

## DELAYED ENFORCEMENT OF NCDs FOR CLINICAL DIAGNOSTIC LABORATORY SERVICES

On November 23, 2001, CMS issued a final rule on coverage and administrative policies for clinical diagnostic laboratory services in the Federal Register. In an addendum to that rule, 23 National Coverage Determinations for clinical laboratory services were announced to become effective November 25, 2002. The NCD's apply to all clinical laboratory services payable under Part B Medicare, regardless of whether they are processed by fiscal intermediaries (FIs) or carriers.

The negotiated rulemaking provision was structured to promote national uniformity in the processing of clinical diagnostic laboratory services. The NCD's are specific to an ICD-9-CM level. To avoid having all Medicare FIs and carriers individually establish separate programs to enforce these policies, CMS is in the process of developing a downloadable system module to enforce the new NCDs. Unfortunately, this new system will not be implemented on November 25, 2002.

Current local medical review policies (LMRPs) need to be eliminated or made consistent with the new NCDs by November 25, 2002 effective date. Contractors may review claims for adherence to the new NCDs beginning with claims submitted on the effective date. If unable to review claims without the downloadable system, you can go back and review claims submitted after the effective date for adherence to the new NCDs once the module is in place January 1, 2003. The NCDs are available in the November 23, 2001 Federal Register which is posted at [www.cms.hhs.gov/coverage](http://www.cms.hhs.gov/coverage). ♦

Avera Laboratory Network *Lab News* is published every other month to provide the latest updates on services from labs of the Avera Laboratory Network.

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## GOOD LABORATORY PRACTICE.... PLAIN AND SIMPLE

The Centers for Medicare and Medicaid Services performed a study in 1999 of waived laboratories, to determine levels of compliance, and found that over 50% of those laboratories were not in compliance with CLIA. Waived labs now must enroll in the CLIA program, pay the applicable fees, and follow manufacturer's test instructions. CMS is currently in the process of inspecting 2% of all waived labs. They continue to identify problem areas and may eventually elect to impose more stringent requirements similar to those applicable to moderate and high complexity labs. Part of this program involved publishing a guidance on Good Laboratory Practice, and communicates exactly what is expected.

- 1) Keep the manufacturer's product insert for the product in use, and be sure it is available to testing personnel. Use the product insert for the kit currently in use.
- 2) Follow the manufacturer's instructions for specimen collection and handling. Are specimens stored at proper temperatures? Are appropriate collection containers used?
- 3) Be sure to properly identify patient  
 Does then name on the test requisition match the patient name?  
 Does the name on patients chart match name on patient identification?  
 If more that one patient is present with the same first and last name, how do you determine which one is the test patient? (social security number, birthdate, middle initials, patient history, etc.)
- 4) Be sure to label the patient's specimen for testing with an identifier unique to each patient.
- 5) Inform the patient of any test preparation prior to a test  
 Become familiar with test procedure  
 Study each step and perform them in proper order  
 Know the time required for performing the test and achieving optimal results
- 6) Read the product insert prior to performing a test.

## OSHA TARGETS REUSABLE NEEDLE HOLDERS

In June of 2002, OSHA released an amendment to the Bloodborne Pathogens Standard which addresses the reuse of needle holders. The original standard stated that "contaminated needles... shall not be bent, broken, recapped, or removed, unless the employer can demonstrate that no alternative is feasible or that such an action is required by a specific medical or dental procedure." The definition was found to be unclear as it pertained to reusable tube holders.

The revised Bloodborne Pathogens Standard CPL-2-2.69 at XIII.D.5 says "removing the needle from a used blood-drawing/phlebotomy device is rarely, if ever, required by a medical procedure. Because such devices involve the use of a double-ended needle, such removal clearly exposes employees to additional risk, as does the increased manipulation of a contaminated device."

The new wording is aimed directly at the double-ended needle collection devices. When the front-end needle is blunted or retracted and the needle removed from the holder, the back-end needle is now exposed and potentially a safety hazard. Also the tube holders themselves are contaminated and pose a risk to patients and workers. One study showed that 50% or more of tube holders are contaminated after just one use. In addition are the injuries caused by improper disposal of contaminated sharps to "downstream" workers such as housekeeping, maintenance, and nursing assistants. Adoption of single-use devices will help eliminate this type of accidental needlestick injury.

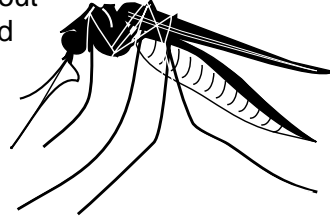
The new directive has sweeping national implications. The practice of using reusable needle holders had economic and practical advantages. Now health care facilities will be required to spend more money to purchase compliant devices, will have a significant increase in the

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## WEST NILE

As the West Nile virus spreads further and further across the United States, we are becoming increasingly more concerned about transmission of the disease and its impact.



Mosquitoes that have fed on infected birds spread the virus. The virus is located in the salivary gland of the mosquito, and during blood feeding, the virus may be injected into the human or animal, where it may multiply, possibly causing disease. Very few mosquitoes are infected with the virus, and even if infected, less than 1% of the people who get bitten and become infected will get severely ill. Following transmission by an infected mosquito, the West Nile virus replicates in the person's blood system and crosses the blood-brain barrier to reach the brain and causing inflammation of brain tissue. The incubation period from infection to onset of disease is 3-14 days. Symptoms of severe infection include high fever, neck stiffness, stupor, disorientation, coma, tremors, convulsions, muscle weakness, and paralysis. It is estimated that 1 in 150 persons infected with the virus will develop a more severe form of the disease.

There is no scientific evidence indicating people can be chronically infected with the West Nile virus. What remains in the person's body for long periods of time are the antibodies and memory white blood cells (T-lymphocytes) that the body produces in response to the

virus. The antibodies are what many diagnostic tests look for when clinical laboratory testing is performed.

There is no evidence of person to person or animal to person transmission of the West Nile disease. Of increasing concern is the possibility of transmission of the disease by blood transfusion or organ transplant. This method of transmission is possible, since the virus may be transiently present in the blood of those infected, but again, the likelihood of being infected is extremely small. There is no validated blood test to screen donated blood. Most people who have West Nile virus do not show symptoms, which makes it difficult to defer them as a donor. However, some individuals develop minor symptoms of fever and headache, so blood banks must be vigilant and defer all those who have had minor illnesses, especially in areas where West Nile has been most active.

Another concern for our region is the impact of West Nile virus on wild game. Hunting season is approaching, and hunters could be at risk if they are bitten by mosquitoes. It is suggested that mosquito repellents be used to prevent mosquito bites. The hunters should also be careful when handling wild animals, and use glove when handling and cleaning animals to prevent blood exposure to bare hands. There is no evidence that West Nile virus can be transmitted to humans through consuming infected birds or animals. In keeping with overall public health practice and due to the risk of food-borne pathogens, people should always follow procedures for fully cooking meat from birds or mammals. ♦

### (OSHA Targets Reusable Needle Holders

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amount of biohazard waste, phlebotomists will have to carry a needle holder for each patient, and storerooms will have to accommodate many more boxes of needle holders.

Several companies have anticipated the new OSHA directive and have products available which are compliant. The most common technology uses a single-use needle holder with a sheathing, retracting, or blunting device for the front-end needle and a hinged flap which is closed over the open end of the tube holder, covering the opening to the back-end needle. Some of the companies with new devices are Tyco Kendall, Sims Portex, Retractable Technologies, Greiner Bio-One, and Becton-Dickinson. Other products can be found such as stackable needle holders and tube holder waist packs which are designed to save room on phlebotomy trays. ♦

### (Good Laboratory Practice.... Plain and simple

*continued from page 1...*)

- Be able to recognize when the test is finished and interpret results. Follow manufacturer's instructions and when a new kit is opened, perform the quality control to be sure the kit works prior to testing patients.
- 7) Follow the storage requirements for the test kit. If the kit can be stored at room temperature, but this changes the expiration date, write the new expiration date on the kit.
  - 8) Do not mix components of different kits!
  - 9) Record the patient's test results in proper place, such as patient chart or laboratory test log, but not on unidentified post-it notes or pieces of scrap paper which can be misplaced.

For more information concerning the CLIA program and CMS activities go to [www.hhs.gov/clia](http://www.hhs.gov/clia). ♦

## FETAL FIBRONECTIN

A 38 year old patient presents for routine prenatal visit at 26 weeks pregnant. Her obstetric history is significant with a previous live birth at 30 weeks gestation. This was a result of preterm labor that could not be stopped. Patient currently works full time as a waitress, has gained 18 pounds thus far, and blood pressure and plasma glucose are normal. At this visit she states her back has been bothering her since the previous night, but that the pain did not feel like the contractions she experienced in her first pregnancy.

In assessing the risks for this patient we note that the probability of spontaneous preterm delivery is about 3%. The rate more than doubles for those women with a history of preterm labor, negative fetal fibronectin screening and a cervical length greater than or equal to 35mm at 24wks gestation. By contrast, those with a history of preterm delivery, a positive fetal fibronectin, and a cervical length of < 25mm at 24 wks gestation were 64% more likely to have preterm labor with a successive pregnancy.

An initial plan should also employ a external fetal monitor to evaluate presence of contractions and fetal well being. In this patients case, the fetal fibronectin test and a transvaginal ultrasound would help in defining her risk. FFN sampling should be obtained prior to performing a digital pelvic exam or transvaginal ultrasound.

The Fetal Fibronectin test is approved as an aid in assessing the risk of preterm delivery in women with symptoms of preterm labor from 24-35 weeks gestation, or in asymptomatic women from 22-31 wks gestation. This test is available as an immunoassay(24 hour TAT) and also in a more rapid format. The rapid test gives results in about 3 hours. Samples must be obtained using a speculum so that the complete cervix is visualized and secretions from the posterior fornix are collected for 10 seconds. If this step is not performed properly, there is an increased chance of a false-negative result.

A negative FFN has been shown to be highly reliable. Its negative predictive value correlates with more than a 99.5% likelihood that delivery will not occur in the next 7 days and a 99.2% likelihood that it will not occur in the next 14 days. If in the case of our patient, her test were negative, she would not require medication and may even be able to continue working, but at a lighter pace. She should also drink plenty of water and take 30 minute breaks every 4 hours to elevate her feet. The FFN should be repeated if she experiences any new or ongoing symptoms.

A positive FFN has less predictive value, and requires additional evaluation including the transvaginal ultrasound to determine the cervical length. If she were to present with other risk factors or symptoms and a cervical length of < 2.5 mm, immediate hospitalization should be considered. FFN should be repeated in 2-4 weeks or with signs and symptoms of preterm labor.

Assessing which patients will or will not deliver before 37 weeks is difficult. The FFN test in conjunction with transvaginal ultrasound can help the provider make appropriate treatment decisions. Those showing to be at higher risk by FFN assay warrant more intensive evaluation, education and treatment. ♦



**October 23-25, 2002  
Ramkota Hotel**

The Avera Laboratory Network invites you to join them to celebrate Laboratory Professionals!

Kick back, relax and take some time out for you. Come and enjoy some food and fun.

ASCLS Tri-State Meeting  
Ramkota Hotel • Room 1123  
Thursday, October 24, 2002  
5:00 p.m. - ??

If you have not seen an informational brochure,  
please call Lori Murray at 322-4652.