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Corporate Responsibility Program Plan
Clinical Laboratory Addendum

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Corporate Responsibility Program Plan
Clinical Laboratory Addendum

Clinical Laboratory Addendum (Addendum) are designed to be implemented and maintained in conjunction with the CommonSpirit Health's Corporate Responsibility Program (CRP). This Addendum is not a stand-alone program but is a part of the overall CommonSpirit Health's 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 CommonSpirit Health'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 System CRP Laboratory Director. 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 CommonSpirit Health 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 CommonSpirit Health 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 CommonSpirit Health 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's Administrative Laboratory Leadership will conduct a clinical laboratory compliance review in form of a checklist. 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 CommonSpirit Health System Director of Laboratory Compliance who will ensure that laboratory leadership take the steps necessary to correct identified problems and to mitigate future problems. The current year's Laboratory Compliance Addendum Checklist is to be used to document completion of each assigned responsibility. Once all assigned responsibilities are completed, review with the entity Corporate Responsibility Officer and submit to the System Director of Laboratory Compliance.

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, CommonSpirit Health System Director of Laboratory Compliance and the National Laboratory Compliance Committee. Any improper conduct identified

[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?

through a Special Fraud Alert will cease and be corrected in coordination with the local Corporate Responsibility Officer. Investigation and corrective action procedures as described in CommonSpirit Health's CRP Plan will be followed as appropriate. Procedures will be implemented to prevent such conduct in the future.

The OIG also provides a 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 OIG's monthly updates 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 CommonSpirit Health Director of Laboratory Compliance at least annually.

SCOPE AND APPLICABILITY

The CommonSpirit Health 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).

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Appendix B

Final Compliance Program Guidance for Clinical Laboratories - 08/1998

Final Compliance Program Guidance for Clinical Laboratories - 08/1998

Department of Health and Human Services, Office of Inspector General, Publication of OIG Compliance Program Guidance for Clinical Laboratories Page 45076 Federal Register / Vol. 63, No. 163 / Monday, August 24, 1998 / Notices

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Appendix C

Final Compliance Program Guidance for Clinical Laboratories - 08/1998

Within various compliance documents, the OIG has identified topics that should be considered when compiling a clinical laboratory compliance program.

1. Coding and Billing:

    a. Billing for items or services not rendered or not provided as claimed
    b. Submitting claims for clinical laboratory tests that are not reasonable and necessary
    c. Double billing resulting in duplicate payment
    d. Billing for noncovered services as if covered
    e. Knowing misuse of physician/practitioner identification numbers, which results in improper billing
    f. Unbundling (billing for each component of the service instead of billing using an all-inclusive code)
    g. Failure to properly use coding modifiers
    h. Upcoding the level of services provided
    i. Contracting with billing services on a percentage collected basis
    j. Professional courtesy discounts, including routinely waiving coinsurance obligations or other out- of-pocket expenses for other physicians or ordering physicians/practitioners and their families

2. Reasonable and Necessary Services:

    a. Billing only for those items or services deemed reasonable and necessary according to the Medicare reimbursement rules and any National and Local Coverage Determination (NCD/LCD)
    b. Notifying patients through Advance Beneficiary Notices (ABNs) when the NCD or LCD indicates that an item or service may not be covered
    c. Proper use of modifiers when submitting claims for noncovered services in order to receive a denial from the carrier/fiscal intermediary/ Medicare Administrative Contractor (MAC), thereby enabling the submission of the denied claim for payment to a secondary payer when recognized by the applicable payer

3. Documentation:

    a. CPT and ICD codes reported on the claim form are supported by documentation in the patient's medical record
    b. The medical record contains all necessary information
    c. The physician/practitioner ordering the service and authentication is able to be determined
    d. The diagnosis code on the claim form reflects what was provided on the requisition by the order document
    e. Modifiers used on the claim form are appropriate

f. Comply with Medicare Secondary Payer (MSP) requirements as they apply to the laboratory

4. Improper Inducements, Kickbacks, Self-Referrals and Gifts:

a. Financial arrangements with outside entities to whom the clinical laboratory may receive referrals for federal health care program business
b. Office and equipment leases with entities contingent upon the clinical laboratory receiving referrals
c. Soliciting, accepting or offering any gift or gratuity to or from those who may benefit from a physician practice's referral of federal health care program business (Refer to CommonSpirit Health's Conflicts of Interest, Gifts and Gratuities)
d. The amount of equipment and supplies provided to referral sources is appropriate for the volume of testing received from that referral source

Appendix D

Sample Monitoring Tool

Monitoring tools that are available include:

Clinical Laboratory Compliance Addendum Checklist

HIPAA Privacy Program Clinical Laboratory Addendum Self-Assessment Checklist

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Appendix E

Special Fraud Alerts, Advisory Bulletins and other Communications by the OIG

Special Fraud Alerts relating to clinical laboratories can be found at the following link:
http://oig.hhs.gov/compliance/

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Appendix F

The Clinical Laboratory Compliance Officer, Laboratory Leadership and Clinical Laboratory Compliance Committee

Each CommonSpirit Health entity clinical laboratory(ies) will appoint an individual to represent laboratory compliance in their regional division. This individual, Division Laboratory Compliance Officer, will participate in the National Clinical Laboratory Compliance Committee and will chair the Division's Laboratory Compliance Committee. The division's Laboratory Compliance Committee will be comprised of all administrative laboratory leadership in their division and the entity's CRO's for their division. If the division prefer not to have a separate committee for Laboratory Compliance, it may be a standing agenda item on an existing Compliance Committee. The name of the individual representing as the Division's Laboratory Compliance Officer will be listed on Appendix G.

Primary responsibilities of the Divisions' Laboratory Compliance Officer include:

- Be a member of the National Laboratory Compliance Committee
- Chair the division's laboratory compliance committee or represent lab compliance on an agenda of compliance meeting
- Communicate changes and implementation of the Clinical Laboratory Addendum to laboratory leadership
- Be a liaison for communicating agenda topics to the National Laboratory Compliance Committee

Administrative Laboratory Leadership's primary responsibilities include[2]:

- Implements the Clinical Laboratory Addendum
- Reporting on a regular basis, at a minimum of annually, to the entity's clinical laboratory leadership, entity CRO, entity Compliance Committee and the CommonSpirit Health System Director of Laboratory Compliance on the progress of implementation and utilization of this Addendum in establishing methods to improve the clinical laboratory's efficiency, quality of services, and to reduce the clinical laboratory's vulnerability to fraud, waste and abuse
- Developing and distributing to all affected employees the written clinical laboratory compliance procedures contained in this Addendum and any other entity level compliance polices/procedures. Coordinating and participating in a multifaceted education and training program that focuses on the elements of this Addendum, and seeks to ensure that all appropriate clinical laboratory staff and management are knowledgeable of, and comply with, pertinent federal, state and private payer standards

[2] Laboratory Leadership is an individual who oversees laboratory operations and manages laboratory staff. Laboratory leadership is assigned the responsibilities listed within this addendum and may perform them in addition to any existing job duties. Depending on the laboratory size and complexity, this individual could be responsible for a single or multiple laboratory (ies). Adapted from the OIG Final Compliance Program Guidance for Clinical Laboratories -08/1998 http://oig.hhs.gov/authorities/docs/cpglab.pdf

Appendix F

The Clinical Laboratory Compliance Officer, Laboratory Leadership and Clinical Laboratory Compliance Committee

- Implementing revisions to the Addendum as directed by CommonSpirit Health's CRP Oversight Committee, the Laboratory Compliance Committee and/or the System Director of Laboratory Compliance to address changes in organizational needs and in the law, policies and procedures of government and private payer health plan
- Ensuring that the physicians/practitioners[3] who order services from the clinical laboratory are informed of the clinical laboratory's compliance program standards with respect to coding, billing, and marketing, and other compliance related issues
- Assisting the clinical laboratory's financial management staff in coordinating internal compliance review and monitoring activities, including annual or periodic reviews of policies
- Independently investigating and acting on matters related to compliance, including the flexibility to design and coordinate internal investigations in conjunction with the entity CRO, Human Resources and the CommonSpirit Health System Director of Laboratory Compliance (e.g., responding to reports of problems or suspected violations) and any resulting corrective action
- Assuring that policies and programs are implemented that encourage managers and employees to report suspected fraud and other improprieties without fear of retaliation. Take all necessary steps to communicate with all employees the availability of the CRP reporting system ensuring the fact that its utilization is free from the risk of retribution against employees who report unethical, illegal, or other conduct not complying with CommonSpirit Health policies, compliance standards and/or procedures.
- Laboratory leadership and the CRO has the authority to review all documents and other information that are relevant to compliance activities, including, but not limited to, leases, technical support/phlebotomy arrangements, consulting arrangements, new immediate response (STAT) laboratories and outpatient specimen collection facilities (OSCF), changes of address of STAT laboratories and OSCF, management agreements, clinical laboratory director agreements, non-entity (contracted) courier arrangements, requisition forms, billing information, claim information, and records concerning marketing efforts of the clinical laboratory and its arrangements with its clients[4].
- This Addendum enables these individuals to review these contracts and obligations (seeking the advice of the entity's CRO, Clinical Laboratory Compliance Committee and CommonSpirit Health System Director of Laboratory Compliance, if appropriate) to ensure compliance with the anti-kickback statute, the physician self-referral prohibition and other legal or regulatory requirements.

[3] For purposes of this Addendum, the term "physician" means (1) a doctor of medicine or osteopathy legally authorized to practice medicine and surgery in the state in which he/she performs such services, (2) a doctor of dental surgery or of dental medicine who is legally authorized to practice dentistry by the state in which he/she performs such services and who is acting within the scope of his/her license, (3) a doctor of podiatric medicine, but only for those services which he/she is legally authorized to perform by the state in which he/she performs such services, and (4) a doctor of optometry, but only for those services which he/she is legally authorized to perform by the state in which he/she performs such services. The term "practitioner" means any of the following to the extent that they are legally authorized to practice by the State and otherwise meet Medicare requirements: Physician assistant; Nurse practitioner; Clinical nurse specialist; Certified registered nurse anesthetist; Certified nurse midwife; Clinical psychologist; Clinical social worker; Registered dietitian; or Nutrition professional.

[4] A client is a party with which the clinical laboratory has direct billing agreements.

Appendix F

The Clinical Laboratory Compliance Officer, Laboratory Leadership and Clinical Laboratory Compliance Committee

The Divisional Laboratory Compliance Committee and clinical laboratory leadership should maintain an open-door policy and encourage all employees and agents to ask questions about compliance issues and/or report suspected violations of policies or laws.

The divisional Clinical Laboratory Compliance Committee's functions include[5]:

- Periodically or as needed meet with the entity and/or divisional CRO to discuss compliance matters
- Analyzing the organization's regulatory environment, the legal requirements with which it must comply, and specific risk areas
- Assessing existing policies and procedures that address these areas for recommendation and possible incorporation into this Addendum if approved by the National Laboratory Compliance Committee
- Working within the clinical laboratory and CommonSpirit Health CRP to promote CommonSpirit Health's Standards of Conduct, policies and procedures to ensure compliance
- Recommending and monitoring the development of internal systems and controls to implement the clinical laboratory's standards, policies and procedures as part of its daily operations
- Determining the appropriate strategy/approach to promote compliance with this Addendum and detection of any potential violations, such as through hotlines and other fraud reporting mechanisms
- Developing a system to solicit, evaluate and respond to complaints and problems

An divisional Clinical Laboratory Compliance Committee, either freestanding or designated as a subset of is comprised of the Divisional Compliance Officer for the division, laboratory administrative director/s, laboratory medical director or medical director representative if multiple laboratories are represented, laboratory marketing representative, and other key laboratory stake holders are responsible for assisting the entity CRO in the implementation and monitoring of the Clinical Laboratory Addendum procedures as they relate to the CommonSpirit Health entity's clinical laboratory operations and practices. Consideration should also be given for committee membership to include other individuals with varying perspectives and responsibilities within the entity. (i.e., Patient Access, Billing, entity CRO, Senior Leadership) If laboratory operational limitations prevent the appointment of a formal laboratory compliance committee; compliance concerns, education and communication may occur during other departmental meetings, similar staff gatherings or communication vehicles.

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[5] Adapted from the OIG Final Compliance Program Guidance for Clinical Laboratories -08/1998 http://oig.hhs.gov/authorities/docs/cpglab.pdf

Appendix G

Names of a Clinical Laboratory Compliance Officer and Clinical Laboratory Compliance Committee Members

[**INSERT ENTITY LABORATORY NAME]**

Divisional Laboratory Compliance Officer, representing the division: **[INSERT DESIGNATED INDIVIDUAL NAME]**

Administrative Laboratory Leadership for the entity & Title: **[INSERT DESIGNATED NAMES] [INSERT TITLE]**

[INSERT DIVISIONAL OR COMPLIANCE COMMITTEE NAME HERE, WHETHER A STAND ALONE COMMITTEE OR IF LAB COMPLIANCE IS AN AGENDA ITEM ON A COMPLIANCE COMMITTEE]

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Appendix H

Education and Training

The laboratory compliance education program is designed to ensure clinical laboratory employees understand the CommonSpirit Health Standards of Conduct and CommonSpirit Health CRP policies including the procedures associated with this Addendum. Furthermore, the laboratory compliance education program will address specific high-risk areas associated with the clinical laboratory. This would include compliance training specific to employees whose jobs are considered a high-risk area for government scrutiny and for compliance problems or concerns. Examples include employees performing functions such as billing and coding, specimen processing, phlebotomy, sales, marketing and business development and for those in a leadership role.

The education program includes:

1. New hire CRP orientation.
2. Mandatory annual CRP education and training for all defined employees found in My CommonSpirit Health Knowledge Hub and My Journey.
3. Mandatory clinical laboratory CRP Laboratory Addendum education and training for all moderate and above level testing personnel within thirty days of hire or 120 days of first joining CommonSpirit Health as a new member organization and annually thereafter.
4. Mandatory nursing and clinic moderately complex testing personnel education utilizing the "Laboratory Compliance Non-Laboratory Personnel Nursing" in My CommonSpirit Health Knowledge Hub and My Journey module within thirty days of testing duty assignment or 120 days of first joining CommonSpirit Health as a new member organization and annually thereafter.
5. Mandatory clinical laboratory Proficiency Testing CRP education and training for all moderate level and above testing personnel within thirty days of hire or 120 days of first joining CommonSpirit Health as a new member organization excluding nursing and clinic testing personnel.
6. Mandatory clinical laboratory billing and processing education and training for all personnel performing job descriptions in billing and coding, processing, or other related job titles performing these functions within thirty days of hire or 120 days of first joining CommonSpirit Health as a new member organization.
7. Role specific education and training—the type, degree, and frequency of these sessions will depend upon the nature of the employee's role in the operations.
8. Education and training in response to deficient auditing and monitoring findings.
9. Education and training to address operations specific to new business lines.
10. Focused education on federal health care program requirements for coding and billing necessary for certain individuals with the clinical laboratory.

At a minimum, items to be covered in clinical laboratory compliance training include:

1. Clinical laboratory orders
2. Medical necessity
3. Improper inducements, kickback and self-referrals
4. Privacy and security of patient information

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Education and Training

5. Non-monetary compensation
6. Research
7. Coding requirements
8. Where appropriate, claim development and submission processes
9. Marketing practices that reflect current legal and program standards
10. Not signing any document for a physician/practitioner (i.e. clinical laboratory order, requisition)
11. The ramifications of altering patient ordering records without the ordering physicians/practitioners specific consent
    a. The need to accurately document any approved ordering record changes
12. Proper documentation of services rendered
13. How to report misconduct
14. When appropriate, proper billing standards and procedures and submission of accurate bills for services or items rendered to federal health care program beneficiaries
15. The personal obligation of each person involved in the billing process to ensure claims are properly and accurately submitted
16. The legal sanctions for submitting deliberately false or reckless billings
17. Informing ordering physicians/practitioners that they cannot receive payment or any type of incentive to induce referrals

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Appendix I

CRP Reporting System

CommonSpirit Health Reporting Process

As an organization and as individuals, we are responsible for promptly reporting potential violations of law, regulation, policy or procedure. Employees are protected from retaliation for making a good- faith report, complaint or inquiry. The CommonSpirit reporting process is described below.

1. Speak with your supervisor or another manager
2. If the supervisor/manager is not available, or you are not comfortable speaking with him/her, or you believe the matter has not been adequately resolved, contact your human resources representative or your local Corporate Responsibility Officer.
3. If you want to anonymously report a concern to a neutral third party, you have two options:

- Call the reporting hotline number: **1.800.845.4310**
- File your report using the Internet: **https://commonspirit.complytrack.com/Portal/CreateForm/450009**

The confidential option described in #3 above is available 24 hours a day, seven days a week. Reports made by phone or online are received by trained staff who document and forward information to your local or CommonSpirit Corporate Responsibility staff for appropriate action. These reports are not traced or recorded. You may remain anonymous if you wish. If you choose to identify yourself, there is no guarantee your identity will remain confidential. However, when you identify yourself, it is easier for Corporate Responsibility staff to respond. Retaliation against any employee who, in good faith, reports potential or suspected violations is unlawful and will not be tolerated.

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Appendix J

Clinical Laboratory Orders/Ordering Procedure

Orders for clinical laboratory tests and services must be documented and include the elements defined in this procedure.

Only tests that are medically necessary, for the diagnosis or treatment of the patient, may be ordered. Medicare does not generally pay for tests for screening except in limited cases allowed by law and may not pay for non-FDA approved tests or those tests considered experimental. Orders for clinical laboratory tests will not be changed unless the ordering physician/practitioner has been contacted. Current CLIA requirements state that an ordering physician's/practitioner's signature[6] is not required on a laboratory requisition/request for a "laboratory only encounter[7]" for hospital outpatient/nonpatient clinical laboratory testing unless required by entity, state or local regulation. The signature/attestation for these orders must reside in the patient's medical record either at the laboratory or off campus medical record. (i.e. The provider or nursing home's medical record.) NOTE: If during a payment audit, a requested ordering provider signature cannot be retrieved, a recoupment of payment may occur.

1. Standing Orders:
   a. The clinical laboratory bills for properly ordered and documented standing orders and maintains appropriate documentation.
   b. Standing orders are renewed at least annually.
   c. Standing orders must contain a frequency, beginning and end date (i.e., once a week from MM/DD/YYYY to MM/DD/YYYY).
   d. Tests with frequency limitations (i.e., lipid panels) should be reviewed for appropriateness before initiating any standing orders.
   e. If the frequency and/or the test(s) ordered should change during the course of the standing order, a new order must be written.
   f. According to need (PRN) or orders with an annual frequency is not considered a standing order.

2. Verbal Orders:
   a. All verbal orders will be followed up with an attempt to obtain a written order within 30 days of the verbal request, or as required by state law or regulations. If after 30 days no response is received from the physician/practitioner, the order may be considered valid according to CLIA requirements. Consideration must be given by each entity as state law can impose additional requirements and timelines. The ordering provider's signature may or may not be required per the instructions provided earlier in this Appendix and footnote 6.
   b. Maintain documentation of all attempts to obtain the written order for the same length of time written orders are maintained.

3. Protocol Orders
   a. Hospital laboratories may use order sets, and protocols for patient orders if the orders and protocols are reviewed and approved by the medical staff and the hospital's nursing and

[6] Signature for the purpose of this Addendum means electronic or written.

[7] Laboratory only encounter is one where the out/ non patient only requires laboratory services, no other outpatient services would be required on same date of service.

pharmacy leadership to determine the continuing usefulness and safety of the orders/protocols; are consistent with nationally recognized and evidence-based guidelines; are dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or by another practitioner responsible for the care of the patient. 42 C.F.R. § 482.24(c)(3). The ordering provider must be able to "opt out" or alter any part of a protocol order which may not be medically necessary. As an example, ER protocol call may require that all incoming patients with a defined presentation have an automatic order for a CBC, CMP and a Urinalysis. The ordering provider must have the ability to deselect any of the three (3) components if not medically necessary.

4. Duplicate Orders
   a. In cases when a physician/practitioner has ordered duplicate testing, it is acceptable to cancel duplicate tests by the same physician/practitioner without notifying the ordering physician/ practitioner.
   b. In cases when multiple physicians/practitioners order duplicate tests for the same date of service, duplicate tests may not be billed to the patient or the patient's insurance.

5. Medicare Secondary Payer (MSP)
   a. CMS requires that laboratories determine if Medicare is the primary or secondary payer for each episode of service when there is a face-to-face encounter with a patient. A face-to-face encounter is defined as when the patient presents to an entity employee to have his/her blood drawn or provide a specimen for testing.
   b. The MSP Questionnaire (MSPQ) is asked of every Medicare beneficiary each time there is a face-face-face encounter with a patient. This requirement may be different for non-acute care or provider-based physician practices.
   c. In the case of a series or recurring patient, the MSPQ must be updated every 90 days. A series or recurring patient is defined as a patient receiving the same tests with the same diagnosis and the same ordering physician/practitioner at least once a month for a duration of at least 6 months. This requirement may be different for non-acute care or provider-based physician practices.

6. End Stage Renal Disease (ESRD)
   a. Medicare makes composite rate payments to clinics/centers which provide dialysis services to such patients. The cost of certain clinical laboratory tests is included in this composite rate payment up to a specified frequency, which varies by test and mode of treatment. Therefore, tests covered within a composite rate may not be billed separately to Medicare by the clinical laboratory. These tests must be billed to the dialysis facility.
   b. There must be an agreement between the clinical laboratory and the ESRD facility outlining the responsibilities of each party and differentiating those tests subject to composite rate classification which are billed to the ESRD facility from those tests which can be separately billed to Medicare. Those tests not included in the composite rate must be billed using the AY modifier.

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Clinical Laboratory Orders/Ordering Procedure

7. Hospice Services
   a. The correct modifier to use for services not related to hospice care is the GW modifier.
   b. Submit the GW modifier when a test/service is rendered to a patient enrolled in a hospice, and the service is unrelated to the patient's terminal condition. All physicians/practitioners must submit this modifier when this condition applies.

8. Ambiguous Orders or Unclear Orders
   a. If an order from a physician/practitioner is not clear or ambiguous, the ordering physician/ practitioner must be contacted to verify the order and its intent.
   b. Documentation of the clarification must include the first and last name of the person supplying the clarification, the date and time, and the first and last name or the unique identifier of the individual requesting the information for the record. This information must be maintained and identifiable for the length of the record retention.
   c. If an order for a test is written by a physician/practitioner and the test name terminology is not the same as listed in the clinical laboratory's Directory of Services or other interpretive charts, test(s) orders may be converted to standard clinical laboratory test names only if there is a one- to-one comparison match of the test(s) included in both instances.

9. Reflex Testing
   If, after a test is ordered and performed, additional related procedures are necessary to provide or confirm the result the provider requested, these tests would be considered part of the original test order.
   a. At the time of order, criteria for reflex testing must be available to the ordering physician/ practitioner (i.e., complete blood count [CBC] with automated differential reflex; urinalysis with microscopic reflex or culture reflex).
   b. Reflex testing may be required by regulatory agencies or mandates or the test manufacturer.
   c. Reflex testing may be considered good clinical laboratory practice in order to provide accurate and complete clinical information to the ordering provider. (i.e. Positive HIV screen with a reflex to Western blot confirmation)
   d. When reflex orders are executed in the above manner, the original test and any performed reflexed tests may be billed and submitted on a patient's insurance claim.
   e. When reflex tests are offered, a non-reflex version must also be easily available as well as the components.

10. Panels Billed to the Medicare and Medicaid Programs
    a. The clinical laboratory only bills the Medicare or Medicaid programs for panels approved by CMS and only when all tests within the ordered panels are actually performed and all components are medically necessary. Claims Medicare Processing Manual, 90.2 Organ or Disease Oriented Panels
    b. CMS Medicare or Medicaid approved panels

• Basic metabolic panel (Calcium, ionized) • Basic metabolic panel (Calcium, total) • Electrolyte panel • Comprehensive metabolic panel • Renal function panel	• Lipid panel • Hepatic panel • Obstetric panel (includes HIV testing) • Acute Hepatitis Panel

c. The clinical laboratory only bills for these same approved panels when the ordering physician/practitioner actually orders them. The clinical laboratory may not, through policy or medical staff approval or instrument reported testing abnormalities, automatically order and bill tests that the ordering physician/practitioner did not actually order (i.e., CBC with automated differential versus CBC, urinalysis versus urinalysis with microscopic).

1) Abnormal CBC results may not cause a CBC with differential to be ordered and billed.
2) The automated differential may be performed and reported as a quality check but not billed.

d. If all components of an approved panel cannot be performed due to the condition of the specimen (i.e., hemolyzed), the panel may not be billed. Only those components actually analyzed and reported may be billed.

11. Custom Panels Billed to the Medicare and Medicaid Programs
    a. Custom panels are discouraged.
    b. If a custom panel is requested by an ordering physician/practitioner, the clinical laboratory will have a process in place that documents the physician's/practitioner's requests, issues a written physician/practitioner acknowledgment annually and will be limited in use to only the ordering physicians/practitioners who actually signs an acknowledgment. Custom Panels pg. 45079 B Notices
    c. The clinical laboratory must make certain that the ordering physician/practitioner knows what tests are included in the custom panel and the coding submitted for billing. The physician/ practitioner must be made aware to order panels only when all of the tests are medically necessary for the current patient encounter.
    d. All tests included in the custom panel will be easily available to order as individual tests.

12. Date of Service (DOS)
    a. The general rule for the date of service is the date the specimen was collected.
    b. Variation for a specimen collected over a period that spans two calendar days, the DOS must be the date the collection ended.

13. Pathology Test Ordering Exception:
    After performing an initial exam or interpretation of a specimen, there may be additional tests, such as special stains, that a pathologist needs to perform, even though they have not been specifically requested by the treating practitioner.

    The pathologist may perform the additional test without a separate order from the treating practitioner as long as: (a) the services are medically necessary so that a complete and accurate diagnosis can be reported to the treating practitioner; (b) the results are communicated to and are used by the treating practitioner in the treatment of the beneficiary; and, (c) the pathologist documents in his/her report why additional testing was done. Benefit Policy Manual, Ch. 15, § 80.6.5.[8]

[8] On its face, this exception for pathology applies to non-hospital services. There is a reasonable argument to extend the exception to hospital services because: (a) there is no policy reason to differentiate between settings in applying the exception; and (b) the example offered in the Manual provision appears to relate to hospital services. It is still best practice for the hospital to document the pathologist's order(s) for follow-up testing in the medical record to satisfy the hospital Conditions of Participation (42 C.F.R. § 482.24).

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Appendix J

Clinical Laboratory Orders/Ordering Procedure

Three exceptions for the DOS of clinical laboratory specimens:

1) DOS for Tests/Services Performed on Stored/Archived Specimens:

If the specimen was stored for less than or equal to 30 calendar days from the date it was collected, the DOS of the test/service must be the date the test/service was performed only if:

a) The test/service is ordered by the patient's physician/practitioner at least 14 days following the date of the patient's discharge from the hospital;
b) The specimen was collected while the patient was undergoing a hospital surgical procedure;
c) It would be medically inappropriate to have collected the sample other than during the hospital procedure for with the patient was admitted;
d) The results of the test/service do not guide treatment provided during the hospital stay; and
e) The test/service was reasonable and medically necessary for treatment of an illness.

If the specimen was stored for more than 30 calendar days before testing, the specimen is considered to have been archived and the DOS of the test/service must be the date the specimen was obtained from storage.

2) DOS for Chemotherapy Sensitivity Tests/Services[9] Performed on Live Tissue:

In the case of a chemotherapy sensitivity test/service performed on live tissue, the DOS of the test/service must be the date the test/service was performed only if:

a) The decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge;
b) The specimen was collected while the patient was undergoing a hospital surgical procedure;
c) It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
d) The results of the test/service do not guide treatment provided during the hospital stay; and
e) The test/service was reasonable and medically necessary for treatment of an illness.

If the specimen was stored for more than 30 calendar days before testing, the specimen is considered to have been archived and the DOS of the test/service must be the date the specimen was obtained from storage.

3) For only outpatient tests granted Advanced Diagnostic Laboratory Test (ADLT) status by CMS and all molecular pathology tests which are excluded from the Outpatient Prospective Payment System (OPPS) packaging policy, only the performing laboratory will be able to bill and be paid by Medicare directly for these tests under the circumstances described below. In the case of a molecular pathology test or a test

[9] A "chemotherapy sensitivity test" is defined as a test that requires a fresh tissue sample to test the sensitivity of tumor cells to various chemotherapeutic agents.

designated by CMS as an ADLT under paragraph (1) of the definition of advanced diagnostic laboratory test in 42 CFR 414.502, the DOS of the test must be the date the test was performed only if—

a) The test was performed following a hospital outpatient's discharge from the hospital outpatient department;
b) The specimen was collected from a hospital outpatient during an encounter (as both are defined in 42 CFR 410.2);
c) It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;
d) The results of the test do not guide treatment provided during the hospital outpatient encounter; and
e) The test was reasonable and medically necessary for the treatment of an illness. **Effective January 1, 2020,** Molecular pathology testing performed by blood banks/blood centers on specimens collected from a hospital outpatient during a hospital outpatient encounter is the **date of specimen collection** (unless another exception to the DOS policy applies, such as the archived specimen exception). As a result, the hospital must bill for the molecular pathology test under arrangements and the blood bank/blood center performing the test should seek payment from the hospital.

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Appendix K

Clinical Laboratory Result Report Procedure

A hospital's patient medical record contains laboratory results generated from its own onsite laboratory and for more esoteric tests not be performed internally, a specimen would be sent for analysis by laboratory staff to a reference laboratory which had been approved by the hospital laboratory medical director. With the proliferation of non-hospital laboratory controlled diagnostic patient testing, there is an increased desire for continuity of care purposes for providers to make those "non-hospital controlled outside laboratory results" available to treating physicians in the hospital Medical Record - Electronic or Otherwise (MR). If those results are included in the hospital MR, there are requirements mandated by licensing and accrediting agencies that must be followed in order to meet current regulations and requirements.

Reference Outside and Internal Laboratory Results

Current Medicare (CLIA) and accrediting agency regulations require that the laboratory medical director evaluate, provide input, and document the quality of any outside laboratory whose results are entered into a hospital MR and ensure that the data entered meets regulatory documentation requirements. The laboratory must maintain documentation of the laboratory's medical director's evaluation/approval to transcribing/scanning outside test results. When approved, include **Appendix K, Clinical Laboratory Result Reporting, Outside Results,** to the Laboratory's Result Reporting policy/procedure to document the laboratory's medical director's evaluation/approval of reporting outside results.

Outside laboratory results must be readily observable (e.g. documented directly on the lab result document) to the authorized person viewing such results that they originated from an outside laboratory.

The location in the MR for these non-hospital controlled outside laboratory results is up to the discretion of the hospital leadership and its medical staff. Some hospitals consolidate these types of results in an isolated section/location of the MR "Outside of the Laboratory result reporting location" or include these results in the "Laboratory" section of the MR. If the results are integrated in the "Laboratory" section/location of the MR, the name and address of the outside laboratory must be available in the primary reporting location. Departments requesting transcribing/scanning of outside laboratory results should contact their local Information Technology (IT) and laboratory leadership.

The following information must be included and considered for any laboratory test result entered/scanned in the MR:

1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number.
2) The name and address of the laboratory location where the test was performed.
3) The test report date.
4) The test performed.
5) Specimen source, when appropriate.
6) The test result and, if applicable, the units of measurement or interpretation, or both.
7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.
8) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the testing results.

9) If results are manually transcribed into the MR, there must be procedure established by the laboratory medical director and documentation of an ongoing process that validates the accuracy of the transcription of the 8 items specified above. Note: Manual transcription is the least desirable mode of entering “outside results” into an MR due to a high probability of transcriptional error.

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Clinical Laboratory Result Report Procedure

The laboratory medical director approves the process of reporting outside test results through the institution's electronic medical record in a section of the medical record outside of the laboratory's primary reporting system. The laboratory's primary reporting system (LIS) is **[ENTER THE NAME OF THE ENTITY'S LIS HERE].**

Outside test results brought by patients will be transcribed and scanned into the electronic medical record in the patient data entry fields. This location in the medical record is outside of the laboratory's primary reporting location, therefore the physician/caregiver viewing the results can clearly identify that the results originated from an outside laboratory/source. The original laboratory test report with the name and address of the outside laboratory will be scanned and available to view by the physician/caregiver.

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Appendix L

Clinical Laboratory Medical Necessity Procedure

Medical necessity validation is applicable to all payers when determining test ordering process and payment. Third party payers may have policies pertaining to the appropriateness for a physician/practitioner to order clinical laboratory testing on his/her patients. CMS and the OIG recognize that physicians and other authorized individuals must be able to order any test(s) that they believe are appropriate for the treatment or diagnosis of their patients. However, claims submitted for tests or services will only be paid if CMS has determined that the service is covered, reasonable, and necessary for an individual patient given his/her clinical condition. Medicare does not generally pay for tests for screening except in limited cases when allowed by law. In addition:

1. The ordering physician/practitioner is required to provide an ICD code or specific narrative description that supports the medical necessity for each test ordered.

2. When the Medicare patient is present, responsible entity staff will obtain and execute an ABN using an entity defined process when it is reasonably anticipated that Medicare will not cover the requested test or there is a frequency limit on a test.

3. When the Medicare patient is not present there are options for delivery other than face to face. ABNs should be delivered in-person and prior to the delivery of medical care which is presumed to be noncovered. In circumstances when in-person delivery is not possible, notifiers may deliver an ABN through one of the following means:

- Direct telephone contact
- Mail
- Secure fax machine or
- Internet e-mail

All methods of delivery require adherence to all statutory privacy requirements under HIPAA. The notifier must receive a response from the beneficiary or his/her representative in order to validate delivery.

When delivery is not in-person, the notifier must verify that contact was made in his/her records. In order to be considered effective, the beneficiary should not dispute such contact. Telephone contacts must be followed immediately by either a hand-delivered, mailed, emailed, or faxed notice. The beneficiary or representative must sign and retain the notice and send a copy of this signed notice to the notifier for retention in the patient's record. The notifier must keep a copy of the unsigned notice on file while awaiting receipt of the signed notice. If the beneficiary does not return a signed copy, the notifier must document the initial contact and subsequent attempts to obtain a signature in appropriate records or on the notice itself.

4. Physician/practitioner provided diagnosis codes are evaluated for Medicare purposes using the entity defined ABN tool in the most current ABN format as described in http://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html, refer to Section 50 of the document).

5. "Blanket" ABNs are not permitted. An ABN for Medicare purposes may only be obtained when it is reasonably anticipated that CMS will deny payment, or when there is a frequency limitation on the testing requested. To do otherwise would be considered obtaining a "Blanket" ABN.

6. Medicare patient test orders will be evaluated in relation to Medicare National or Local Coverage Determinations (NCD/LCD) and for certain clinical laboratory tests that are not FDA approved or are experimental. An ABN will be completed according to Medicare ABN policy when one of these test types is ordered.

7. If the patient is not present and the diagnosis code provided fails the medical necessity check or is unclear, clarification must come from the physician/practitioner, not through chart review. (See Appendix J - Orders/Ordering Procedure, Ambiguous Order or Unclear Orders.)

8. When a specimen is collected by entity personnel and accompanying orders and/or paperwork is missing diagnosis information, the physician/practitioner will be contacted to clarify diagnosis information, but no ABN for Medicare patients will be obtained. (See Appendix J - Orders/Ordering Procedure, Ambiguous Order or Unclear Orders.)

9. Medicare patients will be screened for Medicare Secondary Payer (MSP) at each face-to-face episode of service. This requirement may be different for non-acute care or provider-based physician practices.

10. All panels (organ and disease or custom) will be billed and paid only when all components are medically necessary.

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Appendix M

Clinical Laboratory Coding and Validating ICD Coding Procedure

Coding and Validating ICD Coding

CMS and third-party payers require that physicians/practitioners ordering diagnostic tests provide diagnostic information to document medical necessity at the time of order. Failure to document medical necessity may result in improper billing and/or cause the test to be denied coverage.

An ICD code will be assigned either by the ordering physician/practitioner (or their designee) or based solely on information (narrative diagnosis) provided by the ordering physician/practitioner by entity personnel.

Medicare regulations require a test be reasonable and necessary for the treatment or diagnosis of a beneficiary in order to be paid. Medicare does not generally pay for tests for screening except in limited cases when allowed by law. Medical necessity is determined based on Medicare, Medicaid or payer published coverage policies or regulations and communicated through the diagnosis information or ICD codes provided by a patient's treating, consulting or interpreting physician/practitioner on the claim.

Other medical necessity issues include:

1. Each test ordered clearly communicates the physician's/practitioner's intent to order that test including standing orders, reflex tests, and panel and profile tests.

2. All billed tests are ordered by a patient's treating physician/practitioner and, in the case of an interpreting physician/practitioner, only when allowed by regulation.

3. The number or kind of test(s) ordered is not altered by the clinical laboratory without first contacting the treating physician/practitioner or healthcare practitioners. (See Appendix J - Orders/Ordering Procedure, Ambiguous Order or Unclear Orders.)

4. Diagnosis codes included on claims and how they are derived or obtained.

5. The proper use of ABNs.

6. Documentation in the patient's medical record that supports the information provided on a claim.

Laboratories are prohibited from using ICD codes or the interpretation of a written diagnosis to an ICD ode on claims that are not provided by a treating, interpreting or consulting physician/practitioner. CommonSpirit Health entity staff is prohibited from altering a provided ICD code or written diagnosis in any way without first contacting the treating physician/practitioner who provided the code or diagnosis. If the treating physician/practitioner supplies narrative diagnosis information, the CommonSpirit Health entity staff may translate that information as long as the narrative is sufficient to properly code and the employees doing the translation are properly trained and have the necessary tools to perform the work.

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Clinical Laboratory Coding and Validating ICD Coding Procedure

Requirements for proper ICD coding include:

1. Only the current code or diagnostic information submitted by the ordering physician/practitioner and documented in the patient's medical record may be used. A code from an earlier date of service or previous order (except for standing orders) may not be used.

2. Software that allows the clinical laboratory to automatically insert a diagnosis code without input from the ordering physician/practitioner will not be utilized.

3. "Cheat sheets" which identify codes that have triggered reimbursement in the past will not be utilized.

4. Making up diagnostic information or codes for claims submission purposes is never allowed.

5. The patient may not be asked for the reason for the testing.

6. Activities intended to direct or suggest to the ordering physician/practitioner which code(s) should be used are not allowed.

7. For Medicare claims with an NCD or LCD, if an ordering physician/practitioner or his/her staff fails to provide the diagnosis code or narrative, CommonSpirit Health entity clinical laboratory staff will contact them for that information. The clarifying information received from the ordering Physician/practitioner or his/her staff must be documented. (See Appendix J - Orders/Ordering Procedure, Ambiguous Order or Unclear Orders.)

It is possible for diagnostic information to be submitted by the ordering physician/practitioner through the use of ICD codes or through narrative description. ICD codes are preferred and ordering physicians/practitioners will be encouraged to use these codes when ordering tests. However, in the event that a narrative description has been supplied, coders must exercise special care when translating the narrative into the proper ICD code. If there is any ambiguity or question about the proper code, the coder must not make a guess, but rather the ordering physician/practitioner must be contacted in order to verify the diagnosis. The person obtaining the verification must note this verification alongside the original narrative description. (See Appendix J - Orders/Ordering Procedure, Ambiguous Order or Unclear Orders.)

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Appendix N

Clinical Laboratory Billing Procedure

CommonSpirit Health staff must make every effort to submit accurate claims to all payers including Medicare, Medicaid, other government and third-party payers for the services provided. Staff are trained in the requirements of those payers, both government and private, and are provided the resources, tools and equipment necessary to meet the requirements of this procedure. The Clinical Laboratory Improvement Amendment (CLIA) mandates that virtually all laboratories, including physician office laboratories (POLs), meet applicable federal requirements and have a CLIA certificate in order to receive reimbursement from a federal program. Clinical laboratory compliance procedures ensure that all claims for testing services performed are submitted to Medicare, other federal health care programs and third-party payers correctly and identify the services ordered (See Appendix L) by the physician/practitioner and performed by the clinical laboratory. The CommonSpirit Health standard for laboratory billing is to bill for services provided on test completion and result reporting. This method reduces the risk of billing for tests that have not been completed and therefore are not eligible for payment. If the laboratory chooses not to bill on completion, a monitoring program must be developed to ensure no incomplete or test not performed is billed in error. The results of this monitor will be reported to the entity Corporate Responsibility Officer annually.

CommonSpirit Health staff must ensure that the ICD code or narrative diagnosis provided by the ordering physician/practitioner is used to bill for the service (See Appendix H). CommonSpirit Health clinical laboratory staff must ensure the Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) code used on the claim accurately describes the service that was ordered and performed and documents the medical necessity reason for testing. Laboratories cannot alter the physician's/practitioner's order in any way by either increasing or decreasing the number of services performed without the express consent of the ordering physician/practitioner or other authorized individual. (See Appendix J) Intentional or knowingly upcoding (i.e., the selection of a code to maximize reimbursement when such code is not the most appropriate descriptor of the service) could violate the False Claims Act and/or other civil laws, and criminal law. These codes should be reviewed and verified at least annually or anytime a significant change occurs such as when introducing a new computer billing system or a new billing service (outsource) for the clinical laboratory.

Any specimen received without a valid test order or with a test order which is ambiguous, CommonSpirit Health clinical laboratory staff must verify the test(s) the physician's/practitioner's patient requires before submitting a claim for reimbursement to Medicare or other payers. In this way, if the ordering physician/practitioner or other authorized individual did not order the test, the clinical laboratory will not erroneously bill for it.

Billing for Incomplete or Duplicate Testing

If an ordered test was not performed due to, for example, a clinical laboratory accident, insufficient quantities of specimen or the ordered test was duplicated when a second provider ordered the same test on the same date of service and the second test was not performed but the original result reported to both providers, the clinical laboratory may not submit a claim for non-performed tests or duplicate claim to Medicare or other payers.

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If an approved panel i.e. Basic metabolic Profile (BMP), Comprehensive Metabolic Profile (CMP) is ordered and all components of that panel cannot be completed due to lipemia, hemolysis or some other reason, only of the individual components of the panel which were actually performed may be billed to the payer.

Billing for Noncovered Clinical Laboratory Tests

Ordinarily, a clinical laboratory will not bill the Medicare program for noncovered tests. However, if the beneficiary, or his/her representative, contends that a clinical laboratory test that a physician/practitioner or clinical laboratory believes is noncovered may be covered, the clinical laboratory must file a claim that includes the test to effectuate the beneficiary's right to a Medicare determination. The clinical laboratory annotates the specific claim that they believe is noncovered and are submitting it at the beneficiary's insistence through the use of "modifiers" appended to the CPT or HCPCS code on the claim. Before furnishing a beneficiary a test which the clinical laboratory believes is excluded from coverage as not reasonable and necessary (rather than excluded from coverage as part of a routine physical check-up), the clinical laboratory must obtain a signed ABN from the beneficiary, or his/her representative, which states the clinical laboratory has informed the beneficiary of the noncovered service and that there will be a charge for the test. This protects the clinical laboratory against possible liability for the test under the Limitation of Liability provision.

Billing of Calculations

Consistent with Medicare and other third-party payers' coverage rules, the clinical laboratory does not bill either for calculations (e.g., calculated LDLs, T7s, and indices). Billing may only occur for the tests that are performed to derive such calculations. In many situations, physicians/practitioners are not offered a choice about whether to receive such calculations. The fact that a separate CPT code exists does not mean that Medicare separately reimburses for the service assigned to the code. Billing both for the calculations and the underlying tests constitutes double billing, which may subject a clinical laboratory to sanctions and other remedies available under civil, criminal, and administrative law.

Reflex Testing

Reflex testing occurs when initial test results are positive or outside normal parameters and indicate that a second related test is medically indicated, and, the ordering physician/practitioner requests that the reflex test should be performed. In order to avoid performing unnecessary reflex tests, clinical laboratory staff will design their requisition form in such a way which would only allow for the reflex test when necessary and when requested by the ordering physician/practitioner or other authorized individual. The criteria for the execution of the reflex test will be clearly listed on the clinical laboratory requisition or by other ordering method (e.g., electronic orders) and be readily available to the ordering physician/practitioner. The ordering physician/practitioner will have the option to order a non-reflex version of the test as readily available as the reflex version. In this way, the physician or other authorized individual has a choice of ordering either the reflex or non-reflex version of the test.

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Clinical Laboratory Billing Procedure

Confirmation Testing

There are circumstances when results of a test ordered by an authorized physician/practitioner may not be reported without follow-up (confirmation) testing as required by state or federal law or by the test manufacturer (i.e. positive HIV screening may not be reported unless a confirmation test is performed). It is appropriate under these circumstances to add and bill for the additional testing without a specific additional order. The requisition or electronic order and the clinical laboratory user guide, should inform the ordering physician/practitioner that the additional testing will be performed and additional charges may be incurred and billed by the clinical laboratory.

Urine Drug Testing

- A maximum of one presumptive urine drug test may be submitted and paid per patient date of sample collection (DOS)
- A maximum of one definitive urine drug test may be submitted and paid per patient date of sample collection (DOS) (not the date the test was run)
- Presumptive drug testing is reported with approved and current CPT codes, with only one code from the range being reported per date of service.
- Definitive drug testing be reported with approved and current HCPCS codes, with only one code from the group of codes being reported per date of service (Refer to National Correct Coding Initiative Policy Manual for Medicare Services Ch. 10 for current codes)
- The laboratory may not bill separately for validity testing on urine specimens used for drug testing (for example, if a laboratory performs a urinary pH, specific gravity, creatinine, nitrates, oxidants, or other tests to confirm that a urine specimen is not adulterated, this testing is not separately billed)
- Blanket orders cannot be used for urine drug testing
- The laboratory cannot reflex a test order for definitive urine drug testing (UDT) when presumptive testing is performed at the point of care
- Routine standing orders for urine drug testing for all patients in a physician's practice cannot be used.
- The laboratory may not perform presumptive point of care testing (POCT) and order a presumptive immunoassay (IA) test from a reference laboratory
- IA testing cannot be performed for the purposes of confirming or definitively identifying a presumptive test result obtained by cups, dipsticks, cards, cassettes or other IA testing methods
- Drug testing cannot be performed on two different specimen types from the same patient on the same date of service for the same drugs/metabolites/analytes
- Urine drug testing may not be performed for medico-legal and/or employment purposes or to protect a physician from drug diversion charges

Specimen Collection

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Clinical Laboratory Billing Procedure

A clinical laboratory may bill a specimen collection fee once per episode of care[10] for federally funded payers for specimen collection in an outpatient setting (e.g., nursing homes, patient homes, independent living facilities, assisted living facilities, hospital outpatients and non-patients[11]) when appropriate and when allowed by state or federal law or regulations and only when an employee of the entity has actually performed the service. Hospital inpatients and some hospital outpatient types may be billed as well however payment will be received as part of a negotiated/legislative bundled reimbursement. Denied inpatient stays or observation patients may only be billed one specimen collection fee per twenty-four-hour period.

Travel Fees

Travel fees may be billed only for outpatient and non-patients, homebound patients (as defined by Medicare) and nursing home patients only when a blood draw is also performed on the patient. Per any local or regional payer policy (see separate entity procedure), the clinical laboratory must keep appropriate documentation of such things as the distance traveled, the number of facilities visited and the number of patients visited to support the claim.

DRG Payment Window (Medicare 3 Day Rule/72 Hour Rule)

The 72 Hour Rule or 3 Day Rule activates for a Medicare beneficiary when a clinical laboratory that is wholly owned or operated by a hospital performs clinical laboratory testing within 3 days prior to the beneficiary's admission to that hospital. Such services are generally deemed to be inpatient services. All charges subject to the 72 Hour Rule for the outpatient services are to be rolled into the inpatient payment from the Medicare Program and not billed as an outpatient charge. This includes laboratories within CommonSpirit Health owned physician practices are subject to the 72 Hour Rule requirements.

Skilled Nursing Facilities (SNF) Billing

The cost for skilled nursing care clinical laboratory testing is either included into the bundled payment (consolidated billing) made to the SNF by the Medicare program or separately billable directly to Medicare by the clinical laboratory, depending on the patient's "status" in the SNF. A SNF patient may have a status of Part A (skilled level care) or Part B (custodial level care). The clinical laboratory must bill the SNF for services rendered for their patients who have a status of Part A Medicare coverage (covered as an inpatient service) under a negotiated service agreement between the parties. For SNF patients with a Part B status, either party may bill for the service. Whomever is assigned the responsibility for billing will be

[10] An episode of care begins when a patient arrives at a facility for treatment and terminates when the patient leaves the facility.

[11] Non-Patient -Medicare Claims Processing Manual Chapter 16 - Laboratory Services: For all hospitals (including CAHs) except Maryland waiver hospitals, if a patient receives hospital outpatient services on the same day as a specimen collection and laboratory test, then the patient is considered to be a registered hospital outpatient and cannot be considered to be a non-patient on that day for purposes of the specimen collection and laboratory test. However if any hospital other than a CAH or a Maryland waiver hospital only collects or draws a specimen from the patient and the patient does not also receive hospital outpatient services on that day, the hospital may choose to register the patient as an outpatient for the specimen collection or bill for these services as non- patient on the 14x bill type.

defined in the Part A service agreement or as part of a separate service agreement. Only one entity may bill for the Part B service. Normally the Medicare program makes payments under Part B for clinical laboratory tests only to the entity that performed the test. However, current law permits SNFs to submit a Part B claim to the Medicare payer for clinical laboratory tests that it makes arrangements for another entity to perform for their nonskilled patients on the SNF's behalf. Section1833(h)(5) of the Act (as enacted by The Deficit Reduction Act of 1984, P.L. 98-369) requires the establishment of a fee schedule for clinical laboratory tests paid under Part B and also requires that, with certain exceptions, only the entity that performed the test may be paid. The fee schedule applies to all SNF clinical laboratory services.

Prices Charged to Physicians/Practitioners

Laboratories are paid for their services by a variety of payers in addition to Medicare and other federal and state health care programs. Such payers often include private health insurers, other health care physicians/practitioners, private pay patients and physicians. It is essential that the physician/practitioner take into account the patient's best interest when deciding where to refer the patient's specimen. The prices that the clinical laboratory charges physicians/practitioners for clinical laboratory services are at fair market value. This procedure ensures the clinical laboratory is not providing any inducements to gain a physician's Medicare, Medicaid or any other government funded business by charging the physician/practitioner a price below fair market value for his/her non-federal health care program tests in exchange for government funded tests. Laboratories that charge physicians/practitioners a price below fair market value to induce them to refer their federal health care program business may be risking anti-kickback enforcement and false claims actions.

End Stage Renal Disease (ESRD) Related Clinical Laboratory Tests

With the implementation of the ESRD Prospective Payment System (PPS), effective for claims with dates of service on or after January 1, 2011, all ESRD-related clinical laboratory services are included in the ESRD PPS base rate and must be reported and billed by the ESRD facility and are not separately paid. The list of terms and services subject to consolidated billing located at http://www.cms.gov/ESRD, includes the list of ESRD-related clinical laboratory tests that are routinely performed for the treatment of ESRD. Clinical laboratory services that are not related to the treatment of ESRD are separately billable under the ESRD PPS and may be billed by either the ESRD facility or the contracted clinical laboratory. If the ESRD facility or another clinical laboratory bills a clinical laboratory service that was not related to the treatment of ESRD, the bill must include the modifier AY. The AY modifier serves as an attestation that the item or service is medically necessary for the dialysis patient but is not being used for the treatment of ESRD.

Billing and Coding Errors

In the event a laboratory test billing or HCPC or CPT coding error is discovered, it is imperative that the entity CRO be contacted immediately to evaluate next steps if needed. Repayment documentation should be documented in CommonSpirit Health's Issue and Action Management (IAM) System.

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Appendix O

Marketing, Sales and Business Development of Laboratory Services Procedure, Improper Inducements, Kickback and Self-Referrals

Clinical laboratory staff will practice non-deceptive marketing and sales techniques and comply with CommonSpirit Health's Standards of Conduct for marketing practices. All marketing and sales materials in electronic or printed form will be reviewed and approved by the medical, technical and compliance staff/entity's marketing department's to ensure the testing performed and the claims for the performance of these tests and procedures are accurately presented. It is necessary that the services offered by the clinical laboratory and the financial consequences for payers when tests are billed be fully understood by those who authorize testing.

Pricing and sales proposals will be reviewed and approved by appropriate clinical laboratory and entity leadership. Document language will be approved by the entity CRO, marketing leadership, and/or legal counsel. A pricing/discount strategy should be developed and final pricing approval by appropriate entity leadership before offers are made to any client.

The clinical laboratory and/or entity should consider and determine if any of the following possible regulatory state dependent scenarios apply to their entity before developing a pricing schedule:

1. **Direct Bill State:** The state has a specific law that requires the payment for clinical laboratory services be made only to the person or entity by which the service was performed, except for referrals independent of a physician's/practitioner's office.

2. **Anti-Markup State:** The state has a specific law that prohibits a physician/practitioner or other entity from marking up the cost of a clinical laboratory test or service to a patient or client.

3. **Full Disclosure State:** The state has a specific law that requires a physician/practitioner to disclose or publish the charge of each procedure or test to the patient, the patient's insurer, or other purchaser of service.

4. **Medicaid Best Price:** A situation where a state mandate requires that the Medicaid program receives the best pricing (e.g., comparable discount) for clinical laboratory testing or services as compared to all other clients.

Free Supplies and Equipment

The clinical laboratory may supply its referral sources at no charge with only the supplies needed for the sole purpose of collecting, processing, storing, and shipping specimens for the clinical laboratory. (See also the following exclusions)

Supplies

1. Should be sufficient for the volume and approximate types of testing sent to the clinical laboratory
2. Can only be used by the recipient for testing sent to the clinical laboratory.
3. Should be placed where it can be assured they will be used only for the purpose of the clinical laboratory.

4. Protective gloves may not be supplied by the providing clinical laboratory.
5. The clinical laboratory will have a method incorporated into its risk assessment for tracking supplies furnished to referral sources to ensure that said supplies are provided in quantities that are appropriate.

Computers, Printers, Faxes and Interfaces

The clinical laboratory may place computers, printers and/or fax machines in a referral source as long as the clinical laboratory and/or entity policy and procedure for placement is followed and required written agreements are approved by entity leadership and executed prior to placement.

1. Can only be used for the providing clinical laboratory's purposes.

2. No additional software may be loaded on clinical laboratory owned computers beyond what the clinical laboratory representative provides. This prohibitive language will also be included in any contractual agreements.

3. The clinical laboratory will monitor computers and interface contracts periodically or as required by the entity policy.

4. Computers, printers and fax machines will be clearly labeled with the clinical laboratory's or entity's name to indicate ownership.

Relationships with Referral Sources (Excerpted from CRP policies listed below) Included in this Appendix is information and guidance that is most common or applicable to laboratory concerns as it relates to Improper Inducements, Kickbacks and Self referrals. Additional CommonSpirit Health CRP and Legal Services Group policies, federal and state laws and guidance may be applicable to this area as well and can be accessed on Inside CommonSpirit Health where National policies and resources are maintained, within the CRP and Legal Services Group knowledge communities or consulting appropriate CommonSpirit Health CRP and Legal National staff. Clinical laboratory relationships with referral sources can be complicated and are an area of high risk. These relationships are governed by the Federal Anti-kickback Statute, Physician Self-Referral laws (Stark) and applicable state laws. Special education in this area is required for any clinical laboratory employee dealing in these relationships. These relationships must comply with CRP Standards of Conduct. (Refer to CommonSpirit Health's Conflicts of Interest, Gifts and Gratuities)

1. The payment of a kickback or bribe (cash or in-kind) is prohibited in exchange for referrals from physician/practitioner or other referring entity.
2. Unless an exception under the Stark Law or applicable regulation has been met, the clinical laboratory may not accept or file a claim for referrals from a physician/practitioner that has an ownership interest or a compensation agreement with the clinical laboratory.

An analysis in reference to 1 and 2 above must be conducted by CommonSpirit Health Legal in coordination with the clinical laboratory compliance officer and entity CRO.

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Appendix O

Marketing, Sales and Business Development of Laboratory Services Procedure, Improper Inducements, Kickback and Self-Referrals

Clinical laboratory staff is prohibited from providing the following services without the prior approval of the Clinical Laboratory Compliance Officer and appropriate facility leadership:

1. Offering, soliciting or giving any kind of compensation.
2. Entering into any contractual or legal agreement.
3. Performing services free of charge for referrals or potential referrals is never acceptable.
4. Services may be supplied for charitable events (e.g., health fairs, golf tournaments) as long as a specific physician/practitioner does not benefit and such services are in compliance with CRP Standards of Conduct.

Lease or Rental of Entity Space

1. Usually for the purpose of providing phlebotomy services.

2. If the space is owned by physicians or another entity that is a potential referral source or is in the position to control referrals, the entity leadership and entity CRO must make certain the appropriate criteria of an Anti-kickback safe harbor and the Stark exception(s) are met and that there are no other state or local laws prohibiting such an arrangement.

3. An arrangement with a physician must include a written agreement. (Refer to CRP, Standards of Conduct, Physician Arrangements)

a. CRP, Standards of Conduct, Physician Arrangements is followed
b. The payment is at fair market value (FMV)
c. There is no adjustment in the value or volume of referrals occurred
d. The agreement is commercially reasonable

Phlebotomy Services

1. May be supplied by the clinical laboratory to the referral source at no charge.

2. When allowed by state or local laws, the services of the clinical laboratory's phlebotomists may be used only for the collection and processing of specimens to be tested at the clinical laboratory.

Courier Services

1. May be supplied by the clinical laboratory to the referral source at no charge only if:
   a. These services are used for the transportation of specimens to the clinical laboratory, and for transportation of supplies and clinical laboratory related information to the referral source
   b. The use of the clinical laboratory's courier services for other purposes must be at FMV and specified in an agreement or contract reviewed by the entity CRO and appropriate entity leadership

Appendix O

Marketing, Sales and Business Development of Laboratory Services Procedure, Improper Inducements, Kickback and Self-Referrals

Non-Monetary Compensation (Physician Self-Referral [Stark] Exception)

Corporate Responsibility Standards of Conduct, Physician Self-Referral Law (Stark Law) addresses non-monetary compensation to physicians who are not employed by a CommonSpirit Health entity. Upon approval, clinical laboratory staff or agents may provide non-monetary compensation in the form of gifts or entertainment (not including cash or cash equivalents which are never allowed) to any physician who is not employed by a CommonSpirit Health entity. Any qualifying physician who currently or who could potentially refer testing and receive non-monetary compensation shall be appropriately monitored and tracked in accordance with the Standards of Conduct. Such information will be made available in a timely manner by clinical laboratory staff where appropriate, to the entity employee who is in the position to authorize and monitor the provision of nonmonetary compensation.

Applicability

This procedure is applicable to non-CommonSpirit Health physicians who are authorized to order tests from a CommonSpirit Health clinical laboratory.

If the clinical laboratory is not a department of the hospital, this procedure only applies to nonmonetary compensation provided by the clinical laboratory to non-CommonSpirit Health referral sources.

If the clinical laboratory is a department of the hospital, any non-monetary compensation provided by the clinical laboratory must be included with nonmonetary compensation provided to that individual physician by any other department of the hospital. In the latter case, the hospital cannot exceed the limit set forth by CMS for all departments that provide nonmonetary compensation.

Examples of what this procedure and/or CRP Standards of Conduct covers include such things as food (breakfast or lunch) provided to the physician's office, a fruit basket provided to the office, doughnuts, tickets to sporting events, lunch or dinner at a restaurant and other similar items.

Remedies for Inadvertent Violations

If a violation is discovered, the entity CRO must be notified.

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Appendix P

Clinical Laboratory Research Procedure

The CRP Research Addendum establishes standards for all research conducted by CommonSpirit Health and ensures that all CommonSpirit Health entities comply with federal, state and local regulations with regard to research. "Conducting CommonSpirit Health research" means using CommonSpirit Health data for research; conducting research at a CommonSpirit Health facility; conducting research with a CommonSpirit Health patient; and/or conducting research with animals owned by CommonSpirit Health. The role and responsibilities of CommonSpirit Health laboratories regarding clinical research is to ensure that all officers, managers, associates, trainees and others working in, or conducting clinical research on behalf of CommonSpirit Health shall be trained in the requirements of the CRP Research Addendum and adhere to applicable the research policies and procedures.

Research is managed through CommonSpirit Health Research Institutes and at academic medical centers. All CommonSpirit workforce members and facilities conducting research shall submit research proposals through their respective research institute/center for administrative approval (including Institutional Review Board approval) pursuant to applicable policies. Before disclosing laboratory data or specimens for research purposes, validate the recipient has received required approval. Contact your respective Research Institute or Academic Medical Center research center for further information.

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Appendix Q

Application for Laboratory Licensure (CLIA) License

In order to mediate and reduce risk of laboratory regulatory violations for all CommonSpirit Health facilities and CommonSpirit Health laboratories, all initial applications for moderate or high complexity laboratory licensure are to be submitted for review by the CommonSpirit Health System Director of Laboratory Compliance before being forwarded to a state or federal agency for application consideration. These licensure requests are generally submitted to the local Department of Health on form CMS-116 for non-exempt states. (For exempt states, state specific forms are normally utilized.) In either event, the appropriate form is to be submitted electronically for review by the CommonSpirit Health System Director of Laboratory Compliance prior to making licensure application.

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Appendix R

Non-Routine Information Requests or Communications from Governmental or Regulatory Agencies

All non-routine information requests from any governmental agency or entities issuing either a laboratory Certificate of Waiver, Certificate of Provider Performed Microscopy, Certificate of Compliance or Certificate of Accreditation are to be reviewed by the CommonSpirit Health Director of Laboratory Compliance and Entity Corporate Responsibility Officer before proceeding with a response. Non- routine requests are those not part of a normal survey cycle request or annual information requirement (i.e., annual billable test volumes, proficiency testing ordering clarification or any information request which would be considered normal in the course of maintaining licensure). All adverse action/sanction notifications from any governmental agency or entity issuing either a laboratory Certificate of Waiver, Certificate of Provider Performed Microscopy, Certificate of Compliance or Certificate of Accreditation are to be reviewed by the CommonSpirit Health Director of Laboratory Compliance and Local Corporate Responsibility Officer before proceeding with a response, including phone/email contact with the governmental agency or entity. These types of non-routine information requests or communications from governmental or regulatory agencies would include, but are not limited to:

- Contingent certification of accreditation/certification
- Accreditation/certification with a mandatory follow-up onsite review
- Preliminary denial of accreditation/certification
- Denial/revocation of accreditation or CLIA certificate
- Citation status at the condition level or immediate jeopardy to patient health or safety
- Complaint surveys
- Required self-reporting to payers for billing, coding errors
- Required self-reporting to accrediting, state or federal agencies for clinical errors
- Unsuccessful participation in proficiency testing
- Two consecutive or two out of three unsatisfactory proficiency testing performances for anyone specialty or subspecialty

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Appendix S

Clinical Laboratory Specific Procedures

This section contains additional procedures of the entity clinical laboratory that clarify and expand upon the policies stated within this Clinical Laboratory Addendum.

Each CommonSpirit Health entity has adopted the national clinical laboratory compliance procedures listed in this Addendum. Procedures and/or policies developed by the CommonSpirit Health entity may not supersede any national procedures and/or policies that govern the operations of the CommonSpirit Health affiliate's clinical laboratory(ies).

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CommonSpirit

Appendix T

Proficiency Testing Policy Requirements

Besides describing the actual process for handling the PT specimens and how the specimens are to be rotated to different representative testing personnel during all shifts on which those tests are being performed, the entities PT policy/plan must also include, at a minimum, the following statements:

- The laboratory must not send proficiency testing samples or portions of such samples to another laboratory for analysis.
- The laboratory staff must handle all PT specimens in the same manner as a patient sample. There may be no inter laboratory communication concerning a PT results until after the submission date. Note: For laboratories sharing common data base applications with multiple CLIA licensed laboratories, extreme care must be taken to prevent staff from viewing any other laboratory's PT results. To do so may be considered interlaboratory communication. Additionally, for laboratories with multiple CLIA licenses, PT results must be submitted and approved at the testing CLIA location and must maintain at that location until after the submission date. The person reviewing and approving the PT results cannot be the same individual reviewing and approving PT results at multiple CLIA licensed laboratories. To do so may be considered interlaboratory communication.
- PT samples may only be analyzed on primary equipment and may not be analyzed on secondary equipment until after the submission date, unless testing is required for patient samples.
- Any laboratory personnel who receives proficiency testing samples from another laboratory for testing must notify laboratory leadership, the System Director of Laboratory Compliance, and the entity CRO who will intern notify CMS of the receipt of those samples.

Note, these statements are not inclusive, please refer to your accreditation agency for proficiency testing policy/statement requirements.

The plan must also explicitly emphasize that PT samples are only to be analyzed and reported on behalf of the CLIA licensed laboratory for which they were obtained. Laboratories may not share PT specimens with other licensed CLIA laboratories. Purchased PT samples are tied directly to the CLIA number of the purchasing laboratory and to share that specimen with another CLIA licensed laboratory and to report the result of the second laboratory will be interpreted as specimen referral which carries steep penalties. Any perceived variation from any of the above statements must be immediately reported to leadership, entity Corporate Responsibility Officer and System Director of Laboratory Compliance for follow up analysis and action when appropriate.

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