***Bellin Hospital Corporate Compliance Program— Clinical Laboratories Compliance Plan***

Purpose

Bellin Health Laboratory offers testing services to clients throughout the state of Wisconsin and the upper peninsula of Michigan through its Professional Outreach Services. Some of the clinics owned by Bellin Health Laboratory also operate laboratories (clinic laboratories). The clinic laboratories and the hospital laboratory shall be collectively referred to as “Bellin Laboratories.” Bellin Health Laboratories commit to strict adherence of all current state and federal regulations regarding its business practices. This policy details Bellin Health Laboratory’s efforts to comply with such regulations.

The purpose of this plan is to enable all Bellin Health Laboratories to demonstrate their commitment to integrity and honesty as participants in government health-care programs and their compliance with applicable laws and regulations.

Scope

Hospital laboratory employees, Bellin Medical Group clinic laboratory employees, and all individuals who order laboratory services from Bellin (“Practitioners”).

Policy

Introduction

• Adoption—The following is hereby adopted as the Laboratory Compliance Plan for Bellin Memorial Hospital, Inc. (hereinafter referred to as “Bellin”). This Laboratory Compliance Plan is part is part of the Corporate Compliance Program for Bellin Health System, Inc. Any inconsistencies between this plan and the Corporate Compliance Program shall be resolved consistent with the Corporate Compliance Plan.

• Annual Review—The Laboratory Compliance Plan will be reviewed at a minimum annually and updated as

necessary by the Compliance Officer and approved by the Compliance Committee.

Procedures and Policies

The following policies shall be distributed to all individuals who are affected by the specific policy at issue, along with new and amended or revised compliance policies when available. Individuals should consult the Policy and Procedure Manual and the Laboratory Catalog for additional information concerning these policies.

• Standards of Conduct—It is the policy of Bellin Memorial Hospital, Inc. to use best efforts to avoid fraud, waste, and abuse, and adhere to all guidelines and

regulations covering government health-care programs and to operate all Bellin Laboratories in a manner which demonstrates our commitment to integrity and honesty in all of our dealings with patients, physicians, corporations, other health-care providers, government health-care programs, and third-party insurance programs.

Bellin has adopted Standards of Conduct as part of its Corporate Compliance Program. Bellin Health Laboratory employees (hospital and clinics) should consult the Human Resources Manual for the Standards of conduct applicable to their job. At a minimum, Bellin Health Laboratory employees (hospitals and clinics) should be familiar with the following: “Standards of Conduct Relating to Antitrust,” “Standards of Conduct Relating to Business Ethics,” and “Standards of Conduct Relating to Billing Government Health-Care Programs.”

• Medical Necessity—Claims will only be submitted to government health-care programs for services that the laboratory has reason to believe are medically necessary. Upon request, the laboratory should be able to provide documentation, such as requisition forms containing diagnosis codes (ICD-9 codes), supporting the “medical necessity” of a service the laboratory has provided and billed to a government program. Documentation of “medical necessity” is the responsibility of the health- care provider and must be provided at the time the test is ordered.

Practitioners shall be able to order any tests, including screening tests, that they believe are appropriate for the treatment of their patients. However, practitioners will be made aware that Medicare and Medicaid will only pay for tests that meet the Medicare or Medicaid definition of “medical necessity” and that Medicare and Medicaid may deny payment of a test that the practitioner believes is appropriate, such as a screening test, but which does not meet the Medicare or Medicaid definition of “medical necessity.” The laboratories will advise practitioner clinics that when Medicare or Medicaid reimbursement will be sought, they should only order those tests that they believe are medically necessary for the diagnosis and treatment of their patients. Accordingly, all Bellin Laboratories will implement the following steps to further that objective:

— Requisition Design: All Bellin Laboratories shall standardize their noncustomized test offerings and use common, uniform requisition forms that

emphasize practitioner choice and encourage practitioners to order, to the extent possible, only those tests that they believe are appropriate for each patient. In addition, the requisition forms will require practitioners to document the need for each test ordered by inserting a diagnosis code for each such test. With respect to chemistry tests, requisition forms should be designed to require practitioners to order such tests individually (ie, separately) unless the test is part of a CPT-defined “clinically relevant test grouping” such as an organ or disease panel or profile. In addition, a pointed statement should appear on every requisition form reminding practitioners of the Medicare/Medicaid “medical necessity” requirements.

— Notices to Practitioner Clinics: Bellin Laboratories will provide practitioner clinics with annual written notices that set forth:

• The “medical necessity” policy

• The laboratory reflex testing practices

• The CPT or HCPCS code changes that the laboratory uses to bill the Medicare or Medicaid Program for each test offered

• Information on where to obtain the Medicare laboratory fee schedule

• Notice that a practitioner who orders medically unnecessary tests for which Medicare or Medicaid reimbursement is claimed may be subject to civil penalties by the Office of the Inspector General

The notice also should provide the phone number of the Laboratory Medical Director and advise of his or her availability to discuss appropriate testing and test ordering.

\*\* Customized panels will not be offered by

Bellin Laboratories.

— Test Utilization Monitoring: Bellin Laboratories will retain and analyze test utilization data from year to year, by CPT or HCPCS code, for the top

30 tests (hospital laboratory) and top 10 tests (clinic labs) they perform for Medicare beneficiaries by keeping track of the number of tests performed by CPT or HCPCS code or of the number of claims submitted to Medicare for each test. Bellin will then compute the percentage growth in claims submitted for each of the top 30 tests from 1 year to the next. If a test’s utilization

grew more than 10%, the laboratory should undertake a reasonable inquiry to ascertain the cause of such growth. If the laboratory determines that the increase in test utilization occurred for a benign reason, such as the acquisition of a new laboratory facility, then the laboratory need not take any action. However, if the laboratory determines that the increase in utilization was caused by some action on the part of the facility, the laboratory should take any steps that it deems reasonably necessary to address the issue and to ensure that fraud is not being committed.

• Billing—All claims for testing services submitted to Medicare or Medicaid or other federally funded health- care program should be accurate and correctly identify the services ordered by the practitioner (or other individual authorized) by law and Medical Staff policies to order tests) and performed by the laboratory.

— Maintenance of the Laboratory Charge Master: Appropriate reimbursement requires the correct use of codes. The charge master must be accurate and maintained to assure appropriate reimbursement.

Codes will be assigned to tests and procedures only by personnel with technical expertise in the various clinical areas. Codes are the responsibility of 2 persons:

• Hospital Laboratory Codes: The Laboratory Team Leader or the Team Facilitators- Laboratory Information Services is expected to assign codes after conferring with the Team Facilitator for the laboratory section that provides the test or service.

• Bellin Medical Group Laboratory Codes: The Clinic laboratory Coordinator has the expertise and authority to assign codes.

Other health system personnel may not change codes without authorization from the above- mentioned responsible personnel. Team Leader, Team Facilitators-Laboratory Information Services, and the Clinic laboratory Coordinator shall review and update the charge master at least annually.

— Selection of CPT or HCPCS Codes: The CPT or

HCPCS code that is used to bill Medicare or Medicaid shall accurately describe the service that was ordered and performed. Laboratories should choose only the code that most accurately describes

the ordered and performed test. To ensure code accuracy, codes should be reviewed by individuals with technical expertise in laboratory testing before such codes are approved for claims submissions. If a laboratory continues to have questions about code selection, even after review by technical experts, it should direct its questions to the Compliance Officer for interpretation by its Medicare Carrier or Fiscal Intermediary or the State Medicaid Program.

— Selection of ICD-9CM Codes: At the direction of the Health-Care Financing Administration (HCFA), Medicare carriers and intermediaries have established lists of tests that must be

accompanied by diagnostic information to establish “medical necessity” before Medicare coverage will be assumed (“limited coverage policy”). Such diagnostic information may be submitted either through the use of ICD-9CM codes or a narrative description. Laboratories will only submit diagnostic information obtained from the test- ordering practitioner. Laboratories will not:

• Use diagnostic information provided by the practitioner from earlier dates of service (other than standing orders, as discussed below in “Reliance on Standing Orders”)

• Use “cheat sheets” that provide diagnostic information that has triggered reimbursement in the past

• Use computer programs that automatically insert diagnosis codes without receipt of diagnostic information from the practitioner

• Make up diagnostic information for claims submission purposes

Laboratories should:

• Contact the ordering practitioner to obtain diagnostic information in the form of an ICD-

9 code in the event that the practitioner has failed to provide such information, and

• Provide services and diagnostic information supplied pursuant to a standing order executed in connection with an extended course of treatment

Where diagnostic information is obtained from a practitioner or the practitioner’s staff after receipt of the specimen and the requisition form, documentation of the receipt of such information should be created and maintained.

— Tests Covered by Claims for Reimbursement: Laboratories will only submit claims for tests that were both ordered and performed. If a laboratory receives a specimen without a test order or with an ambiguous test order that is subject to multiple interpretations, the laboratory should check with the practitioner to determine what tests he or she wanted performed before submitting a claim for reimbursement to Medicare or Medicaid. Thus, if the laboratory performed a test that the practitioner did not order, the laboratory will not erroneously bill for that test. Similarly, if a laboratory cannot perform an ordered test due to, for example, a laboratory accident or insufficient quantities of specimen, the laboratory should not submit a claim to Medicare or Medicaid. The laboratory will document the additional information provided by the provider on the requisition form or an attachment. All additional documentation should

be initialed by the author.

— Billing of Automated Multichannel Chemistry Tests: The laboratory will bill Medicare and Medicaid appropriately for automated multichannel chemistry tests. All tests appearing on HCFA’s most recent list of automated

multichannel chemistry tests should be billed using

the appropriate CPT codes.

— Billing of Calculations: The laboratory will not bill for both calculations (eg, calculated LDLs, T7s, indices, to name only a few) and the tests that are performed to derive such calculations. The fact that a separate CPT code exists does not mean that Medicare separately reimburses for the services assigned to the code.

— Reflex Testing: Reflex testing occurs when initial

test results are positive or outside normal parameters and indicate a second related test is medically appropriate. The laboratory will not perform reflex testing except in accordance with its reflex testing practices which can be found in the Schedule of Laboratory Services. Providers are allowed to “opt-out” of reflex testing by notifying the laboratory of its election to decline reflex testing.

• Hospital Issued Notice of Noncoverage/Advance

Beneficiary Notices (“Waivers”)—While providers may order any tests that they want, Medicare will reimburse according to its rules, and certain tests may not be paid, such as some screening tests or tests that are subject to Local Medical Review Policies (LMRP) or

National Coverage Decisions (NCD). When Medicare denies a claim from a provider because the service was not a covered service or was not reasonable or necessary, the provider may bill the beneficiary if there is an appropriately executed Waiver. The Waiver must be executed prior to providing the service to allow the beneficiary the option to choose whether to have the service provided and pay for it out of pocket or forego the services. The purpose of the Waiver is to notify the beneficiary of potential personal liability for the charges. After being notified, the beneficiary has the choice to either (1) decide to receive the service and sign the agreement to pay on the Waiver or (2) decide not to receive the service and therefore does not sign the Waiver. The Waiver must contain the name(s) and date of service(s) involved and the reason the provider thinks the service(s) will not be paid by Medicare.

Providers are expected to stay informed about LMRP or NCD and to obtain Waivers prior to providing a service whenever there is a concern that Medicare may not reimburse for a service.

Providers are prohibited from obtaining Waivers from all Medicare beneficiaries or for all services to be provided. Waivers are to be obtained on an individual case-by-case basis only when there is likelihood of denial.

The Bellin Medical Group Medicare Waiver Policy can be found in the Bellin Medical Group Policy and Procedure Manual.

— Routinely Repeated Services and Standing Orders: It is not necessary to obtain a separate Waiver for services intended to be provided routinely over a period of time, such as monthly prothrombin times or periodic hemoglobin A1C. If a Waiver is necessary for the service, each time the service is provided, you may have the patient date and sign the form, as long as the language of the form is applicable.

If there is a change in the standing order, such as additional services are added to the order, a new Waiver is required.

— Noncovered Services: Noncovered services, such as some screening tests are never paid by Medicare. Because of this, Medicare should not be billed for these services unless the beneficiary

insists upon it. While Medicare regulations do not require a Waiver for noncovered services, a “Notice of Exclusion from Medicare Benefits” form may be used as an explanation tool.

Occasionally, the beneficiary may request that Medicare be billed, either because the beneficiary feels that the service is actually covered or needs the denial to bill supplemental insurance. In these situations, Bellin bills Medicare in order to obtain the denial that the beneficiary wants to have, using the appropriate routine/noncovered diagnosis matched to each line item.

—Reliance on Standing Orders: Standing orders are

not prohibited in connection with an extended course of treatment but may lead to fraudulent and abusive practices. However, the laboratories will monitor existing standing orders to ensure their continuing validity. All standing orders must be in writing and must include an effective date and an expiration date. Annually, all laboratories shall contact all Practitioners from which the laboratory has received such standing orders and request that they confirm in writing the validity of all current standing orders.

—Compliance with Fraud Alerts: The Office of

Inspector General of the Federal Department of Health and Human Services (“OIG”) periodically issues Fraud Alerts setting forth activities believed to raise legal and enforcement issues. Any and all Fraud Alerts issued by the OIG will be carefully considered by the Compliance Officer who shall seek guidance from legal counsel as needed. Moreover, each laboratory will cease and correct any conduct criticized in such a Fraud Alert if applicable to it and take reasonable action to prevent such conduct from recurring in the future. If appropriate, a laboratory should take the steps to

investigate, report, and correct identified problems.

—Marketing: All laboratories shall engage in honest, straight forward, fully informative, and nondeceptive marketing. Practitioners shall be informed of the services offered by the laboratory, the services that will be provided when tests are ordered, and the financial consequences for Medicare, as well as other payers, for the tests ordered. All marketing information is clear, correct, nondeceptive, and fully informative. Information shall be communicated through the following means:

—Catalog: The primary means of communication with clients is through the Schedule of Laboratory Services (Test Catalog). The catalog is reprinted about every 2 years and also provided in an online version. The catalog provides:

• A chapter with general information to assist clients with such details as specimen handling and requisition preparation

• A separate chapter is maintained to address specific Medicare information

• Detailed test information. Reflex testing and the billing consequences are clear for each test

• Extensive cross-indexing

—Requisition: Any requisitions must be designed in a manner that will not influence or impede the practitioner’s ability to only order “medically necessary” tests. Requisitions are designed to encourage the client to provide all necessary information including diagnosis coding.

—Local Medical Review Policy (LMRP)/National Coverage Decision (NCD): Bellin Laboratories will assist clients in understanding both the LMRPs and NCDs.

—Special Notices: Notices may be developed as needed to communicate with practitioners.

• Services and Supplies

— Phlebotomy Services: Bellin Health Laboratory will provide phlebotomists in practitioner clinics that are not owned by Bellin under the following conditions:

• The phlebotomist only provides phlebotomy services at the clinic for tests performed by Bellin. No other services are performed by the phlebotomist.

• The provision of phlebotomy services are approved by the Compliance Officer.

— Supplies: Bellin Laboratories will only provide supplies to practitioner clinics that are necessary and directly related to the laboratory tests performed by Bellin. Bellin will not provide free pickup of hazardous waste.

• Prices Charged Practitioners—Special pricing may be offered to clients but must never be tied to Medicare referrals. Special pricing must be provided according to a written formula and applied to all clients evenly according to the Bellin Health Laboratory Pricing Policy. Special pricing may be offered as needed but not in order to obtain Medicare business. All nonstandard

pricing agreements must be documented and must never be below fair market value.

• Retention of Records: All records required either by federal or state law, including requisition forms, test results, and the Medicare claim will be maintained for a minimum of 7 years.

• Compliance as an Element of a Performance Plan: Promotion of and adherence to compliance shall be an element in evaluating the performance of managers and supervisors. They, along with other employees, shall be periodically trained in new compliance policies and procedures. In addition, all managers and supervisors involved in the sale, marketing, or billing of laboratory services, and those who oversee phlebotomists should be on an annual basis.

— Discuss with all supervised employees the compliance policies and legal requirements applicable to their function

— Include Corporate Compliance training as part of new employee orientation and annual education

— Inform all supervised personnel that strict compliance with these policies and requirements is a condition of employment

— Disclose to all supervised personnel that the laboratory will take disciplinary action up to and including termination for violation of these policies or requirements.

Managers and supervisors will be sanctioned for failure to adequately instruct their subordinates or for failing to detect noncompliance with applicable policies and legal requirements, where reasonable diligence on the part of the manager or supervisor would have led to the discovery of any problems or violations given the laboratory the opportunity to correct them earlier.