MercyOne Laboratories Compliance Policy

Purpose
MercyOne Clinical Laboratories are committed to a high standard of individual and organizational ethics and business practices. The MercyOne Laboratory Compliance Policy is designed to promote prevention, early detection, and prompt resolution of non-compliant practices.

Policy
MercyOne laboratories strive to prevent fraud, abuse, and waste in the clinical laboratory and promote quality service and care to all patients.

The MercyOne Laboratory Compliance Policy includes the seven elements recommended by the Office of the Inspector General (OIG).

1. Standards and Procedures.
2. Designation of a Compliance Officer.
3. Effective education and training programs for employees.
4. Develop an open line of communication.
5. Disciplinary action and enforcement.
6. Regular audits to evaluate the compliance policy.
7. Corrective action for detected offenses.

1. Standards and Procedures.
MercyOne laboratories follow ***CHI's Standards of Conduct***:

- Exercise good faith and honesty in all dealings and transactions.
- Create a work place that fosters community and honors and cares for the dignity, safety and well-being of all persons in mind, body and spirit.
- Maintain a high level of knowledge and skill among all who serve in order to provide a high quality care and safety.
- Observe all laws, regulations and policies that govern what we do.
- Maintain the integrity and protect the confidentiality of patient, resident, employee and organizational information.
- Avoid conflicts of interest and/or the appearance of conflicts.
- Use our resources responsibly.

MercyOne laboratories provide resources to our healthcare providers for the proper ordering and billing of laboratory tests that are based on industry guidelines and the CHI corporate compliance policy.

Questions related to proper ordering and billing of lab tests should be directed to the MercyOne laboratory where testing will be performed.

Medical Necessity
Claims submitted for services will only be paid if the service is covered, reasonable and necessary for the patient, given his/her clinical condition. MercyOne laboratories take all

reasonable steps to ensure that submitted claims meet these requirements. Medicare may deny payment for a test that the physician believes is appropriate, but which does not meet the Medicare coverage criteria, or where the documentation in the entire patient record does not support the tests that were reasonable and necessary for a given patient.

To assist with the ordering and billing of laboratory tests, MercyOne laboratories utilize electronic data systems to integrate laboratory orders, patient demographics, insurance information and medical necessity documentation between the provider and the performing laboratory.

Key points to ensure compliance incorporated in these data systems include, but are not limited to:

- Diagnosis requirement (ICD-10 code preferred).
- Medicare statement indicating Medicare generally does not cover routine screening tests.
- Certain lab tests are offered with the option of follow up reflex testing, if indicated. Physicians also have the ability to order without the reflex option.
- Advanced Beneficiary Notice (ABN) information.

If required/necessary information is missing/unclear on the test requisitions, the performing laboratory will contact the ordering provider for clarification. Laboratory staff **should not**:

1. Use information provided from an earlier date of service.
2. Create diagnosis information that has triggered reimbursement in the past.
3. Use computer programs that automatically insert diagnosis codes without the receipt of diagnosis information from an ordering provider.
4. Make up information for claim submission purposes.

Each MercyOne laboratory will conduct an annual review on the top volume tests performed each year. If test utilization increases by 10%, the respective laboratory investigates the reason and follows up appropriately.

- MercyOne laboratories have a policy in place for proper management of standing orders.
- MercyOne laboratories have policies in place for how test requests are accepted.
- MercyOne laboratories have policies/procedures in place for completing ABN forms.

A letter is sent to ordering providers and clients on an annual basis.

Billing

For laboratories performing tests for outreach clients, fee schedules are provided at time of contracing and reviewed periodically. The fee schedule includes test descriptions, CPT codes, and charges to client or facility.

MercyOne laboratories will bill only for tests that are performed and test that were ordered by an authorized provider. If a test is ordered and is not performed due to specimen integrity, provider

request, or there is no payable diagnosis, the charge will be credited. If a MercyOne laboratory staff member orders a test in error and performs/results the test, the charge will be credited. In the event a provider requests repeat testing because the results of the original test are not consistent with clinical findings, charges for the repeat testing will be credited. Policies and procedures are in place for handling credits.

MercyOne laboratories do not bill for both test calculations (e.g. LDL) and the tests that are performed to derive such calculations.

Additional Medicare Information

The American Medical Association's (AMA) CPT code book lists numerous Organ and Disease-Oriented Panels. CPT codes for these panels range from 80047-80076. Panels should only be ordered and billed when all components of the panel are medically necessary. When panels are ordered that do not fit the AMA coding and descriptions, Medicare pays for each component of the custom panels separately. Like the AMA panels, each component of these custom panels must be reasonable and necessary and meet all medical review policies.

Medicare generally does not pay for routine screening tests. Medicare may deny payment for a test that the physician believes is appropriate, but does not meet the medical coverage criteria, or where the documentation in the entire patient record, including that maintained in the physician's records, does not support the tests were reasonable and necessary for a given patient.

MercyOne laboratories strive to provide the most current information regarding medical necessity guidelines. Current up-to-date CMS medical necessity guidelines can be found using the following links:

https://www.cms.gov/medicare-coverage-database/indexes/lcd-list.aspx?Cntrctr=268&ContrVer=1&CntrctrSelected=268*1&name=Wisconsin+Physicians+Service+Insurance+Corporation+(05901%2C+MAC+-+Part+A)&s=56&DocType=All&bc=AggAAAAAAAAAAA%3D%3D&#ResultsAnchor

https://www.cms.gov/medicare-coverage-database/indexes/lab-ncd-index.aspx?bc=BAAAAAAAAAAA

Active policies for Local Coverage Determinations (LCD) and National Coverage Determinations (NCD) can be accessed utilizing links provided on the above website.

Information on Medicare preventative services and frequency can be found at the following website:

https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html

Advanced Beneficiary Notice (ABN)

If the patient's diagnosis is not included in the medical review policy as a payable benefit, or there is reason to believe that Medicare will not pay for a test (ordered too frequently, screening or research test), the patient should be informed *prior* to collection of specimen and/or testing. MercyOne laboratories provide ABN forms for this purpose.

Electronic ordering systems will automatically have ABN forms generated when entered patient information deems an ABN form is necessary. It is the responsibility of the ordering provider to determine the need for an ABN form prior to drawing the patient. It is not acceptable to have patients sign a blank ABN form. Instructions for filling out ABN forms can be found on the following link:

http://www.mercydesmoines.org/Portals/0/media/documents/MCL/Medical%20Necessity%20and%20Advanced%20Beneficiary%20Notice%20March%202015.pdf

Reflex Testing

The purpose of reflex testing is to provide additional significant diagnostic information for appropriate patient care. All reflex testing performed at MercyOne laboratories will be specified by policy at each laboratory site. Individual laboratories are responsible to maintain test menus that coincide with established policies regarding use of reflex tests. When criteria exist to perform a reflex test, this test will be ordered and billed, as appropriate.

Standing Order Management

The use of standing orders may increase the likelihood of claims being rejected by insurers and/or Medicare contractors.

MercyOne laboratories recognize the benefit of using standing orders in the extended treatment of patients and follows the following protocol to help avoid rejected claims.

Standing Orders need to include:
1) Patient name, address, date of birth.
2) Standing order test(s) and frequency.
3) Diagnosis for the test(s) ordered.
4) Patient insurance information.
5) Start date.
6) Expiration date - not to exceed 12 months.
7) Providers signature.

Standing orders are valid for 12 months from the order date, not start date. MercyOne laboratories will validate all standing orders by laboratory site on an annual basis. For standing orders placed in the ambulatory electronic health record (AEHR), parameters have been defined to limit standing orders to no more than 12 months duration.

One-Time Orders

Laboratory testing should be timely for appropriate and optimal patient care.
Orders are valid for 30 days from date written or date of requested collection, whichever is longer. Orders exceeding this timeframe will be conisdered invalid and a new order must be obtained from the provider.

Custom Profiles

While the Center for Medicare and Medicaid Services (CMS) does not discourage the use of customized profiles, it should be noted that there is an increased risk of ordering tests that are not covered, reasonable or necessary when ordering via customized profiles and therefore will not be billed. The provider is responsible to ensure that each test in the profile meets these requirements when placing a customized profile order. The provider will also be asked to sign an annual Custom Profile Agreement document.

2. Designation of a Compliance Officer.

MercyOne Medical Center - Des Moines (MMC) including it's wholly owned entities (i.e. hospitals and clinics) have implemented a Corporate Responsibility Plan (CRP). A Corporate Responsibility Officer (CRO) has been designated and is responsible for the development, implementation, and administration of the CRP for all entities within MMC. Additionally, a Clinical Laboratory Compliance Officer has been designated to oversee laboratory compliance for all laboratories operating within MMC. The Clinical Laboratory Compliance Officer chairs the Clinical Laboratory Compliance Committee which includes representation from all of the laboratories within MMC. The Clinical Laboratory Compliance Committee reports jointly to the Mercy Corporate Compliance Committee and to the Catholic Health Initiatives (CHI) Corporate Laboratory Compliance Committee.

3. Effective Education and Training Programs for Employees.

New hire orientation includes a session on Corporate Compliance. Annual refresher courses are required thereafter and include, but are not limited to training in: Federal and State statutes, regulations, program requirements, private payer policies, and corporate ethics.

4. Develop an Open Line of Communication.

MercyOne laboratories utilize the CHI reporting process in which an individual may seek guidance or disclose information about compliance issues. The CHI reporting process is included in the *Our Values and Ethics at Work Reference Guide,* which is given to all new employees during orientation. An individual may report concerns:
1) directly to their supervisor or manager,
2) to the MBO Corporate Responsibility Officer (CRO) or CHI National CRO, or
3) anonymously using the CHI hotline or Internet reporting tool.

MercyOne laboratories follow CHI's non-retaliatory policy, which provides the individual who makes a report, complaint, or inquiry in good faith, with protection from retaliatory action.

5. Disciplinary Action and Enforcement.

MercyOne laboratories will follow the CHI *Corporate Corrective Action Policy and Procedure* for disciplinary action as it relates to Corporate Compliance issues. All laboratory employees will be subjected to the same disciplinary action for similar offenses. Managers and Supervisors are encouraged to contact local HR Representatives if questions arise.

6. Regular Audits to Evaluate the Compliance Policy.

CHI and MMC conduct annual risk assessments to identify and examine risks and to evaluate the effectiveness of current policies and procedures. The annual risk assessment is based on information received from the Office of the Inspector General (OIG) annual work plan, supplemental guidance, and identified focus reviews. Additional audits are performed on a regular basis to review adherence to compliance policies and are specific to processes at each laboratory site.

7. Corrective Action for Detected Offenses.

Issues or concerns brought forth either through direct communication, anonymous notifiction or via an auditing process are thoroughly investigated. If indicated, action plans are implemented to address the immediate concern and to eliminate or reduce future risk.

It is important to note 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.

References

Corporate Responsibility Community, Inside CHI website. Accessed August 2015. http://collab.catholichealth.net/gm/folder-1.11.114541

Publication of OIG Compliance Program Guidance for Clinical Laboratories. Department of Health and Human Services Office of the Inspector General. Federal Register/Vol.63, No.163/August 24, 1998.

Approval and Review Signatures for this Major Revision [show signatures for all versions of the document]

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