



Ascension

To: Physicians and Providers

From: Vanessa Freitag, Vice President, Pharmacy & Lab
Guillermo Martinez-Torres MD, Medical Director, Ascension Wisconsin Laboratories

CC: Ascension Wisconsin Laboratory Compliance Team

Date: January 2, 2021

RE: 2021 Annual Laboratory Compliance Notice to Physicians and Providers

The Office of the Inspector General (OIG) of the Department of Health and Human Services (DHHS) and other Federal agencies are charged with the responsibility for enforcement of Federal Law. The OIG believes that compliance plans offer a vehicle to achieve significant reductions in fraud and abuse. Therefore, in alignment with the OIG's guidelines for a model compliance plan for clinical laboratories, the Ascension Wisconsin Laboratory Network has chosen to incorporate those recommendations in our current compliance activities. In alignment with Ascension Wisconsin's approach, we regard these compliance measures as a business imperative in the current and continuing environment of close federal scrutiny and aligned with strict adherence to all State and Federal laws.

Ordering Diagnostic Tests - According to 42 CFR 410.32, the federal government describes the conditions for ordering laboratory tests. All diagnostic laboratory tests must be ordered by the provider who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the provider who is treating the beneficiary are not deemed reasonable.

Medical Necessity - Laboratory tests are reimbursed under federally funded programs if they are deemed "medically necessary" for the diagnosis and treatment of the patient. The Centers for Medicare and Medicaid Services (CMS) has developed national and local coverage decisions that identify those tests that CMS determined will be covered under the Medicare program. Coverage for these services is based on the diagnosis / sign / symptom assigned at the office visit. CMS' National Coverage Decisions (NCDs) and Local Medical Review Policies (LMRP) can

be accessed at: <http://www.cms.hhs.gov/mcd/overview.asp> It is a requirement that a numeric (ICD-10) code is linked to each test ordered.

CMS Approved Organ and Disease Panels

80047	Basic Metabolic Panel with Ionized Calcium
80048	Basic Metabolic Panel with Calcium Total
80050	General Health Panel
80053	Comprehensive Metabolic Panel
80061	Lipid Panel
80069	Renal Function Panel
80074	Acute Hepatitis Panel
80076	Hepatic Function Panel
80055	Obstetric Panel (80081 with HIV)

Requests for Customized Test Panels – important awareness when requests for customized test profiles are made:

- Medicare reimbursement is paid at the panel component level
- Using a customized test panel may result in the ordering of tests which are not covered, reasonable or necessary and the tests may not be billed
- The OIG takes the position that an individual who knowingly causes a false claim to be submitted may be subject to sanctions or remedies available under civil, criminal and administrative law.
- Ascension Wisconsin Laboratory Network may request physician signature when customized test panels are requested to acknowledge his/her understanding of ordering such panel types

Advanced Beneficiary Notice (ABN) – If a particular test that is ordered for a Medicare patient does not meet the NCD or LCD medical necessity guidelines, or is frequency restricted, the patient should be provided an ABN by the requesting physician or provider. The ABN informs the patient of his/her potential financial responsibility for the tests if Medicare denies the service. The patient has the right to waive billing Medicare, assume the expense of the test or refuse the test that is not covered by Medicare payment.

Medicare and Medical Assistance Billing – Additional information:

- Medicare Secondary Payer (MSP) Screening – Medicare requires that all healthcare providers make a good faith effort and have procedures in place to ensure that Medicare is the primary payer.
- Medicare Reimbursement Fee Schedule – Medicare reimburses laboratory services based upon their published fee schedule. A copy of this reimbursement fee schedule can be found online at www.cms.hhs.gov
- Medical Assistance (or Medicaid) reimbursement for laboratory services is equal to or less than the amount Medicare reimburses.

Ascension Wisconsin Laboratory Network – Clinical Consultant:

Guillermo Martinez-Torres MD, President, North Shore Pathologists SC, Ascension Wisconsin Medical Director, Pathology and Laboratory Services is available to assist with laboratory testing questions, including ordering and interpretation, and may be reached at 414-585-1448 or Guillermo.Martinez-Torres@Ascension.org

Corporate Compliance

Ascension has a Compliance Program that functions as a collaborative partner with the Ascension Wisconsin Laboratory Network and will provide expertise and guidance to comply with applicable laws, regulations and rule, promotes a culture of compliance to protect the integrity of the organization, and provide compliance training and education annually and as needed.