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Adding Ancillaries

Waived lab services

This is the ninth in a series of articles on specific ancillary services that can boost your bottom line and keep you and your practice busy in a competitive market.

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Adding a lab to your practice can definitely improve patient satisfaction and increase your revenues. But the more complex the testing you do, the more you'll pay for equipment, staff, regulatory compliance, and just about everything else.

Big practices that generate lots of volume can handle these expenses, but that's typically *not* the case with smaller practices.

Enter the delightfully low-overhead option of waived testing. Easy-to-administer and low risk, waived tests—ovulation, blood glucose, dipstick or tablet reagent urinalyses, rapid strep tests, and the like—escape all but the most minimum requirements under CLIA, the Clinical Laboratory Improvement Amendments of 1988. They also require minimal space and equipment and no special staff, and the training needed to do the tests is very manageable.

Waived testing is also modular. "You can add tests as you need them, depending on your patient mix, volume, and your profit margin," says Charles Root, president of CodeMap, a consulting firm in Barrington, IL. As of last August, approximately 52,000 physician office labs held a CLIA waiver certificate.

Until recently, though, turning a profit has been a problem, especially for some of the first-generation waived tests. That's because the federal government has tended to reimburse these tests at lower nonwaived rates. But two developments are changing this reimbursement picture. First, doctors have started to push the AMA to assign separate CPT codes when non-waived tests are administered at the point of care. And second, as waived tests themselves become more com-

plex—immunoassays or antigen assays, for instance—reimbursements have been moving up.

And there's other good news. This past November, Cholestech, one of the leading point-of-care testing manufacturers, announced its intention to produce the first CLIA-waived Complete Blood Count. (Currently, CBC testing is restricted to more-complex labs, using large, costly analyzers.) If this happens, other major tests are sure to follow, continuing the trend toward better-reimbursed, more-complex waived tests.

To help get you started in this growing area, we looked at the following:



Equipment

Instruments for most waived tests tend to be small, handheld kits or else desk-phone or toaster-size readers, with slots for a specimen cartridge. The number of "desk-phones" or "toasters" will depend on which tests you're doing that require a reader. Common ones that do include Cholestech LDX (lipid panel, glucose, etc.), Clinitek 50 (urinalysis), CoaguChek (INR), HemoCue Hb 201+ (hemoglobin), and Abaxis Piccolo (chemistry and electrolyte panels).

Space

Because equipment needs are minimal, you only need a small space to do waived testing. "Most offices dedicate

part of a table top in the nurse's work area," says FP Paul B. Fischer, of Martinez, GA, who's written and lectured extensively on the subject of physician office labs. The table top should be at least 3 to 4 linear feet.

You'll also need to dedicate enough space to ensure safety, adequate privacy, and sufficient storage. (Regarding the latter, have available at least two 3- to 4-foot shelves for storing manuals, extra test kits, and so forth.) The space should also be well lit and ventilated. Extreme temperatures can cause a host of problems, including degradation of reagents and test components.

Staff/training

Most offices will not need to add staff to do waived testing, nor does CLIA specify any special education or training requirements. According to surveys conducted by CMS, 69 percent of the waived sites are directed by doctors; 17 percent by nurses. Testing personnel tend to be nurses (46 percent) and medical assistants (25 percent), and 7 percent had no more than a high school diploma.

The CDC, in its recent report, "Good Laboratory Practices for Waived Testing Sites," *does* recommend that waived labs set their policies and procedures in writing—and that the procedural part of this document be used to train testing personnel. (For more information, see www.cdc.gov/mmwr/preview/mmwrhtml/rr5413a1.htm.) Many training resources are available—from the manufacturers, from state agencies, and from professional organizations. An example of the latter is COLA, a private education, accreditation, and consulting organization. For a list of its online training courses, go to www.cola.org/labu.html.

Costs

You'll pay \$150 every two years to maintain your CLIA certificate of waiver. (To apply, go to www.cms.hhs.gov/clia, and click on "How to Apply for a CLIA Certificate.")

The cost of the actual tests will depend on the ones you run. Here are per-test prices for some common tests: HbA1c (\$11); influenza A and B (\$13); H. pylori (\$1.96 to \$2.50, depending on type of test and manufacturer); mononucleosis (\$1.73); pregnancy (\$1.20 for urine test by visual color); strep A (\$1.30 to \$2.00, depending on manufacturer); TSH (\$16); and urinalysis (\$1.25 or less, depending on type of test and manufacturer). You can get pricing from www.cliawaived.com, which specializes in point-of-care tests direct from manufacturers.

You can also choose from a wide variety of CLIA-waived drug tests, including multidrug screening for up to seven drugs (\$7.50). If you're doing cholesterol screening, expect to pay \$2,000 or more for Cholestech's LDX system. Cassettes cost \$52 and up for a pack of 10.

Overall, primary care doctors can expect to spend anywhere from \$800 if all they're buying are handheld kits to \$5,000 if they're investing in a number of readers, according to Ann Bachman, executive director of the American Association of Physician Offices & Labs.

Charges

"Doctors can't always count on health plans to reimburse them for point-of-care tests," says Maxine Lewis, president of Medical Coding/Reimbursement Management, in Cincinnati. But Medicare does. In 2005, the government started reimbursing for cholesterol screening—including screening done at the point of care. (For Cholestech LDX, it pays \$6.08 [CPT code 82465QW].)

Among other waived tests, it reimburses \$14.02 for an ovulation test by visual color (84830), \$18.09 for Germaine Laboratories Aimstep H. pylori (86318QW), \$16.76 for Abbott Diagnostics Signify Strep A test (87880QW), and \$19.24 for Acon one-step multidrug, multiline test (80101QW).

Potential revenue

A three-to-five doctor practice could easily expect to bring in additional revenue of \$10,000 to \$20,000 annually, Root says.

Other concerns

Clinical lab services fall under the Stark self-referral prohibition. But you won't trigger Stark as long as the testing you do is considered an "in-office ancillary service." For this exception to apply, testing must be conducted or supervised by members of the group practice, group members can't be compensated based on the volume or value of the tests they order, and so on. Check with your attorney if you're unsure how Stark applies to your situation.

Each CLIA-waived site must comply with OSHA's standards for workplace hazards, such as the Blood-borne Pathogens Standard. Most medical practices should already be in compliance with these standards. ■