Federal anti-kickback law, 42 U.S.C. §1320a-7b; and

All Federal and State laws and regulations relating to billing and claims submission.

If yes to both, go to UU. If no to either, go to YYY.

Y N UU. Does the compensation meet all the following requirements?

It is in the form of items or services, not cash or cash equivalents; and

The aggregate value does not exceed \$355 per year or such greater amount as set forth at http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp; excluding the value of one annual medical staff appreciation event for the entire medical staff, but including any gifts or gratuities provided in connection with any such event (if the aggregate value exceeds this limit by 50% or less, this requirement is still met if the physician returns the excess within 180 days of the date of receipt or by the end of the calendar year, whichever is earlier);

It does not take into account the volume or value of DHS referrals or other business referred by the physician that the physician does not perform personally; and

It is not solicited by the physician or the physician's practice (including employees and staff members).

If yes to all, you need not go further. If no to any, go to VV.

Y N VV. Does the compensation meet all the following requirements?

- It is in the form of items or services, not cash or cash equivalents; and
- It is offered by a DHS Provider that has a bona fide medical staff to every member of its medical staff in the same specialty without regard to the volume or value of referrals or business generated between the parties; and
- It is provided for use only on the hospital campus, during periods when the physician is making rounds or performing other duties that benefit the provider or its patients (except in the case of hospital advertising) or, in the case of a communication device is used only to access hospital information or patients or personnel on the provider's campus; and
- It is reasonably related to the provision of, or designed to facilitate directly or indirectly the delivery of, medical services at the provider's facilities; and
- The value is less than \$30 per occurrence or such greater amount as set forth at http://www.cms.hhs.gov/PhysicianSelfReferral\10_CPI-U_Updates.asp; and
- The total value does not take into account the volume or value of referrals or other business generated between the parties that the physician does not perform personally.

If yes to all, you need not go further. If no to any, go to WW.

Y N WW. Is the compensation in the form of information technology items or services that are provided to allow access to, and sharing of, electronic health care records and general health information in order to enhance overall community health?

If yes, go to XX. If no, go to YY.

Y N XX. Does the arrangement meet both of the following requirements?

- The community-wide information systems are available to all providers, practitioners and residents of the community who desire to participate; and
- The items or services provided to the physician are necessary to participate, are principally used by the physicians as part of the information system, and are not provided in a manner that takes into account business generated by the physician.

If yes to both, you need not go further. If no to either, go to YY.

Y N YY. Is the compensation in the form of free or discounted health care items or services?

If yes, go to ZZ. If no, go to AAA.

Y N ZZ. Does the arrangement meet all the following requirements?

- The DHS Provider has a formal medical staff;

- It is offered to all physicians on the provider's bona fide medical staff or in the community without regard to business generated between the parties; and
- The items and services are of a type routinely provided by the provider; and
- It is pursuant to a written policy approved in advance by the provider's governing body; and
- It is not offered to a beneficiary of a federal health care program (e.g. Medicare) unless there is a good faith showing of financial need.

If yes to all, you need not go further. If no to any, go to AAA.

Y N AAA. Is the DHS Provider a hospital, a federally qualified health center or a rural health clinic as defined at 42 C.F.R. §405.2401 (the term "hospital" includes the legal entity that operates a hospital and any subsidiary, related entity, or other entities that perform services for the hospital's patients and for which the hospital bills, but excluding entities that perform services "under arrangements" with the hospital as defined in Medicare regulations)?

If yes, go to BBB. If no, go to PPP.

Y N BBB. Is the compensation provided to induce the physician to locate a practice in either of the following in order to be a member of the facility's medical staff?

- The DHS Provider's geographic service area (as defined in Appendix 4); or
- If the Hospital is in a rural area (as defined in 42 C.F.R. §411.351), any area determined by the Secretary of HHS to have a demonstrated need for the physician.

If yes to either, go to CCC. If no to both, go to MMM.

Y N CCC. Has the physician been in practice for more than one year?

If yes, go to DDD. If no, go to FFF.

Y N DDD. Has the physician been employed on a full-time basis for at least 2 years by one of the following (and did not maintain a private practice during that time)?

- A federal or state agency that operates correctional facilities, to serve a prison population.
- The Department of Defense or the Department of Veterans Affairs, to serve active or veteran military personnel or their families.
- An Indian Health Service facility, to serve patients who receive medical care exclusively through the Indian Health Service.

If yes to any, go to FFF, if no to all, go to EEE.

Y N EEE. Has the Secretary of HHS determined in an advisory opinion that the physician does not have an established medical practice that serves or could serve a significant number of actual or potential patients of the hospital.

If yes, go to FFF. If no, go to MMM.

Y N FFF. Is the physician relocating his practice from outside the hospital's service area (as defined in Appendix 4)?

If yes, go to GGG. If no, go to MMM.

Y N GGG. Does either of the following apply?

The physician's practice is moving at least 25 miles; or

The physician will likely derive at least 75% of revenues from patients not seen or treated by the physician during the prior 3 years.

If yes to either, go to HHH. If no to both, go to MMM.

Y N HHH. Is the recruited physician joining the practice of another physician or physicians?

If yes, go to III. If no, go to OOO.

Y N III. Are any payments being made to the existing physician practice or being passed through by the recruited physician to the practice?

If yes, go to JJJ. If no, go to KKK.

Y N JJJ. Are all amounts paid to the practice passed on to the recruited physician except for actual costs incurred in recruiting the physician (such as headhunter fees, travel expenses and moving expenses associated with the recruitment, and the cost of tail malpractice insurance covering the physician's prior practice, not including costs incurred after the physician is recruited and has joined the group)?

If yes, go to LLL. If no, go to KKK.

Y N KKK. Does the arrangement meet both of the following requirements?

The arrangement is a minimum guarantee of the income or revenues arising from services rendered by the recruited physician; and

The costs allocated by the practice to the recruited physician do not exceed the actual additional incremental costs attributable to him or her (if the area is rural

and the recruited physician is replacing a physician who died, retired or moved out of the area in the last 12 months, up to 20% of the practice's aggregate costs can be allocated to the physician on a per capita basis).

If yes to both, go to LLL. If no to either, go to MMM.

Y N LLL. Does the arrangement meet all the following requirements?

- The agreement is signed by each party to whom payments are directly made; and
- Cost and payment records are required to be kept for 5 years and made available to the Secretary of HHS; and
- The recruited physician is not required to agree to any unreasonable restrictions on his or her ability to practice in the service area (such as a noncompetition covenant whose duration or geographic scope is unreasonable).

If yes to all, go to OOO. If no to any, go to MMM.

Y N MMM. Is the DHS Provider's service area a rural area (as defined in 42 C.F.R. §411.351), a health professional shortage area ("HPSA") or an area with demonstrated need for the physician as determined in an advisory opinion by the Secretary of HHS?

If yes, go to NNN. If no, go to PPP.

Y N NNN. Does the arrangement meet all the following requirements?

- The remuneration is being paid in order to retain the physician's practice in the DHS Provider's service area; and
- The physician has a bona fide firm, written recruitment offer or offer of employment from a hospital, academic medical center or physician practice entity that is unrelated to the DHS Provider, or has certified in writing that he has a bona fide opportunity for future employment by any such party, which certification contains the steps taken by the physician to effectuate the opportunity, the identity and location of the prospective employer and employment location, the anticipated income and benefits (which may be a range), the date on which the physician would relocate his practice, and information sufficient for the DHS Provider to verify the information contained in the certification; and
- If the physician has provided such a certification, the hospital has taken reasonable steps to verify that the physician has a bona fide employment opportunity that requires him or her to relocate outside the hospital's service area; and

- ___ The bona fide offer or opportunity would require the physician to relocate the practice at least 25 miles and outside of the DHS Provider's service area (as defined in Appendix 4) unless the Secretary of HHS waives this requirement under an advisory opinion; and
- ___ The amount of remuneration does not exceed the lower of (i) the amount that the physician's income would increase from current levels by providing comparable services under the bona fide offer over a 24 month period (or in the case of a physician's certification of an employment opportunity, 25% of the physician's current income, measured over no more than 24 months, using a reasonable and consistent methodology that is calculated uniformly), and (ii) the amount that the DHS Provider would have to expend to replace the retained physician; and
- ___ Any payment is subject to the same obligations and restrictions, if any, on repayment or forgiveness of indebtedness as the original offer; and
- ___ At least 75% of the physician's patients reside in a medically underserved area or are members of a medically underserved population (as designated by the Health Resources and Services Administration of HHS); and
- ___ The DHS Provider has not entered into a retention arrangement with the same physician during the prior 5 years; and
- ___ The terms of the arrangement are not altered during the term and do not vary with the volume or value of business generated by the physician.

If yes to all, go to OOO. If no to any, go to PPP.

Y N OOO. Does the arrangement meet all the following requirements?

- ___ It is in a writing signed by the DHS Provider and the physician; and
- ___ It is not conditioned on the physician's referral of patients to the DHS Provider; and
- ___ The amount of remuneration is not determined in a manner that takes into account (directly or indirectly) the volume or value of any actual or anticipated referrals for DHS or other business generated between the provider and the physician or any group that he or she is joining except for services performed personally by the physician; and
- ___ The physician is not precluded from establishing staff privileges at another provider or referring business to another entity except for a restriction set forth in a written employment or service agreement signed by the parties that is related to the physician's services covered by the agreement, is reasonably necessary to effect the legitimate purposes of the agreement, and does not apply if (i) the patient experiences a different preference; (ii) the patient's insurer

prohibits or penalizes referral to the required provider or (iii) the referral is not in the patient's best medical interests, in the physician's judgment; and

___ The practice will be located in the DHS provider's service area (as defined in Appendix 4).

If yes to all, you need not go further. If no to any, go to PPP.

Y N PPP. Is the compensation for the provision of services or tangible items (excluding real property) by the physician or family member or by a group of physicians (whether or not it meets the requirement for a "group practice")?

If yes, go to QQQ. If no, go to RRR.

Y N QQQ. Does the compensation meet all the following requirements?

___ It is for the provision of items (other than the rental of office space) or services by the physician or family member or by a group of physicians (whether or not a "group practice") to the DHS Provider or by the DHS Provider to any such party; and

___ It is in a writing signed by the DHS Provider and the entity that is paid by the DHS Provider, which specifies the items and services, the compensation, and the term of the agreement; and

___ It is for a period of one year, or if less than a year, is not renewed during the year unless the terms do not change; and

___ The specified compensation to be paid over the term of the arrangement:

___ (1) is set in advance in sufficient detail to be objectively verified; and

___ (2) cannot be changed during the course of the arrangement in a manner that in any way reflects the volume or value of any referrals or other business generated by the physician; and

___ (3) does not exceed fair market value; and

___ (4) is not determined in a manner that takes into account the volume or value of DHS referrals or other business generated by the physician that he or she does not perform personally, except that a "per use" or "per unit of service" fee for items or services actually provided by the physician is permitted, even if the number of uses or units of service increases with the physician's referrals (e.g. test interpretations), if the fee does not exceed fair market value for the items or services provided in transactions with parties who do not make referrals; and

___ It involves a transaction that is commercially reasonable (taking into account the nature and scope of

the transaction) and furthers the legitimate business needs of the parties; and

- If the ordering physician is required to make referrals to a particular party, the requirement is set forth in a written agreement signed by the parties; is related to the physician's services that are covered by the agreement; is reasonably necessary to effectuate the legitimate purposes of the arrangement; and does not apply if (i) the patient expresses a different preference, (ii) the patient's insurer prohibits or penalizes referrals to the required party, or (iii) the referral is not in the patient's best medical interests, in the physician's judgment; and
- It does not involve the counseling or promotion of an arrangement or activity that violates State or Federal law.

If yes to all, you need not go further. If no to any, go to RRR.

Y N RRR. Are the referrals to an immediate family member of the referring physician or provider as to which such family member has an ownership interest or compensation arrangement?

If yes, go to SSS. If no, go to TTT.

Y N SSS. Are all the following requirements met?

- The patient resides in the rural area; and
- No other party is available to furnish the services in a timely manner within 25 miles of or 45 minutes transportation time from the patient's residence (if the services are furnished at the patient's home, this requirement does not apply); and
- The financial relationship does not violate the federal anti-kickback law and the Federal or State law or regulation governing billing and claims submission.

If yes to all, you need not go further. If no to any, go to TTT.

Y N TTT. Is the compensation paid under a risk-sharing arrangement (such as a withhold, bonus or risk pool) by a managed care organization or an independent physician's association (either directly or indirectly through a subcontractor) for services to enrollees of a health plan?

If yes, you need not go further. If no, go to UUU.

Y N UUU. Is the arrangement a bona fide charitable donation by the physician or family member to an organization that is exempt from federal income tax?

If yes, go to VVV. If no, go to WWW.

Y N VVV. Is the donation solicited or offered in any manner that takes into account the

volume or value or referrals or other business generated between the physician and the entity?

If yes, go to WWW. If no, you need not go further.

Y N WWW. Did the arrangement cease to comply with an exception from the Stark Law for reasons beyond the control of the DHS Provider?

If yes, go to XXX. If no, go to YYY.

Y N XXX. Are all the following requirements met?

___ For the immediately prior 180 consecutive calendar days, the arrangement complied with an applicable exception other than the exceptions and non-monetary compensation under \$355 (see UU. above) and for medical staff related benefits under \$30 (see VV. above); and

___ Less than 91 days have passed since the arrangement ceased to meet an exception; and

___ The provider promptly took steps to rectify the non-compliance; and

___ The arrangement does not violate the federal anti-kickback statute; and

___ The provider has not relied on this exception for any arrangement with the same physician (or a member of his or her family) in the prior 3 years; and

___ The claim or bill for the referred services satisfies all Federal and State law and regulations.

If yes to all, you need not go further. If no to any, go to YYY.

Y N YYY. It appears that for at least some Federal DHS, the arrangement may not qualify for any exception, and the physician may be prohibited from ordering such DHS provided by the DHS Provider. CONTACT THE COMPLIANCE OFFICER IF THERE IS ANY DOUBT AS TO WHETHER THE ARRANGEMENT IS PERMISSIBLE.

Appendix 1

Designated Health Services

The following constitute “designated health services” (“DHS”) unless they are furnished by a Medicare-certified provider (e.g. skilled nursing facility, ambulatory surgical center, end-stage renal disease (ESRD) facility, hospice) as part of a composite or per diem payment for a group of services that includes services other than DHS. (For example, hospital and home health services are DHS even though paid by a composite or per diem rate.)

- Clinical laboratory services and anatomic pathology services.*
- Durable medical equipment and supplies.
- Home health services and supplies.
- Inpatient and outpatient hospital services, including services provided under arrangements with a hospital and billed by the hospital, but excluding physician services and lithotripsy services even if billed by a hospital.
- Occupational therapy services, whether or not performed by an occupational therapist, including teaching of compensatory techniques for individuals with physical or cognitive impairments.*
- Orthotics, i.e. leg, arm, and neck braces.
- Outpatient prescription drugs.
- Parenteral and enteral nutrients, equipment, and supplies.
- Physical therapy services, whether or not performed by a physical therapist, including assessments, function tests and measurements, therapeutic exercises, massage and use of physical medicine modalities, devices and equipment, and establishment of maintenance therapy programs.*
- Prosthetics, i.e. artificial legs, arms and eyes.
- Prosthetic devices, i.e. devices (other than dental devices) that replace all or part of an internal body organ, including colostomy bags and one pair of eyeglasses or contact lenses furnished subsequent to cataract surgery with insertion of an intraocular lens.
- Prosthetic supplies, i.e. supplies that are necessary for the effective use of a prosthetic device (e.g. colostomy supplies).
- Radiation therapy services and supplies.*
- Radiology procedures and physician interpretations, including magnetic resonance imaging, computerized axial tomography scans, ultrasound and other imaging services, but excluding

certain invasive procedures, procedures performed immediately after a procedure to confirm the placement of an item inserted during the procedure, and certain procedures that are integral to and performed during nonradiology procedures.*

- Outpatient speech-language pathology services, including diagnosis and treatment of speech, language and cognitive disorders such as swallowing and other oral-motor dysfunctions.*

Note: Services that may be excluded under one category are still considered designated health services if they are included under another category (e.g. hospital services).

* An Appendix to the Stark Law regulations clarifies this item by specifying the covered services by CPT and HCPCS codes. See http://www.cms.hhs.gov/PhysicianSelfReferral/11_List_of_Codes.asp.

Appendix 2

Definition of DHS Provider

“DHS Provider” means an individual or legal entity that performs Federal DHS,* whether or not that party bills for the services. If the DHS Provider is a hospital, “DHS Provider” also includes any separate entity that performs Medicare-covered services for the hospital’s patients and for which the hospital bills. If a party has assigned the right to bill to another party under a reassignment of benefits, term “DHS Provider” also includes the recipient of the reassignment unless it is one of the following:

- (1) an entity that furnishes or arranges for the furnishing of items or services to enrollees, or furnishes insurance coverage for the provision of such items and services, in exchange for a premium or a fee, and which satisfies one of the following descriptions (collectively, “Health Plans”):
 - (i) it operates in accordance with a contract, agreement or statutory demonstration authority approved by the Centers for Medicare and Medicaid Services or a State health care program;
 - (ii) it charges a premium and its premium structure is regulated under a State insurance statute or a State enabling statute governing health maintenance organizations or preferred provider organizations;
 - (iii) it is an employer, if the enrollees of the plan are current or retired employees, or is a union welfare fund, if the enrollees of the plan are union members; or
 - (iv) it is licensed by the State, is under contract with an employer, union welfare fund, or a company furnishing health insurance coverage as described in conditions (ii) and (iii) above, and is paid a fee for the administration of the plan which reflects the fair market value of those services;
- (2) a managed care organization (“MSO”), provider-sponsored organization (“PSO”) or independent practice association (“IPA”) that contracts with a Health Plan, as to services provided to enrollees of that plan;

except that if any such entity employs a party that furnishes services covered under Medicare Part B or operates a facility that could accept reassignment from such a party, the entity is considered a DHS Provider with respect to any DHS provided by that party. “DHS Provider” does not include a physician’s practice that bills for a diagnostic test in accordance with 42 C.F.R §414.50 (certain purchased diagnostic tests that are disclosed as having been purchased from another party and billed at the practice’s cost).

* The word “perform” has its common meaning. For example a physician who does all the work necessary to bill for the physician’s services, but who assigns the right to bill to a hospital, performs

the service. However, an entity that leases or sells space or equipment used for the performance of the service, furnishes supplies that are not separately billable but used in the performance of medical service, or provides management, billing services, or personnel to the entity performing the service, does not necessarily “perform” DHS.

Appendix 3
Services “Incident to” A Physician’s Services.

42 C.F.R. §410.26 covers services and supplies (and drugs and biologicals that cannot be self-administered) furnished by nurses, technicians and others “incident to” the services of a physician if they are:

- **Not specifically listed in the Medicare statute as a covered benefit (without regard to whether they are furnished incident to a physician’s services). For example, the term “incident to services” does not include diagnostic tests because diagnostic tests are eligible for coverage under 42 U.S.C. §1395x(s)(3) and 42 C.F.R. §410.32.**
- **Of a kind commonly furnished in a physician’s office or clinic.**
- **Of a kind commonly furnished without charge or included in the supervising physician’s bill.**
- **Furnished in a setting other than a hospital or nursing facility unless the patient is a patient of that facility.**
- **Furnished as an integral (though incidental) part of a physician’s personal professional services.**
- **Furnished under the “direct supervision” of the physician. “Direct supervision” means that the physician is available in the office suite and immediately available to furnish assistance and direction throughout the performance of the services. It does not mean that the physician must be present in the room where the services are performed. The supervising physician need not be the same physician whose professional services provided the basis for “incident to” billing.**
- **Billed using the billing number of the physician who supervised the services.**

See Medicare Benefits Policy Manual, Chapter 15, §§60-60.3 for further guidance.

Appendix 4 **Service Area Definition**

In the case of a hospital, the service area” is the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75% of its inpatients. (This may include zip codes from which the hospital draws no inpatients if they are entirely surrounded by zip codes in this contiguous area). If there is no such set of contiguous zip codes, then the service area is all contiguous zip codes from which the hospital draws inpatients.

A hospital in a rural area can elect to use a different definition of “service area”—the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 90% of its inpatients. If such a hospital draws fewer than 90% of its inpatients from any set of contiguous zip codes, it may include non-contiguous zip codes starting with the one with the highest number of inpatients, and proceeding until the area includes at least 90% of the hospital’s inpatients.

EXHIBIT 1.5A DESIGNATED HEALTH SERVICES

The following constitute “designated health services” (“DHS”) unless they are furnished by a Medicare-certified provider (e.g. skilled nursing facility, ambulatory surgical center, end-stage renal disease (ESRD) facility, hospice) as part of a composite or per diem payment for a group of services that includes services other than DHS. (For example, BVHS and home health services are DHS even though paid by a composite or per diem rate.)

- Clinical laboratory services and anatomic pathology services.*
- Durable medical equipment and supplies.
- Home health services and supplies.
- Inpatient and outpatient hospital services, including services provided under arrangements with a hospital and billed by BVHS, but excluding physician services and lithotripsy services even if billed by a hospital.
- Occupational therapy services, whether or not performed by an occupational therapist, including teaching of compensatory techniques for individuals with physical or cognitive impairments.*
- Orthotics, i.e. leg, arm, and neck braces.
- Outpatient prescription drugs.
- Parenteral and enteral nutrients, equipment, and supplies.
- Physical therapy services, whether or not performed by a physical therapist, including assessments, function tests and measurements, therapeutic exercises, massage and use of physical medicine modalities, devices and equipment, and establishment of maintenance therapy programs.*
- Prosthetics, i.e. artificial legs, arms and eyes.
- Prosthetic devices, i.e. devices (other than dental devices) that replace all or part of an internal body organ, including colostomy bags and one pair of eyeglasses or contact lenses furnished subsequent to cataract surgery with insertion of an intraocular lens.
- Prosthetic supplies, i.e. supplies that are necessary for the effective use of a prosthetic device (e.g. colostomy supplies).
- Radiation therapy services and supplies.*
- Radiology procedures and physician interpretations, including magnetic resonance imaging, computerized axial tomography scans, ultrasound and other imaging services, but excluding

certain invasive procedures, procedures performed immediately after a procedure to confirm the placement of an item inserted during the procedure, and certain procedures that are integral to and performed during nonradiology procedures.*

- Outpatient speech-language pathology services, including diagnosis and treatment of speech, language and cognitive disorders such as swallowing and other oral-motor dysfunctions.*

Note: Services that may be excluded under one category are still considered designated health services if they are included under another category (e.g. hospital services).

* An Appendix to the Stark Law regulations clarifies this item by specifying the covered services by CPT and HCPCS codes. See http://www.cms.hhs.gov/PhysicianSelfReferral/-11_List_of_Codes.asp.

EXHIBIT 3.2

Notice to Agents, Vendors and Contractors

Blanchard Valley Health System (“BVHS”) has created a Compliance Support Program to ensure we comply with all laws and regulations. This includes laws concerning health and safety, Medicare and Medicaid, fraud and abuse, tax, antitrust, environmental and labor laws, among others.

We cultivate a culture of compliance from the Board Rooms to front-line care-givers, and we include our credentialed providers, vendors and contractors in that commitment. We commit to an effective Compliance Support Program to sustain that culture. Our program includes education, communications methods to encourage reports of concerns, investigations into concerns, monitoring and auditing for compliance and accuracy, and accountability and corrective action when we detect an error.

Vendors and contractors must be aware of, and agree to abide by, the following three provisions of our Compliance Support Program as a continuing condition to doing business with us:

Eligibility to Do Business

1. As a Medicare-participating organization, we are prohibited from hiring or doing business with any entity or person who has been:
 - A. Excluded from participating in federal or state health programs by the Office of Inspector General of the U.S. Department of Health and Human Services;
 - B. Barred from contracting with the U.S. Government by the General Services Administration; or
 - C. Listed as a Terrorist Organization or supporting individual by the Office of Foreign Asset Control of the U.S. Department of the Treasury.
2. Vendors must certify their eligibility to do business with BVHS by certifying that neither the organization, nor its owners or principals or any vendor employee (collectively, “staff,”) who will provide services to BVHS is prohibited from doing business with BVHS under paragraph 1.
3. Eligibility is a continuing condition of any contract with BVHS and vendors must agree to notify BVHS immediately if the government takes adverse action in paragraph 1 against the vendor or any of its staff. Vendors must also notify BVHS if they learn of an investigation that could reasonably result in adverse action in paragraph 1 against the vendor or its staff. BVHS may terminate a contract where the government takes adverse action listed in paragraph 1 against the vendor or its staff.

Business Ethics, Gifts and Gratuities

1. BVHS does business in an open, fair, impartial and transparent manner and engages in arms-length negotiations with potential vendors, contractors or business partners. BVHS requires our employed associates, credentialed providers, board members and volunteers to act in the best interests of BVHS at all times. This includes avoiding conflicts of interest that might jeopardize the impartiality of their judgment and decision-making, as well as avoiding situations that create a reasonable appearance of a conflict of interest or an appearance of favoritism, partiality, personal gain or insider-dealing.

2. BVHS associates may not seek, request or accept any gift, gratuity or other item, regardless of value, that is intended to influence a business decision, or that is offered to them because of their position in a pending business decision. BVHS associates may not accept gifts, gratuities, discounts or other things of value from anyone doing business with, or desiring to do business with, BVHS or any BVHS entity, except in nominal amounts, which they must disclose to their reporting superior.
3. The Compliance Support Program includes Compliance Officer who can assist or respond to any vendor concern about possible violations of BVHS's policies or applicable laws or regulations. Associates are required, and vendors are encouraged, to report any concerns to either the Compliance Department at 419-429-7662, or to BVHS's ReportLine, which is available 24/7/365 and where anonymous reports can be made, at 419-423-5580 or to compliance@bvhealthsystem.org. BVHS policy prohibits retaliation for a report made in good faith.

Required Education on the False Claims Act and Whistleblower Protections for Providers of Medicaid-covered Services

Because BVHS and its related entities receive in excess of \$5M in annual Medicaid reimbursements, we are required to provide additional education to our employed associates, vendors and contractors related to the False Claims Act and whistleblower protections available under those laws. Our vendors and contractors are required to ensure that their employees who will provide services to BVHS receive the following educational information also:

BVHS associates work hard to ensure that we create accurate and truthful patient bills and submit accurate claims for payment from any payer, including Medicare and Medicaid, commercial insurance, or our patients. It's the right thing to do, and federal and state laws require accuracy in health care billing.

The Federal False Claims Act (31 USC 3729-33) prohibits for any person or organization to knowingly make a false record or file a false claim with the government for payment. "Knowing" can include deliberate or reckless ignorance of facts that make the claim false.

Examples of possible false claims include someone knowingly billing Medicare for services that were not provided, or for services that were not ordered by a physician, or for services that were provided at sub-standard quality where the government would not pay.

A person who knows a false claim was filed for payment can file a lawsuit in Federal Court on behalf of the government and, in some cases, receive a reward for bringing original information about a violation to the government's attention. Penalties for violating the Federal False Claims Act can be up to three times the value of the false claim, plus from \$5,500 to \$11,000 in fines, per claim. Additional Federal administrative remedies for false claims include fines of up to \$5,000 for each claim and an assessment by the United States for up to twice the amount of the false claim if the Government has made payment (31 USC 3802).

Under Ohio law, no person may knowingly make a false statement to secure payment or other benefit administered by a government agency (O.R.C. 2921.13). Violators are guilty of a first degree

misdemeanor. Ohio Medicaid law includes civil penalties for engaging in “deception” with respect to Medicaid claims, and defines "deception" to include acting in deliberate ignorance or reckless disregard of the truth or falsity of facts that make a claim false (O.R.C. 5111.03). Ohio law also imposes criminal penalties for knowingly making (or causing to be made) a false or misleading statement or representation for use in obtaining Medicaid payments or fraudulently obtaining money from third parties for items or services rendered to Medicaid recipients in violation of program rules(O.R.C. 2913.40) or to obtain eligibility for Medicaid benefits (O.R.C. 2913.401).

The False Claims Act protects anyone who files a false claim lawsuit from being fired, demoted, threatened or harassed by their employer for filing the suit. If a court finds that the employer retaliated, the court can order the employer to re-hire the employee, and to pay the employee twice the amount of back pay that is owed, plus interest and attorney’s fees. Ohio law provides equivalent protections from retaliation by an employer for civil service employees who report Medicaid fraud to the authorities (See O.R.C. §124.341).

BVHS’s Compliance Support Program supports compliance with the False Claims Act by:

- Monitoring and auditing business activities to prevent or detect errors in coding or billing.
- Educating our associates, vendors and contractors that they are responsible to report any concern about a possible False Claim at a BVHS facility.
- Investigating all reported concerns and correcting any billing errors discovered.
- Protecting our associates, vendors or contractors from adverse action when they do the right thing and report any genuine concern. BVHS will investigate any allegation of retaliation against an associate for speaking up.

EXHIBIT 5.3A

AGENT COMPLIANCE CERTIFICATE

I hereby certify that I have received access to, read, and understand Blanchard Valley Health System (“BVHS”) Compliance Support Manual (the “Manual”), which is available at www.bvhealthsystem.org under About BVHS/Compliance. I agree to comply fully with all of the policies and procedures set forth in the Manual, as well as all other policies and procedures that may be implemented from time to time by BVHS. I understand that my compliance with the Manual and BVHS’s other policies and procedures is a condition to my continued association with BVHS and that violation of the Manual or such other policies and procedures may result in disciplinary action at the discretion of BVHS, including possible termination.

I further certify that, except as set forth below, I have fully complied with the Manual and all other BVHS’s policies and procedures, and I am not aware of any Compliance Incident (as that term is used in the Manual) by others that has not been reported as provided in the Manual (explain any exceptions on the lines below or state “none”; attach additional sheets if necessary):_____

I acknowledge that the Manual and BVHS’s other policies and procedures are for the sole and exclusive benefit of BVHS and do not in any way constitute or otherwise create any employment or other legal right, privilege, assurance or contract of any kind or nature with respect to my employment or otherwise.

Signature: _____

Print Name: _____

Date: _____

Title: _____

Facility: _____

EXHIBIT 5.3B

SUPERVISOR ANNUAL COMPLIANCE CERTIFICATE

TO: The Compliance Officer

I hereby certify that I have reviewed BVHS (“BVHS”) Compliance Support Manual (the “Manual”) and made the Manual available to each person under my supervision (including employees and agents hired from the time of the last certification). In addition, I certify that all new employees and agents required to be audited have been the subject of a new employee/agent audit. I agree to comply fully with all of the policies and procedures set forth in the Manual, as well as all other policies and procedures that may be implemented from time to time by BVHS. I understand that my compliance with the Manual and BVHS’s other policies and procedures is a condition to my continued employment or association with BVHS and that violation of the Manual or such other policies and procedures may result in disciplinary action at the discretion of BVHS, including possible termination.

I further certify that, except as set forth below, I have fully complied with the Manual and all other BVHS policies and procedures, and I am not aware of any Compliance Incident (as that term is used in the Manual) by others that has not been reported as provided in the Manual (explain any exceptions on the lines below or state “none”; attach additional sheets if necessary): _____

I acknowledge that the Manual and BVHS’s other policies and procedures are for the sole and exclusive benefit of BVHS and do not in any way constitute or otherwise create any employment or other legal right, privilege, assurance or contract of any kind or nature with respect to my employment or otherwise.

Signature: _____

Print Name: _____

Date: _____

Title: _____

Facility: _____

EXHIBIT 7.1

COMPLIANCE REPORT FORM

Date: _____

Name of Reporter: _____

Facility: _____

Phone No. of Reporter: _____

Position: _____

Supervisor: _____

Concise Description of Concern:

Narrative of Concern:

BLANCHARD VALLEY HEALTH SYSTEM

COMPLIANCE SUPPORT MANUAL

SHUMAKER, LOOP & KENDRICK, LLP
419-241-9000