Catholic Health Initiatives

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Corporate Responsibility Program Plan
Clinical Laboratory Addendum

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The Clinical Laboratory Addendum (Addendum) and its companion "Laboratory Compliance - Nursing and Clinic Laboratory Testing Staff Overview" are designed to be implemented and maintained in conjunction with the Catholic Health Initiatives (CHI) Corporate Responsibility Program (CRP). This Addendum is not a stand-along program, but is a part of the overall CHI CRP Plan, a comprehensive effort for ensuring regulatory compliance throughout the entire organization. The Corporate Responsibility Plan must be consulted in addition to this Addendum for complete details. The Addendum establishes standards for the implementation and operation of the CRP within CHI's clinical laboratories. The Addendum includes, but is not limited to, risk areas, Office of Inspector General (OIG) fraud alerts, and recommended policies and procedures specific to the laboratory. This Addendum will be reviewed on an annual basis by the National CRP Director responsible for the Addendum. This Addendum will also be reviewed by the entity Corporate Responsibility Officer **(**CRO), and when appropriate according to local policy, by entity personnel responsible for implementation to ensure the plan is operating effectively and is current with any regulatory or CHI changes or additions.

The information included in the Addendum may be modified periodically as a result of, but is not limited to:

- Recommendations from CRP staff and other functional area staff
- Additional guidance as provided by regulatory agencies
- OIG Fraud Alerts
- Other as applicable

The Clinical Laboratory Addendum includes several appendices as noted in the table of contents.

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Appendix A
Clinical Laboratory Overview

The Office of Inspector General (OIG) Compliance Program Guidance for Clinical Laboratories – 08/1998 indicates the statutes, rules, and program instructions that apply to each CHI entity's clinical laboratory(ies) should be reflected in the entity's clinical laboratory written policies and procedures. See Appendix B for a hyperlink for program guidance recommended by the OIG.

Additionally, the OIG has identified certain Special Risk Areas of Concern that should be considered when incorporating compliance risks into each CHI clinical laboratory(ies) policies and procedures. See Appendix C for a listing of areas which the OIG has identified in various compliance documents that should be considered when compiling a clinical laboratory compliance program.

On an annual basis, the entity Clinical Laboratory Compliance Officer/Committee in conjunction with the entity CRO will develop and perform a clinical laboratory compliance review to be conducted by entity laboratory staff in accordance with pre-established comprehensive review procedures. The review may include some or all of the following: (1) self or external on-site assessments (see Appendix D for an example of a laboratory monitoring tool); (2) interviews with personnel involved in management, operations, billing, sales, marketing, and other related activities; (3) reviews of policy and procedures used by the clinical laboratory; (4) trend analysis studies[1] and (5) comparison of sample orders to final bill for correct claims submission. Formal review reports will be prepared and submitted to the entity CRO and the CHI Director of Laboratory Compliance who will ensure that laboratory leadership take the steps necessary to correct identified problems and to mitigate future problems.

The OIG identifies areas of concern through Special Fraud Alerts and advisory bulletins that relate to clinical laboratories. Those publications (See Appendix E) will be reviewed as they are published and considered for inclusion in the risk assessment process by the entity Clinical Laboratory Compliance Officer, entity Laboratory Compliance Committee, CHI Director of Laboratory Compliance and the National Laboratory Compliance Committee. Any improper conduct identified through a Special

[1] One such example of auditing activity should be test utilization monitoring*:* The OIG believes that laboratories can and should take the steps described above to help ensure that ordering physicians/practitioners will make a determination and document the medical necessity of tests billed to the Medicare program. They also believe that there are steps laboratories can take to determine whether ordering physician/practitioner are being encouraged to order medically unnecessary tests. The OIG suggests that a clinical laboratory which has reason to believe that its physicians/practitioners are ordering medically unnecessary tests has a duty to determine why that behavior has occurred. More importantly, if the clinical laboratory discovers that it has in some way caused that behavior, the clinical laboratory has the duty to correct the cause. An example of this would be the addition of a new testing procedure to replace one that may be less sensitive or diagnostic. The implementing clinical laboratory could choose to monitor the newly implemented test to determine such things as:

- Has the ordering volume of the new test replaced the ordering of the less sensitive one?
- Is the new test being ordered and justified with the appropriate medical necessity?
- Is education/communication improving the ordering physicians/practitioner's use of the new test?

Fraud Alert will cease and be corrected. Investigation and corrective action procedures as described in CHI's CRP Plan will be followed as appropriate. Procedures will be implemented to prevent such conduct in the future.

The OIG also provides an annual work plan to describe the activities that the OIG plans to initiate or continue to focus on during that fiscal year. The work plan is a summary of the OIG's investigative, enforcement and compliance activities deemed of greatest risk or potential impact to Department of Health and Human Services (DHHS) programs or beneficiaries. The annual work plan can be found on the OIG Website at: http://oig.hhs.gov/reports-and-publications/workplan/index.asp Any OIG clinical laboratory related focus areas highlighted in the work plan will be specifically monitored by each entity for compliance and the results will be reported to the CHI Director of Laboratory Compliance at least annually.

SCOPE AND APPLICABILITY

The CHI Clinical Laboratory Compliance Addendum addresses those activities specific to the operations of the clinical laboratory(ies) that are considered essential in meeting established standards for an effective compliance program. It addresses the primary compliance risk areas impacting clinical laboratories including but not limited to billing, coding, reasonable and necessary services, documentation and improper inducements/kickbacks/self-referrals. It incorporates the compliance risk areas identified by DHHS, the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA), the Centers for Disease Control (CDC) and the OIG's Compliance Program Guidance for Clinical Laboratories (see Appendix B).