Reimbursement Guide
For the INRatio PT/INR Monitoring System

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1. About CLIA Compliance

What is CLIA?
The Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88), are a series of federal laws that regulate laboratory testing. They were put into effect to ensure high quality, reliable, safe and accurate testing in laboratories throughout the US. Laboratory tests are classified as “waived” or “non-waived”, based on the cumulative score after ranking seven different criteria by difficulty.

The HemoSense INRatio monitoring system is classified as waived status. The INRatio is easy to use, and provides accurate INR results. Testing is allowed and reimbursed only if the provider meets the requirements of the guidelines outlined by the CLIA act. To bill Medicare for laboratory tests:
1. The provider must have a CLIA Certificate applicable to the complexity of the testing performed, and
2. The CLIA number must appear on the claim.

How to get the Certificate?
CLIA applications can be obtained online from the Centers for Medicare and Medicaid Services (CMS) CLIA website, http://www.cms.hhs.gov/clia/. The site contains an updated list of waived tests with applicable codes for billing. Fill out the application and mail it back to the appropriate State Department of Health. Do not send a check with your application.

The State Department of Health will generate a coupon for the fee. As of January 1998, the fee is $150 for 2 years. The coupon will have your CLIA ID number on it. You can mail in the fees after this and start billing using the CLIA number. Your local surveyor can advise you further.

2. Medicare Coverage

How does Medicare Reimburse?
The 2006 National Fee cap for a PT test is $5.49. Medicare pays 100% of the allowed amount. CMS annually publishes the coverage according to a fixed fee schedule. To be eligible for coverage of coagulation tests, the Medicare beneficiary must have elected Part B coverage. Additionally, the coagulation test should meet two other requirements:
1. The test should be prescribed by a licensed Medical Practitioner.
2. The test should be medically necessary.

What is considered “medically necessary” by Medicare?
The test should be necessary for diagnosing and treating the illness or condition of the patient. That means it should not be experimental or investigational, it should be safe, effective, and provided in an appropriate setting by qualified personnel. Any procedure that screens for asymptomatic conditions is not paid.

What is the ICD-9 Code?
The necessity can be identified by using a specific International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) code. This diagnosis code documented on the claim is used by CMS to determine necessity and eventual coverage. There are many ICD-9 codes. These should be specified by the attending physician. However, for home testing, Medicare currently reimburses for mechanical heart valve replacement patients only.

V43.3 is the ICD-9-CM code for organ or tissue replaced by other means; heart valve, applies.

What CPT code should be used for the PT/INR test?
Current Procedural Terminology (CPT) codes are used to identify medical tests and procedures including laboratory tests. Modifiers are added to a CPT code to provide more information about the waived or non-waived status of the test. The CPT code for Prothrombin Time (PT) is as follows:

85610   CPT code for Prothrombin Time
QW      Modifier indicating this is a waived test.
Will the finger stick be reimbursed also?
No, Medicare reimburses for venous samples but not finger sticks.
If the patient having the in-house PT test is covered by Private Insurance, you may be able to bill CPT code 36416 (Collection of capillary blood specimen e.g., finger stick, heel, ear stick) for the finger stick. Check with the insurance company for more information.

What is the reimbursement pricing for my state?
The reimbursement policies listed are those administered by CMS. The 2006 National Fee cap for a PT test is $5.49. All states pay this amount except:
- Wyoming: $4.44
- Iowa: $4.89
- Maryland: $5.25
Medicare billing rules generally apply to Medicaid billing but the reimbursements vary from state-to-state. Please contact private insurers directly as eligibility, coverage, billing and payment requirements may vary depending on the location and patient’s plan.

What will be the deductible before claims can be reimbursed?
Medicare B covered patients must satisfy a $100 deductible for one calendar year. Once the deductible is satisfied, the patient pays no out-of-pocket charges. The usual 20% patient co-payment does not apply to the laboratory tests.

3. States that Require Additional Regulatory Requirements with CLIA
A summary of state regulations below provides a detailed state analysis. The address and telephone number for the state regulatory office responsible for CLIA in each state are also provided in the summary. Please contact your local carrier as well as state regulatory agency to obtain a list of complete requirements for your region.

States that require CLIA registration with no other regulatory restrictions:
- Alaska
- Arizona
- Arkansas
- Colorado
- Delaware
- Hawaii
- Dist of Columbia
- Illinois
- Indiana
- Iowa
- Louisiana
- Michigan
- Minnesota
- Mississippi
- Nebraska
- New Hampshire
- New Jersey
- New Mexico
- New York
- North Carolina
- Ohio
- Oklahoma
- South Carolina
- South Dakota
- Texas
- Vermont
- Virginia
- Wisconsin
- Wyoming
- Nevada
- North Dakota
- Oregon
- Pennsylvania
- Rhode Island
- Utah
- Washington
- West Virginia

States that require CLIA registration and other regulatory restrictions:
- Alabama
- California
- Connecticut
- Florida
- Georgia
- Idaho
- Kansas
- Kentucky
- Maine
- Maryland
- Massachusetts
- Missouri
- Montana
- Nebraska
- Nevada
- New Jersey
- New Mexico
- New York
- North Dakota
- Oregon
- Pennsylvania
- Rhode Island
- Utah
- Washington
- West Virginia
4. Special Restrictions for Some States
* For most current updated regulatory information, please contact your State Department of Health.

California
Must complete CLIA and State registration forms. Call the State for registration form (213) 620-6160. Follow CLIA rules for waived testing. Personnel must meet the qualification rules for phlebotomists and testing analysts. Call Pam at (213) 576-6746 for phlebotomist's criteria (it is facility and site dependent).

Florida
Must get a “Certificate of Exemption” license from the State of Florida. Get the State and CLIA certificate at the same time. All information can be found at the following address:
http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/initial.shtml

Pennsylvania
Application can be found at:
http://www.dsf.health.state.pa.us/health/lib/health/clinical_laboratory_application.ps.pdf
The state has testing in three levels. An INRatio test is a LEVEL 2 test. The Medical Director must be a MD or DO and must send in CV with application with Tax Identification Number and Medical License Number. The application must be signed by both the owner and the director. The State and CLIA applications are to be sent together with all sections completed or the application will be returned to the sender. PT is required but if it is not available, split sample specimens may be used every six months. They must document QC at the frequency recommended by manufacturer. They may be required to run stability study of 10 sets of controls to show upper and lower limits. Don’t start testing prior to hearing from the State. Level 2 laboratory may have an inspection. CLIA applies to Long Term Care only.

Maryland
Get a Maryland license – call Lois Feldstein (410) 402-8025 to get the state license application. She wants to talk to the laboratory to ensure they get all the necessary documents in place. Must enroll PT if available otherwise follow manufacturer’s instructions. They require split sample testing twice a year if no PT testing program is available. They may get an inspection after 90 days. The regulations may be subject to change.

Nevada
Call the office of Vickie Estes, MT (ASCP) (775) 687-4475 ext. 229. The laboratory director must be MD, DO or PhD with board certification. Laboratory must follow manufacturer’s recommendations, day-to-day temps, QC (two levels – can be internal/built-in), and competency assessments.

New York
Contact for questions is: James Holland, Health Program Administrator, Clinical Laboratory Evaluation Program, (518)402-4141, Fax: (518)485-5414. Community or physician owned entity: Limited service laboratory registration – follow the manufacturer’s recommendations. POL: Must be owned and operated by physician(s) only – all other are limited service registration. (518) 485-5352
Required application materials may be downloaded from the following website. Go to the bold heading Limited Testing Sites and complete an Ownership & Controlling Interest Disclosure Statement (DOH-3486) and a Limited Testing Registration Form (DOH-4081) for each test site:
http://www.wadsworth.org/labcert/clep/Administrative/ChangeForms.htm
### 5. Summary of State Regulations

<table>
<thead>
<tr>
<th>State</th>
<th>Contact</th>
<th>Address</th>
<th>Phone</th>
<th>Is CLIA Recognized?</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alabama</td>
<td>Faye Allen</td>
<td>Department of Public Health</td>
<td>334-206-5120</td>
<td>No</td>
<td>The regulation applies to clinical laboratories and hospitals, but not POLs or other medical facilities that are state licensed.</td>
</tr>
<tr>
<td>Alaska</td>
<td>Diana Parks</td>
<td>Health Facilities Licensure Cert.</td>
<td>907-561-8081</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Arizona</td>
<td>Cecilia Mesa</td>
<td>Arizona Dept. of Health Services</td>
<td>602-364-0741</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Arkansas</td>
<td>Laura Moody</td>
<td>Division of Health Services</td>
<td>501-661-2201</td>
<td>Yes</td>
<td>There are regulations that apply to laboratory testing, but a federal certificate of waiver is recognized. See above.</td>
</tr>
<tr>
<td>California</td>
<td>Donna McCallum</td>
<td>Laboratory Field Services</td>
<td>213-620-6160</td>
<td>No (State regulations)</td>
<td>There are regulations that apply to laboratory testing, but a federal certificate of waiver is recognized. See above.</td>
</tr>
<tr>
<td>CLIP (CLIA equivalent for Federal Labs)</td>
<td></td>
<td>Office of Clin. Lab. Affairs Armed Forces Inst. of Path. 8403 Colesville Rd. Metro Plaza 2 Suite 860 Silver Spring, MD 20910</td>
<td>301-295-7217</td>
<td>Yes</td>
<td>INRatio is automatically waived under CLIP.</td>
</tr>
<tr>
<td>Colorado</td>
<td>Yvonne Herman</td>
<td>Dept. of Public Health, Div. of Labs, CDH CLIA Programs  P.O. Box 17123 Denver, CO 80217</td>
<td>303-692-3291</td>
<td>Yes</td>
<td>Facilities performing only waived tests are exempt.</td>
</tr>
<tr>
<td>Connecticut</td>
<td>John Murphy</td>
<td>Dept. of Public Health, Bureau of Laboratories 150 Washington Street Hartford, CT 06106</td>
<td>860-509-7400</td>
<td>No (State regulations)</td>
<td>Facilities performing only waived tests are exempt.</td>
</tr>
<tr>
<td>Delaware</td>
<td>Fred France</td>
<td>Office of Health Facilities, Certification and Licensure 3 Mill Road, Suite 308 Wilmington, DE 19806</td>
<td>302-692-3291</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>District of Columbia</td>
<td>Solomon Yimam</td>
<td>Agency for Healthcare Administration 2727 Mahan Drive Tallahassee, FL 32308</td>
<td>202-442-4706</td>
<td>Yes</td>
<td>State regulations do not apply to waived tests. However, anyone doing waived tests is required to register with the state of Florida and pay a $100 fee. See above.</td>
</tr>
<tr>
<td>Florida</td>
<td>Pat James</td>
<td>Dept. of Human Resources Office of Regulatory Svcs. 2 Peachtree Street Atlanta, GA 30303</td>
<td>850-487-3109</td>
<td>No (State regulations fdhc.state.fl.us)</td>
<td>Testing regulations do not apply to physicians performing tests on their own patients. There is also an exemption for screening and monitoring tests, and Georgia recognizes the INRatio with on-board controls as an acceptable test.</td>
</tr>
<tr>
<td>Georgia</td>
<td>Betty Logan</td>
<td>Dept. of Health Hospital and Medical Facilities Branch 1270 Queen Emma St., Suite 1100 Honolulu, HI 96813</td>
<td>404-657-5447</td>
<td>CLIA and State dhr.state.ga.us</td>
<td>State regulations do not apply to POL. Otherwise all testing must be done in the lab and collected by a qualified individual.</td>
</tr>
<tr>
<td>Hawaii</td>
<td>Susan Naka</td>
<td>Dept of Health Laboratory and Medical Facilities Branch 1270 Queen Emma St., Suite 1100 Honolulu, HI 96813</td>
<td>808-692-7420</td>
<td>CLIA and State</td>
<td>State regulations do not apply to physicians performing tests on their own patients. There is also an exemption for screening and monitoring tests, and Georgia recognizes the INRatio with on-board controls as an acceptable test.</td>
</tr>
<tr>
<td>Idaho</td>
<td>David Eisenrager</td>
<td>Laboratory Improvement Section Bureau of Laboratories 2220 Old Penitentiary Road Boise, ID 83712</td>
<td>208-334-2235</td>
<td>Yes (State regulations)</td>
<td>POL and Clin Labs not waived.</td>
</tr>
<tr>
<td>Illinois</td>
<td>William Garrett</td>
<td>Department of Public Health Laboratory Regulations Unit 525 W. Jefferson Street, 4th Floor Springfield, IL 62761</td>
<td>217-782-7412</td>
<td>Yes</td>
<td>Regulations do not apply to waived tests.</td>
</tr>
<tr>
<td>Indiana</td>
<td>Wanda Profitt</td>
<td>State Department of Health Division of Acute Care Svcs. 1330 W. Michigan St., Box 1964 Indianapolis, IN 46206</td>
<td>317-233-7502</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Iowa</td>
<td>Nancy Grove</td>
<td>Division of Health Facilities Department of Inspections Lucas State Office Building, 3rd Floor Des Moines, IA 50319</td>
<td>319-335-4500</td>
<td>Yes</td>
<td></td>
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<tr>
<td>State</td>
<td>Name</td>
<td>Address/Location</td>
<td>Phone</td>
<td>Notes</td>
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<tr>
<td>Kansas</td>
<td>Ruby Brower</td>
<td>Dept. of Health and Environment Laboratory Certification Building 740, Forbes Field</td>
<td>785-296-3811</td>
<td>CLIA and State Hospital</td>
<td></td>
</tr>
<tr>
<td>Kentucky</td>
<td>Debbie James</td>
<td>Div. of Licensing and Cert. Dept. of Human Resources 275 East Main St.</td>
<td>502-564-2800</td>
<td>Regulation applies only to clinical laboratories. POLs or those performing only waived tests are exempt.</td>
<td></td>
</tr>
<tr>
<td>Louisiana</td>
<td>Staci Glueck</td>
<td>Department of Health and Hospitals P.O. Box 3767 Baton Rouge, LA 70804</td>
<td>225-342-9324</td>
<td>Yes LA has state regulations, but recognize INRatio as waived.</td>
<td></td>
</tr>
<tr>
<td>Maine</td>
<td>Susan J. Grondin</td>
<td>Dept. of Health Div. of Licensing and Certification State House Station #11</td>
<td>207-287-9339</td>
<td>CLIA and State</td>
<td></td>
</tr>
<tr>
<td>Maryland</td>
<td>Louis Feldstein</td>
<td>Office of Licensing &amp; Certification Div. of Lab. Licensure 4201 Patterson Ave., Fourth Floor Baltimore, MD 21215</td>
<td>410-402-8025</td>
<td>POL specific regs: MD can only do testing on his own patients. Must apply yearly &amp; pay fee. QC is required - they will accept INRatio's on-board QC, but we are waiting for them to put that in writing. See Above.</td>
<td></td>
</tr>
<tr>
<td>Massachusetts</td>
<td>Pamela Stroub</td>
<td>Clinical Laboratory Program 305 South Street, Room 224 Jamaica Plain, MA 02130</td>
<td>617-983-6739</td>
<td>No There are state laboratory regulations that are different from CLIA. Small POL practices are exempt from the state regulation. There are also separate regulations for each health care facility type.</td>
<td></td>
</tr>
<tr>
<td>Michigan</td>
<td>Ronald Ray</td>
<td>Michigan Department of Public Health 3500 N. Logan, Box 30035 Lansing, MI 48909</td>
<td>517-241-0821</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Minnesota</td>
<td>Shellae/Phil Balazs</td>
<td>Dept. of Health Survey and Certification Division 393 N. Dunlop St., Box 64900 St. Paul, MN 55164</td>
<td>651-215-8704</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Mississippi</td>
<td>Theresa Irwin</td>
<td>Licensure and Certification Department of Public Health P.O. Box 1700 Jackson, MS 39215</td>
<td>601-576-7300</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Missouri</td>
<td>David Lewis</td>
<td>CLIA Program Bureau of Hospital Licensing and Cert. P.O. 570 Jefferson City, MO 65102</td>
<td>573-751-6318</td>
<td>CLIA and State Hospital</td>
<td></td>
</tr>
<tr>
<td>Montana</td>
<td>Ed Adams</td>
<td>Licensure and Cert. Bureau, Quality Assurance Division CLIA Program, Cogswell Building Helena, MT 59620</td>
<td>406-444-1451</td>
<td>CLIA and State</td>
<td></td>
</tr>
<tr>
<td>Nebraska</td>
<td>Val Rykman</td>
<td>Consumer Safety Section Div. of Environmental Health 31 Centennial Mall S., P.O.B. 95007 Lincoln, NE 68509</td>
<td>402-471-8687</td>
<td>Yes Physicians may perform point of care tests, and medical professionals can perform tests at the patient's residence. However, all non-physician personnel must apply to the state as an office laboratory assistant. See Above.</td>
<td></td>
</tr>
<tr>
<td>Nevada</td>
<td>Vickie Estes</td>
<td>Dept. of HR Bureau of Lic. and Cert., Lab. Section 1550 E. College Pkwy. Suite 15B Carson City, NV 89710</td>
<td>775-687-4475x 229</td>
<td>CLIA and State</td>
<td></td>
</tr>
<tr>
<td>New Hampshire</td>
<td>Sylvia Miskoe</td>
<td></td>
<td>603-271-4832</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>New Jersey</td>
<td>Alicia Waln</td>
<td>Department of Health CLIA Program CN 360 Trenton, NJ 08625</td>
<td>609-292-0016</td>
<td>CLIA and State</td>
<td></td>
</tr>
<tr>
<td>New Mexico</td>
<td>Julie Aragon</td>
<td>Health Facilities Licensing Public Health Div., DOH 525 Camino De Los Marquez, Ste. 2 Santa Fe, NM 87501</td>
<td>505-841-4524</td>
<td>CLIA and Hospital rules</td>
<td></td>
</tr>
<tr>
<td>New York</td>
<td>Edward Maziarz for POL</td>
<td>State Dept. of Health CLIA Unit Empire State Plaza, P.O. Box 509 Albany, NY 12201</td>
<td>518-485-5352 518-485-5378</td>
<td>CLIA for POL The state regulation applies only to Clinical Laboratories and Blood Banks. POLs, etc. come under CLIA. See Above.</td>
<td></td>
</tr>
<tr>
<td>State</td>
<td>Name</td>
<td>Address/Contact Information</td>
<td>Phone Number</td>
<td>ApprovedCLIA and State Requirements</td>
<td>Notes</td>
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<tr>
<td>North Carolina</td>
<td>Azzie Conley</td>
<td>Dept. of Human Svcs. Div. of Facility Svcs. Cert. Secretary 701 Barbour Dr. Raleigh, NC 27626</td>
<td>919-733-1610</td>
<td>Yes</td>
<td>Regulations do not apply to physicians, nurses or phlebotomists doing &quot;bedside screening tests&quot; doing testing on their own patients.</td>
</tr>
<tr>
<td>North Dakota</td>
<td>Bridget Weidner</td>
<td>Dept of Health &amp; Consolidated Labs CLIA Program State Capital, 600 E. Boulevard Ave. Bismarck, ND 58505</td>
<td>701-328-2352</td>
<td>CLIA and State</td>
<td>If a doctor's office is wholly owned by MDs, it is subject to CLIA but not to RI state licensure. Testing personnel either have to be licensed as Clinical Science Practitioners, or by a profession for which lab testing is in scope of practice i.e. MD, DO, RN.</td>
</tr>
<tr>
<td>Ohio</td>
<td>Michelle Iraabe</td>
<td>Ohio DOH Laboratory Certification Branch 246 N. High St. 3rd Floor Columbus, OH 43266</td>
<td>614-644-1845</td>
<td>Yes</td>
<td>There are laboratory regulations in Tennessee. However, they have their own list of waived tests, and PT/INR is on that list.</td>
</tr>
<tr>
<td>Oklahoma</td>
<td>Dean Bay</td>
<td>DOH, Special Health Svcs. Medical Facilities 1000 NE 10th Oklahoma City, OK 73117</td>
<td>405-271-6576</td>
<td>Yes</td>
<td>Schedules for POC testing in nursing homes. See above.</td>
</tr>
<tr>
<td>Oregon</td>
<td>Rita Schu</td>
<td>Public Health Labs. CLIA Program Coordinator P.O. Box 275 Portland, OR 97207</td>
<td>503-229-5853</td>
<td>CLIA and State</td>
<td>Schedules for POC testing in nursing homes. See above.</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>Marianne Porter</td>
<td>Department of Health Bureau of Laboratories P.O. Box 500 Exton, PA 19341</td>
<td>610-280-3464x3233</td>
<td>CLIA and State</td>
<td>If a doctor's office is wholly owned by MDs, it is subject to CLIA but not to RI state licensure. Testing personnel either have to be licensed as Clinical Science Practitioners, or by a profession for which lab testing is in scope of practice i.e. MD, DO, RN.</td>
</tr>
<tr>
<td>Puerto Rico</td>
<td></td>
<td>Medicare Coordinator Department of Health Former Ruiz Soler Hospital, Road #2 Bayamon, PR 00619</td>
<td>8097820120</td>
<td>Yes</td>
<td>Schedules for POC testing in nursing homes. See above.</td>
</tr>
<tr>
<td>Rhode Island</td>
<td>Nancy Hines</td>
<td>Department of Health Div. of Facilities Regulation 3 Capital Hill Providence, RI 02908</td>
<td>401-222-4526</td>
<td>CLIA and State</td>
<td>Schedules for POC testing in nursing homes. See above.</td>
</tr>
<tr>
<td>South Carolina</td>
<td>Paula Lundy</td>
<td>Dept. of Health and Environmental Control, Bureau of Cert. 2600 Bull St. Columbia, SC 29201</td>
<td>803-545-4291</td>
<td>Yes</td>
<td>There are laboratory regulations in Tennessee. However, they have their own list of waived tests, and PT/INR is on that list.</td>
</tr>
<tr>
<td>South Dakota</td>
<td>Connie Richards</td>
<td>Licensure and Cert. Prog. Dept. of Health, CLIA Program 445 East Capitol Pierre, SD 57501</td>
<td>605-773-3694</td>
<td>Yes</td>
<td>There are three levels of POL labs with different requirements, we are a level 2: $125 fee, training log, procedure manual, PT, daily QC (on-board ok) and inspection are required (equivalent to moderately complex). Testing must be done under the direction of a physician. There are provisions for POC testing in nursing homes. See above.</td>
</tr>
<tr>
<td>Tennessee</td>
<td>Jerry Duke</td>
<td>Health Care Facilities Dept. of Health and Environment 483 Plus Park Blvd. Nashville, TN 37317</td>
<td>615-741-7023</td>
<td>CLIA and State</td>
<td>There are laboratory regulations in Tennessee. However, they have their own list of waived tests, and PT/INR is on that list.</td>
</tr>
<tr>
<td>Texas</td>
<td>Rockne Demler</td>
<td>Health Fac. Cert. Div., Texas DOH 1100 West 49th Street Austin, TX 78756</td>
<td>512-834-6650</td>
<td>Yes</td>
<td>There are laboratory regulations in Tennessee. However, they have their own list of waived tests, and PT/INR is on that list.</td>
</tr>
<tr>
<td>Utah</td>
<td>Rebecca Christiansen</td>
<td>Bureau of Lab Improvement, Div. of Lab Svcs., CLIA Program 46 North Medical Drive Salt Lake City, UT 84113</td>
<td>801-584-8471</td>
<td>CLIA and Hospital rules</td>
<td>There are laboratory regulations in Tennessee. However, they have their own list of waived tests, and PT/INR is on that list.</td>
</tr>
<tr>
<td>Vermont</td>
<td>Carol Drawbaugh</td>
<td>CLIA Laboratory Program, Vermont DOH Lab 195 Colchester Avenue Burlington, VT 02125</td>
<td>802-652-4145</td>
<td>Yes</td>
<td>There are laboratory regulations in Tennessee. However, they have their own list of waived tests, and PT/INR is on that list.</td>
</tr>
<tr>
<td>Virginia</td>
<td>Sarah Pendergrass</td>
<td>Virginia DOH Office of Health Facility Regulation 3600 Center Ste. 216 Richmond, VA 23230</td>
<td>804-367-2107</td>
<td>Yes</td>
<td>There are laboratory regulations in Tennessee. However, they have their own list of waived tests, and PT/INR is on that list.</td>
</tr>
<tr>
<td>State</td>
<td>Name</td>
<td>Address</td>
<td>Phone</td>
<td>CLIA Deemed</td>
<td>State Regulations</td>
</tr>
<tr>
<td>---------------</td>
<td>-------------------</td>
<td>----------------------------------------------</td>
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<td>-------------------</td>
</tr>
<tr>
<td>Washington DC</td>
<td>Department of Consumer and Regulatory Affairs</td>
<td>164 H Street NW, STE 1007 Washington, DC 20001</td>
<td>202-727-7200</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Washington State</td>
<td>Gail Neuenschwander</td>
<td>Office of Lab Quality Assurance Department of Health 610 NE 150th Street Seattle, WA 98155</td>
<td>206-361-2805</td>
<td>CLIA deemed State only</td>
<td>There are state regulations, but they consider INRatio waived. Customers should apply directly to them. They have a different form (deemed under CLIA). <a href="http://www.doh.wa.gov/lqa.htm">www.doh.wa.gov/lqa.htm</a> Get application, follow manufacturer's guidelines.</td>
</tr>
<tr>
<td>West Virginia</td>
<td>Jerry Gross</td>
<td>Office of Laboratory Services 167 11th Ave, South Charleston, WV 25303</td>
<td>304-558-3530</td>
<td>CLIA and State</td>
<td>They go strictly by CLIA except facilities should notify them in writing prior to adding a new instrument or adding or deleting tests.</td>
</tr>
<tr>
<td>Wisconsin</td>
<td>Sharon Abraham</td>
<td>Dept. of Health and Social Svcs. Clinical Lab Unit P.O. Box 309 Madison, WI 53701</td>
<td>608-243-2023</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Wyoming</td>
<td>Dewey Long</td>
<td>Division of Preventive Medicine CLIA program 2300 Capitol Ave., Hathaway 5th Fl. Cheyenne, WY 82002</td>
<td>307-777-6057</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>
6. Billing of E & M Codes (Physicians and Staff)

What is the reimbursement for providing services for a physician's office?
The tasks of evaluation and management of a patient’s condition based on the test result are considered supporting services. These services are referred to as E&M Services. Since the physicians or their staff can perform these tests in their offices, the E&M services may be reimbursed. The difference in the amount will be based on the skills of the staff and classified as Non-Advanced Practice and Advanced Practice. The specific levels with assigned CPT codes have specific reimbursement amounts.

What qualifies as E&M Services?
These services involve the following:
1. Patient history documentation.
2. Patient examination.
3. Making medical decisions such as dose adjustments.

Other important features of the services rendered are providing patient care with counseling, spending time with the patient and the complexity of the decisions to be made. These factors will determine the E&M billing.

What are the E&M Service codes to be used?
99201 - 99205   E&M of New Patients.
99211 - 99215   E&M of Established Patients.

They are determined on the level of services provided. For physicians and specific advanced practitioners, a range of E&M codes is available depending on the level of services.

What is the reimbursement amount for E&M codes?
The reimbursement amount varies depending on the code used, the testing locality, and relative value units (RVUs). The ranges for the E&M codes are shown below.*

New Patients (Office or Outpatient visit)

<table>
<thead>
<tr>
<th>E &amp; M Codes</th>
<th>99201</th>
<th>99202</th>
<th>99203</th>
<th>99204</th>
<th>99205</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simple History, Examination, Decision, 10 min face-to-face.</td>
<td>$28.94 – $45.59</td>
<td>$52.26 - $79.59</td>
<td>$77.86 - $117.42</td>
<td>$111.36 - $164.55</td>
<td>$142.96 - $207.06</td>
</tr>
<tr>
<td>Detailed History, Examination, low complexity decision, moderate severity, 30 min face-to-face</td>
<td>$16.09 - $28.61</td>
<td>$30.20 – $48.37</td>
<td>$41.95 - $65.35</td>
<td>$66.28 - $101.57</td>
<td>$98.12 - $144.64</td>
</tr>
</tbody>
</table>

*2006 Medicare Fee Schedule payment rates effective January 1, 2006. The rates can be subjected to geographic adjustments and local rates will vary.
How to support the E&M Code with documentation?
The physician or staff must have a patient log sheet that shows:
1. Prothrombin Time was performed.
2. Results were made known to the patient or family member.
3. If any dose adjustments or additional tests were required or not.
4. Depending upon the risk associated with the result and problem, the options of management offered to the patient or family member.
5. Time spent with the patient by the physician should be documented along with the total duration of the visit.

Can the Anticoagulation Clinic also bill for E&M Codes?
Anticoagulation clinics operated by the physician and his staff can meet the E&M requirements. Hospital-owned anticoagulation clinics should contact their Reimbursement Department.

Can any other Health Professional bill the E&M Codes?
Only physicians, certified nurse practitioners, certified nurse-midwives, physicians assistants, and clinical nurse specialists can bill higher than E&M codes higher than 99211. All other professionals can bill only at 99211 levels.

Can Pharmacists use the E&M Codes?
If the services are necessary and supervised by a physician, then they can bill under code 99211.

7. G Codes for Home Monitoring by Physicians/IDTF

List of criteria for home PT/INR monitoring:
Medicare now covers home PT/INR monitoring to patients with mechanical heart valves. The following criteria need to be met:
1. Should have Mechanical Heart Valve and is on anticoagulation (warfarin) therapy for at least 12 weeks.
2. Should have the prescription from their doctor.
4. Should be testing at least once a week.

Who “manages” the dosage?
The equipment and supplies are purchased and provided by either a physician directly, to be given to his patients, or through a referral to an Independent Diagnostic Testing Facility. The IDTF will manage the provision of supplies, perform training on the use of the home monitor, and collect and provide the results called in by the patient to the physician. However it’s the physician who will interpret and adjust the dose as required. The physician need not speak directly with the patient, as long as the results are documented.

How does the physician bill for home PT/INR services?

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Medicare Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>G0248</td>
<td>Demonstrate use of home PT/INR monitor</td>
<td>$ 240.22</td>
</tr>
<tr>
<td>G0249</td>
<td>Provide equipment and other test supplies</td>
<td>$ 143.98 for 4 tests only</td>
</tr>
<tr>
<td>G0250</td>
<td>Physician’s interpretation of test and patient management</td>
<td>$ 9.04 for 4 tests only</td>
</tr>
</tbody>
</table>

How can the IDTF bill for the home PT/INR services?
The IDTF can also bill for codes G0248 and G0249, however they cannot use the code G0250, which is for physician use only.

Is the Hospital Outpatient Prospective Payment System (HOPPS) different for billing?
Yes
G0248 is allowed $150.
G0249 is allowed $150 per 4 tests.
Like the IDTF, G0250 is not applicable for billing.

8. Additional Resources

General Medicare Information
http://www.cms.hhs.gov/home/medicare.asp

National Coverage Analysis Decision Memo
http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=72

Prospective Payment Systems General Information
http://www.cms.hhs.gov/ProspMedicareFeeSvcPmtGen/

Physician Fee Schedule
http://www.cms.hhs.gov/PhysicianFeeSched/

Clinical Laboratory Fee Schedule
http://www.cms.hhs.gov/ClinicalLabFeeSched/

Disclaimer
The Reimbursement Guide for INRatio Monitoring System is for information purposes only. No guarantee of payment is stated or implied. It is the responsibility of the health care provider to properly code and seek reimbursement for medically appropriate and necessary services actually rendered.

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