Following is an explanation of the compliance rules and regulations as interpreted by Bellin Health Laboratories. This information is published and distributed to our customers annually to keep you informed of changes in compliance. This information is based on many sources, including but not limited to:

- WPS Medicare Communique monthly publications
- Washington G-2 National Intelligence Reports biweekly publications
- Clinical Laboratory Management Association publications and conferences
- G-2 Medicare Reimbursement Manual for Clinical Laboratory Services
- Various internet sources
- Bellin policy and procedures

This information should be shared with any staff involved in the billing, requisitioning, and/or coding of laboratory tests. Providers, laboratory staff, and billing staff need to be aware of the rules and the impact upon both your facility and Bellin Health Hospital Laboratory.

Statement of Commitment

It is the policy of Bellin Health Laboratory to use best efforts to avoid fraud, waste, and abuse and to adhere to all guidelines and regulations governing federally and state funded health-care programs and to operate in a manner which demonstrates our commitment to integrity and honesty in all of our dealings with patients, physicians, corporations, other health-care providers, and federal and state funded health-care programs.

Bellin Health Laboratory is committed to the highest ethical standards for testing and reporting patient data. Our commitment extends to the billing of tests to Medicare and Medical Assistance. We believe in full disclosure of our testing and billing policies and all information that assists our customers with compliance regulations.

In general, rules which apply to Medicare also apply to Medicaid.

To fulfill our commitment:

- We provide customers with a test catalog which provides all pertinent information for tests, including CPT codes to be billed and any reflex testing that may be associated with certain tests. A provider may "opt-out" of any standard reflex testing as described in the individual tests in the catalog by simply stating that information on the request form. Courtesy testing is prohibited.
- Customers may call our toll-free number, 800-236-1639, with questions about testing.
- Notices are sent to customers when changes occur with test offerings, billing policies, and CPT codes.
- We assess and monitor non-compliance with federal regulations.
- We remain current with compliance issues and regulations including changing policies to incorporate the latest requirements.
- Educating our customers is an important part of our job.

This information is presented with the best of intentions. Your facility should have available all pertinent information from your carrier. If you believe that our interpretations are incorrect or you receive conflicting information, please contact us so that we may correct and enhance the information we provide.

The Power of the Government

The U.S. Justice Department and HCFA’s Office of Inspector General rely heavily on the False Claims Act to seek penalties and settlements in cases involving improper coding, “medical necessity” issues, and bundling violations. By using the False Claims Act, prosecutions may be initiated against anyone who knowingly presents a false or fraudulent claim for payment. No specific proof of intent to defraud is required. Fines can include damages and penalties of $5,000 to $10,000. Providers may also lose their ability to participate in the Medicare program.

Especially vulnerable are claims where it should be known that the service is not medically necessary or claims which show an effort to upcode and obtain greater reimbursements. More than $500 million have been recovered in fines and settlements.

Under section 1862 (a)(1) of the Medicare law, Medicare requires that 2 basic criteria be met before they pay for a service:

- Medicare must cover the service. Most screening procedures are not covered.
- The service must be medically necessary. The HCFA payment policy as stated in the Social Security Act excludes routine examinations and most routine screening procedures. Therefore, a screening service, even though it may be a medically appropriate service, may not be a Medicare benefit. Medicare does not pay...
for screening services unless mandated through a statute (ie, a screening Pap smear every 2 years). Therefore, claims for screening services other than those mandated through statute should not be submitted to Medicare.

Medical Necessity
Medically necessary means that the test is necessary for the diagnosis and/or treatment of disease. It means that the test is essential to diagnosing and/or treating the patient for the reason the patient is seeing the provider at the time the test is ordered.

Routine tests and most tests used to screen for disease in the absence of signs and history are not medically necessary.

Medicare determines whether a test is deemed medically necessary by the diagnosis code(s) on the claim forms. These diagnosis codes tell the Medicare Carrier or Fiscal Intermediary the medical reason of justification for the test.

If services are not medically necessary, the provider is required to notify the beneficiary through an Advance Beneficiary Notice (ABN) prior to performing the tests, that based on their condition and the Medicare policy, the service may be denied for “medical necessity.” In order to bill the patient for the test when Medicare denies payment, an ABN must be signed. It is up to the provider to explain to the patient the importance of the test even though Medicare policy may not deem the test medically necessary.

The Balanced Budget Act of 1997 as amended requires the ordering provider to give diagnostic information to the laboratory to enable the laboratory to bill Medicare for the test since the laboratory does not have access to the information necessary to convert narrative diagnostic information into a billable ICD-9 code.

If your facility does not supply Bellin Health Laboratory with documentation of “medical necessity” at the time the test is requested, Bellin Health Laboratory will bill the cost of the test(s) back to your facility’s account. Bellin Health Laboratory cannot resubmit these claims to Medicare with a different diagnosis code.

Contact your carrier for information on appealing “medical necessity” denials.

Local Medical Review Policies (LMRP)
Because Medicare only pays for tests related to the treatment and diagnosis of disease and since many tests are used for both treatment and diagnostic purposes, HCFA needed a way to define screening vs. diagnostic use of a test. The mechanism used is the LMRP. An LMRP defines Medicare approved use of tests by specifically indicating what clinical circumstances justify the use of the test. These policies contain ICD-9 codes that the Carrier or Fiscal Intermediary will accept for payment that must be included on the claim form. Everything else is considered not “reasonable and necessary” use of the test and the claims are rejected as not medically necessary. Carrier advisory committees usually develop the LMRPs.

Tests which have LMRPs published are also known as limited coverage tests since the LMRP sets forth the indications and additional limitations of coverage for the test.

National Coverage Decision (NCD)
Beginning January 2003, there will be NCDs put into place by the Center for Medicare Services (CMS). All carriers and fiscal intermediaries must adhere to these regulations as well as their own LMRPs.

Waiver—Advance Beneficiary Notices (ABN)
A waiver or ABN is a notice to the patient that tests being ordered by the provider may not be covered by Medicare either because it is a screening test or the patient does not have a diagnosis that meets Medicare’s “medical necessity” criteria. HCFA prohibits billing a patient for services that are not covered by Medicare without the beneficiary being warned that they may be responsible for the charges. Therefore, a waiver must be signed PRIOR to providing a service. Waivers must be specific for the tests and the date of service.

Examples of when a waiver may need to be signed are:

- The provider wants to order a test that is a limited coverage test, but the patient does not have a diagnosis that fits the LMRP.
- A patient requests to have a limited coverage test performed but does not have the signs or clinical history to fit the LMRP for the test.
- A limited coverage test is used as part of a routine physical.
- The provider is screening for disease.

Blanket waivers are waivers that do not specifically name the test or service and the reason why the provider thinks the test or service will be denied. Blanket waivers are invalid.
Waivers cannot be signed and placed in the patient’s chart just in case there is a denial from Medicare. The waiver must be specific for the test(s) and the date of service.

If a patient refuses to sign a waiver, the provider is protected from the liability as long as the attempt to have the patient sign the waiver is witnessed by another employee. The event should be documented on the waiver, and both the provider and the witness should sign the waiver. Therefore, the patient is responsible for payment because they have been properly informed just as if they had signed the waiver.

**Notice of Exclusion from Medicare Benefits**

An optional form known as a “Notice of Exclusion from Medicare Benefits” may be used on-site when collecting laboratory specimens for Medicare Part B beneficiaries. This form is used as a tool to explain to the beneficiary that some or part of the services being performed are not part of their Medicare benefits and will never be covered. A copy of this form, along with any secondary insurance information and a notation that the beneficiary requests Medicare submission for review, may be sent to Bellin Health along with all pertinent billing information for Medicare submission. This will ensure that the beneficiary or their secondary insurance receives a complete and accurate Explanation of Benefits.

**Reflex Testing**

Reflex testing occurs when additional testing is automatically performed based on the results of initial testing. An example of reflex testing is when sensitivity is automatically performed on a culture with growth or a positive HIV test is followed up with confirmation testing. If a provider does not want reflex testing performed, the laboratory must be notified in advance.

A listing of reflex testing performed by Bellin Health Laboratory can be found in “Bellin Health Laboratory—Schedule of Reflex Testing” in “General Instructions.”

**CPT Coding**

CPT (current procedural terminology) codes listed in the catalog are provided as a guide to assist you with billing. The CPT codes listed reflect our interpretation of the CPT coding requirements. CPT codes are subject to change at any time. It is your responsibility to verify the accuracy of the codes before you submit them for billing.

**Diagnosis Coding**

Laboratory staff are not coders. Please provide codes rather than narrative so that proper information is provided to Medicare.

The laboratory is unable to provide you with any diagnosis codes for your patients.

Once a claim has been denied, we are unable to resubmit claims with a changed diagnosis code.

**Ways to Limit Your Liability in “Medical Necessity” Issues**

- Assign someone in your office to be current on all rules and to be a resource to all staff.
- Provide ICD-9 codes at the time a test is ordered.
- Order only those tests that are medically necessary.
- Be sure that providers and laboratory staff understand what is required for documentation.
- Remain current on all carrier policies (LMRP).
- Be certain that all patient records contain documentation which support all tests ordered and the diagnosis codes provided.
- Trace all ICD-9 codes to the ordering provider.
- Obtain waivers when necessary.
- Cooperate with Bellin Health Laboratory’s effort to obtain the necessary information for your patients. We reserve the right to bill your account for tests which cannot be billed to Medicare because of insufficient information.

**Bellin Health Laboratory Medicare Billing Agreement with Clients**

When a client requests Bellin Health Laboratory to bill Medicare for patient testing, they agree to the following stipulations:

- Clients ask Bellin Health Laboratory to bill Medicare for services only when the services are covered and are medically necessary. The client will not bill the patient or Medicare for any services that Bellin Health Laboratory is submitting to Medicare.
- Maintenance of the Medical Record: The client maintains the medical records of any patient for whom they have requested Bellin Health Laboratory to perform laboratory tests. The maintenance of these medical records must include all documentation which is
required to deem the ordered tests as medically necessary. This documentation must include the ICD-9 codes that are submitted on the test requisition, and the ordering physician must be the source for the ICD-9 codes. All signs, symptoms, and definitive codes must be included in the medical record. For tests, which are not deemed medically necessary, a signed ABN for the date of testing must be included in the chart. This information shall be made available to Bellin Health Laboratory upon audit or request. If physician documentation does not support a paid claim, Bellin Health Laboratory may recoup losses from the client.

- The following data must be provided for Bellin Health Laboratory to bill Medicare: patient’s full name as it appears on the Medicare card, gender, date of birth, Medicare number, current full address, guarantor, referring physician and UPIN or NPI number, and the appropriate diagnosis codes.
- In the case of incomplete requisitions, Bellin Health Laboratory performs the requested tests without waiting for further patient information. The client shall forward all missing information as soon as possible. If information is not submitted within 24 hours of the receipt of the requisition, the client is billed for the tests.
- Add-on testing are accepted and billed in the same way as the original requisition.
- Tests may be cancelled prior to setup, and the charges will be cancelled. If the tests are in progress when the client requests a cancellation, the test will be finished and billed. Any tests cancelled due to improper specimen submission or interfering substances prior to setup will not be charged.
- Occasionally, a patient’s test may have been billed to the client and subsequently need to be billed to Medicare. Bellin Health Laboratory will credit the client and bill Medicare if no more than 60 days have passed since receipt of the requisition.
- The nursing home client will not submit for Medicare billing any services which are covered by the Medicare part A or by Medicaid’s per diem rate to a skilled nursing facility. Bellin Health Laboratory charges a phlebotomy charge and trip charge to Medicare for any blood collection performed for a skilled nursing facility patient.
- The end-stage renal disease (ESRD) client will not submit for Medicare billing any laboratory tests included in the ESRD facility’s composite rate.
- Policy for denials: Bellin Health Laboratory reserves the right to bill back to the client any Medicare denials for services not covered or not medically necessary. The client may then bill the patient if an ABN is on file. The client is responsible for any services requested by any non-physician staff. In the event that Medicare rejects any such claims, Bellin Health Laboratory bills those services back to the client. The client assumes ultimate responsibility for any tests submitted to Bellin Health Laboratory.
- Bellin Health Laboratory provides education to the client to supplement Medicare instructions provided by its carrier. Such education includes a section in the test catalog on billing and coding issues and periodic informational messages to clients. In addition, clients may call Bellin’s Customer Service Representatives at 920-433-3652 or 800-236-1639 with specific questions.
- Bellin Health Laboratory does not honor requests for “professional courtesy” testing.