Annual Notification to Physicians:
Laboratory Medicare Charge and Billing Requirements for 2020

As part of Clinical Laboratories’ Compliance Plan for the Federal Office of Inspector General (OIG), we are required to notify all providers annually of the following policies, which are developed to reflect government guidance:

(1) Medical Necessity Requirement:
- Medicare will only pay for tests that meet the Medicare coverage criteria and are reasonable and necessary for the beneficiary, given his or her clinical condition. Documentation supporting the medical necessity of the service provided and billed by the laboratory should be available in the medical record.
- Medicare national and local medical review policies exist for certain lab tests. Specific information on NCDs (National Coverage Determination) and LCDs (Local Coverage Determination) can be found on the CMS website: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?CoverageSelection=Local&ArticleType=All&PpolicyType=Final&ss=Colorado&KeyWord=lab&KeyWordLookUp=Title&KeyWordSearchType=And&bc=2698032915&
- Providers must provide ICD-10 codes or diagnoses with all outpatient laboratory requests to support medical necessity. Code the condition(s) to the highest degree of certainty for that encounter/visit.

(2) Review of Tests Combined into a Group/Profile:
- Providers should understand ordering testing customized into “profiles” or groups may result in the ordering of tests which are not covered, reasonable or necessary. Providers should order only testing which is medically necessary for the diagnosis or treatment of a patient related to the encounter in which the tests are ordered. For laboratories to bill Medicare, every test, including each component of a panel, must be medically necessary. Customized groups/profiles should only be utilized when all the tests included in the group are necessary. 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.
- AMA Approved “Panels”:
  Basic Metabolic panel (BMP) - Calcium, (ionized), Carbon dioxide, Chloride, Creatinine, Glucose, Potassium, Sodium, Urea Nitrogen.
  BMP with Calcium (total) - as above with total Calcium vs ionized.
  Electrolyte Panel - Carbon dioxide, Chloride, Potassium, Sodium.
  Comprehensive Metabolic Panel (CMP) - BMP, plus Albumin, Bilirubin, (total), Alkaline Phosphatase, Protein, (total), Alanine Amino Transferase (ALT), Aspartate Amino Transferase (AST).
  Lipid Panel - Cholesterol, serum total, Lipoprotein, HDL (direct measurement), Triglycerides.
  Renal Function Panel - Albumin, Calcium (total), Carbon dioxide (bicarbonate), Chloride, Creatinine, Glucose, Phosphate, Potassium, Sodium, Urea nitrogen.
  Hepatic Function panel - Albumin, Bilirubin (total and direct), Alkaline Phosphatase, Protein total, Alanine Amino Transferase (ALT), Aspartate Amino Transferase (AST).
  Acute Hepatitis Panel - Hepatitis A Antibody IgM, Hepatitis B Core Antibody IgM, Hepatitis B Surface Antigen, Hepatitis C Antibody.
  General Health Panel - CBC with Differential, Comprehensive Metabolic Panel (CMP), Thyroid Stimulating Hormone (TSH).
(3) The 2020 Clinical Laboratory Fee Schedule is available at:
   - Note this fee is what Medicare is reimbursing, not what is being charged by the hospital.
   - The Medicaid reimbursement amount will be equal to or less than the Medicare reimbursement amount.
   - A list of changes to Pathology and Laboratory CPT codes for 2020 is available through the lab upon request.

(4) Refex Testing:
   - Refex testing and confirmatory testing may be medically indicated when the initial test results fall within certain parameters. The Clinical Laboratory uses Medical Board-approved testing algorithms whenever possible to avoid delays in patient care. A list of laboratory tests that may generate additional testing and the conditions under which they are performed is available through the lab upon request.

(5) Contact information for a clinical consultant:
   - CLIA Laboratory Medical Director - Mark A Lovell, MD 720-777-5468
   - CLIA Laboratory Medical Director (Network of Care Locations) - Melkon DomBourian, MD 720-777-5421
   - DPLM Chair - Jennifer Black, MD 720-777-1852
   - Anatomic Pathology - Michael Arnold, MD 720-777-2080
   - Biochemical Genetics - Steven Goodman, MD 720-777-0506
   - Clinical Chemistry/Toxicology - Melkon DomBourian, MD 720-777-5421
   - Clinical Microbiology - Sam Dominozquez, MD PhD 720-777-8883
   - Hematology/Flow Cytometry - Xiang Liang, MD 720-777-5421
   - Mitochondrial Testing - Johan Van Hove, MD, PhD 303-724-2365
   - Precision Diagnostics - Amanda (Amy) Treece, MD 720-777-4337
   - Transfusion Medicine - Kyle Annen, DO 720-777-2721

The laboratory needs providers to be aware of the national review policy for lab testing (referred to above) as well as institutional policies which are available at:
   - Children’s Hospital Colorado Medical Staff Policies and Procedures.
   - Organizational Charge Capture Policy.
   - Laboratory Charge Capture Policy.

This notification and the associated list of reflex testing was approved by the Medical Board of Children’s Hospital Colorado December 2, 2019.

Respectfully submitted,

Mark A. Lovell, MD
CLIA Laboratory Medical Director