***Bellin Healthcare Provider Laboratory Compliance***

***Information***

Dear Provider,

Bellin Health System Laboratory Services is supplying all providers with this annual notice of our continued commitment to Federal and State laws pertaining to health plans. This notice is provided in compliance with the regulations and requirements of the Office of Inspector General (OIG) of the Department of Health and Human Services at the Center for Medicare and Medicaid Services (CMS).

Please be assured that the information enclosed in this notice is also meant to address how Bellin Health intends to adhere to these regulations as they relate to laboratory services.

Medical Necessity

According to policies developed by CMS, Medicare will pay only for laboratory testing that they have deemed reasonable and necessary to diagnose and treat a patient. Medicare has provided some screening benefits for very specific situations.

The policies developed are referred to as National Coverage Determinations (NCD) and define the specific diagnosis codes for which 23 select laboratory tests will be covered. These policies can be accessed on the CMS website at: <http://www.cms.hhs.gov/center/clinical.asp>or also through Bellin Health web page at: <http://www.bellin.org/customers/laboratory/>which will provide an index and a link to the policies. The policies pertain to the following laboratory testing:

• Alpha-Fetoprotein (AFP)

• Blood Counts

• Blood Glucose

• Carcinoembryonic Antigen (CEA)

• Collagen Crosslinks (N-Telopeptide)

• Digoxin Assay

• Fecal Occult Blood Test

• Gamma Glutamyltransferase (GGT)

• Hepatitis Panel Acute

• Human Chorionic Gonadotropin (hCG)

• Human Immunodeficiency Virus (HIV) Diagnosis

• Human Immunodeficiency Virus (HIV) Prognosis

• Lipid Testing

• Partial Thromboplastin Time (PTT)

• Prostate Specific Antigen (PSA)

• Prothrombin Time

• Serum Iron

• Thyroid Testing

• Tumor Antigen (CA 125)

• Tumor Antigens (CA 15-3/CA 27.29)

• Tumor Antigen (CA 19-9)

• Urine Culture Bacterial

These NCDs are binding policies for all Medicare carriers and fiscal intermediaries. Be aware that any screening tests may have frequency limits. As a provider your responsibility is to:

• Document the medical necessity or reason you are ordering the laboratory test in the patient’s permanent medical record.

• Provide the appropriate diagnostic information in the form of an ICD-9 code or a narrative, which matches the ICD-9 coding language for any laboratory testing you are ordering. This information must be provided at the time the laboratory testing is ordered and reflect your reason for ordering the particular test. All orders must be signed and legible.

There are additional tests that are covered based on policies developed by local carriers and fiscal intermediaries as required by the State of Wisconsin. Links to these policies are found on the Bellin Health website stated above under Wisconsin Physician Services (WPS) Carrier and National Government Services (NGS) Fiscal Intermediary Local Medical Review Policies (LMRP). Those tests include:

• WPS

— Helicobacter pylori

— Syphilis Testing

— Heavy Metal Testing

• NGS

— Serum Magnesium

Advance Beneficiary Notices (ABN)

Although Medicare may deny payment for a test based on medical necessity policies, the provider may believe it is appropriate and necessary in order to treat the patient. Medicare also states that a laboratory cannot bill Medicare for these services unless the patient is notified in writing and has verified receipt of this information with a signature prior to the services being provided.

If a provider orders tests that will not be covered by Medicare as stated in the NCD or LMRP, the written order and/or requisition for laboratory services must be accompanied by a completed and signed ABN or “waiver.” If this ABN or “waiver” is submitted, the laboratory must note the presence of

such at the time the testing is billed to Medicare. If the presence of the signed ABN or “waiver” is not noted on the claim at the time it is submitted, the patient is not responsible for these charges however, the providers and their facility are responsible for this omission. CMS has two forms of ABN forms available on their website at h[ttp;//www.cms.hh](http://www.cms.hhs/gov/BNI/02-)s/gov[/BNI/02](http://www.cms.hhs/gov/BNI/02-)- ABNGABNL.asp.

The Form No. CMS-R-131-L is specific for laboratory while Form No. CMS-R-131-G is for general use. Regardless of which form you use, the form must contain the following information:

• The service requested and the diagnosis provided that does not meet Medicare Medical Necessity policies

• The service requested that does not meet frequency limitations as established by Medicare

• Any routine screening tests that are requested and not covered by Medicare

• Any experimental or research testing not covered by

Medicare

• The estimated cost of these services from the performing laboratory

• The patients election to have the testing

• Patient’s signature and date

Each test must be accompanied by the specific reason that Medicare may not pay for the test. Blanket ABNs or “waivers” for all testing ordered are not allowed by Medicare and may invite further investigation.

Reflex Laboratory Testing

Based upon results of initial testing, Bellin Health Laboratory may perform additional testing resulting in additional charges. The number of reflex testing scenarios is limited to what constitutes common guidelines for best patient care. A list of these reflex-testing situations is attached to this notice, found on the reverse side of “Outreach Laboratory General” requisitions, and also listed in Bellin Health Outreach Laboratory online and printed Test Directory.

If the provider determines that he/she would not want the typical reflex-testing performed, it should be indicated by the use of the term “No reflex testing” on the written orders.

Approved Organ and Disease Panels

The American Medical Association (AMA) has created certain panels of tests that are used for specific like purposes and are

included under a single CPT code. When a provider orders additional testing to that found in the approved panel, those additional tests would be billed separately. Medicare will only pay for these approved panels based on Medicare’s interpretation that all components of the panel are medically necessary.

All panels as well as each additional test must be accompanied by a valid diagnosis code at the time the testing is ordered.

Bellin Health will not provide and bill test panels that are not based on AMA approved guidelines (custom panels).

CPT Coding

Each laboratory test is billed using a CPT or Current Procedural Terminology Code, which best describes the testing performed in numerical code.

CPT codes are listed in the printed and online Bellin Health Test Directory as a guide to assist with billing. The CPT codes reflect our best interpretation of the coding requirements and are subject to change at any time. If you are using these codes for billing purposes it is your responsibility to verify the accuracy of these codes before claim submission.

Office of Inspector General (OIG) Penalties Please note that the OIG monitors compliance programs for both our hospital system and all clinic systems. Failure to

follow the approved guidelines listed in brief above may subject

you or your facility to OIG civil penalties.

Clinical Consultant

Bellin Health Laboratory Medical Director is Dr. Thomas Fredeen. Our team of pathologists as well as technical and administrative personnel are available to assist with laboratory testing questions, including ordering and interpretation.

Please call our pathology department at 920-433-3653 or Bellin

Health Laboratory Customer Service at 920-433-3650.