WASHINGTON G–2 REPORTS

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 25th Year of Publication

Vol. 25, No. 13, April 19, 2004

Feds Expand Specimens Allowed For Worker Drug Testing

The impact will be felt far beyond the federal workforce because SAMHSA standards are widely followed by thousands of other employers, public and private. An estimated 33 million workplace drug screens are run each year by U.S. employers

In a major update of the federal workplace drug testing program, the government is proposing to allow federal agencies to use specimens of head hair, sweat and saliva to screen for drugs of abuse. Currently, only urine samples are tested. Further, the government would permit selected specimen testing at the time and place it is collected.

The changes, more than five years in development, were proposed by the HHS Substance Abuse & Mental Health Services Administration in the Apr. 13 *Federal Register*. According to the agency, the proposal "is predicated on scientific advances that allow these [alternative] methods to be used with the same level of confidence that has been applied to urine." Federal agencies aren't required to use the alternative methods. It's up to them to consider their own needs and whether employees may regard these tests as less intrusive and less invasive of privacy than the collection of urine specimens.

The proposal would require that all specimens taken for drug abuse testing be split, to allow the person being tested to request a double-check if a laboratory reports a positive test result. For further details, see the *Focus*, pp. 4-6.

Medicare Pay Hikes Are Managed Care Windfall

In less than a year, private health plans serving beneficiaries enrolled in the Medicare Advantage program (formerly Medicare+Choice) will see their Medicare payments increase by around 17%, thanks to an overhaul of rate-setting formulae enacted in the Medicare reform law (Public Law 108-173).

The latest increase—an estimated 6.6% boost in capitation rates in 2005—comes on the heels of the 10.6% pay hike that took effect Mar. 1 of this year (*National Intelligence Report, 25, 8/Feb. 9, '04, p. 1*). In announcing the estimate, the Centers for Medicare & Medicaid Services said final capitation rates for all counties will be released May 10.

Congress approved higher reimbursement to encourage private health plans to enter and remain in the Medicare market. Many had pulled out, contending that annual pay increases, capped at around 2%, did not keep up with the double-digit rise in costs, leaving thousands of beneficiaries to scramble for coverage elsewhere. ➟ *p. 2*

INSIDE *NIR*

Medicare Pay Hikes, *from p. 1*

CMS notes that the Medicare managed care program has stabilized over the past year and expects it to be further strengthened by the higher financial incentives. Since the passage of Medicare reform, CMS says it has added six Medicare Advantage plans and expanded the service areas of another 14. Currently, 10 new plans and 10 service area expansions are pending CMS approval.

Of Medicare's 41 million beneficiaries, 4.6 million are enrolled in Medicare Advantage plans, down from a peak of 6.3 million in 1999. "Health plans already are using the increases from the new Medicare law to expand benefits and reduce premiums," said CMS chief Mark McClellan, MD, PhD. He expects them to continue to do so in 2005. Plans may use the payment increases for other purposes as well, for example, to expand provider networks and to establish a reserve fund to accommodate market fluctuations.

CMS also announced that it will continue to phase-in the risk adjustment methodology (CMS-Hierarchical Condition Category), initiated for payment purposes in 2004 and designed to increase payments to plans that care for the sickest beneficiaries. Current payments are a blend of adjustments for the health status of enrollees and the previous demographic-only system. The phase-in is to be completed in 2007.

Trends For Medicare Managed Care

According to CMS projections:

- Number of beneficiaries enrolled to expand to as much as one-third of total pool by 2009, equally divided between HMOs and PPOs.
- Payments to private health plans to increase by $46 billion over 10 years.

The Congressional Budget Office has lower expectations. It projects that only 9% of beneficiaries will move to managed care at an increased cost of $14 billion.

Other analysts foresee that enrollment in traditional fee-for-service Medicare will decline from 2006-2009, as will many provider payments.

Medicare Raises Payments To Rural, Small Urban Hospitals

The payment hikes account for nearly half the estimated $25 billion in rural provider relief approved under Medicare reform legislation. The cost is offset in part by the 5-year freeze on updates to the Part B lab fee schedule

Hospitals in rural areas, as well as urban areas with fewer than one million residents, will get higher Medicare reimbursement totaling nearly $12 billion over the next 10 years under Medicare reform provisions that the government began implementing Apr. 1. In addition, the outlier threshold for all hospitals eligible for extra payments for unusually costly cases will drop from $31,000 to $30,150.

In accord with the Medicare Modernization Act of 2003, signed into law last December, hospitals serving a disproportionate share of low-income Medicare and Medicaid patients will get a boost in their DSH rates, beginning with discharges on or after Apr. 1 of this year. The cap on DSH rate adjustments will rise from 5.25% to 12% for urban hospitals with fewer than 100 beds, sole community hospitals and rural hospitals with fewer than 500 beds. There is no cap on rural referral centers, large urban hospitals with more than 100 beds or rural hospitals with more than 500 beds.

The Act also makes permanent a provision, due to expire Mar. 31 of this year, creating a uniform standardized amount as the basis for Medicare payments for individual inpatient stays. Previously, there were two standardized amounts: one for

hospitals in large urban areas (with a population of more than one million), and a lower one for hospitals in other areas. A separate standardized amount applies to hospitals in Puerto Rico.

Because of changes in the payment formula applicable only to Puerto Rico, hospitals on the island will get an additional $400 million over 10 years. Medicare is gradually boosting the federal share of blended-rate payments to these hospitals from 50% to 62.5% as of this Apr. 1 and to 75% this coming Oct. 1, with the remaining share paid on Puerto Rico-specific rates.

LabCorp Protest Stalls Florida Bidding Competition

For the second time in as many months, a Florida Medicaid competition for a winner-take-all, statewide contract for testing services from independent clinical laboratories has hit a snag.

This time, LabCorp, the second largest U.S. independent lab company, objected, on Apr. 12, just a week after it and nine other labs had notified the state Medicaid agency of their intent to compete for the contract (*NIR, 25, 10, Mar. 8, '04, p. 2*). The protest is likely to further delay the project.

At stake is as much as $37 million in annual revenue that would go to a single independent lab under a three-year contract to serve all Medicaid recipients throughout the state

An earlier protest from Royco Inc. in Fort Lauderdale had stalled the contract over language limiting awards to labs with CAP or JCAHO certification. Royco withdrew its objection after the Florida Agency for Health Care Administration (AHCA) issued an addendum specifying CLIA certification instead.

LabCorp argues that the addendum, together with the original specs, rendered the request-for-proposals "so unclear that a reasonable bidder cannot assess how to respond." Of special concern to the company is the fact that other lab providers, like hospitals, physician office labs and ESRD facilities, don't have to compete to get paid under the state's Medicaid program. Lab Corp fears they could charge full price for services the winning bidder would have to provide at a discount. Further, the exempted labs remain free to perform only higher-paying work, forcing the winner to take on more of the lowest-paying tests.

After Royco's protest, the trade group for large independent labs, the American Clinical Laboratory Association, wrote the AHCA, contending that the contemplated award of a single contract could decimate Florida's smaller clinical labs. Making it further tough to compete, ACLA says, are requirements that bidders be able to interface with an electronic prescription tracking and dispensing system, and that they seek state approval of subcontracts that must be established prior to submission of a proposal.

Nonetheless, three of ACLA's large members—Quest Diagnostics, LabCorp and Specialty Laboratories—have submitted a notice of intent to bid. Others doing likewise include Cognoscenti Health Institute, Doctors Laboratory Inc., DSI Laboratories, Florida Reference Laboratory, J.E. Viloria Pathology, PathNet Esoteric Laboratory Institute and Royco Inc. (ESRD Laboratories).

focus on: Workplace Drug Testing

Feds Open The Door To Alternative Specimens, Testing Options

In 1988, the Federal Government began a massive program to screen its workforce for use of illegal drugs. Scientific and technical guidelines were established for screening and confirmatory testing, and standards were set to certify laboratories to perform the work. The program relied on the method then most available and reliable—traditional lab-based urine testing. Only testing for marijuana and cocaine was required; testing for opiates, amphetamines and PCP was authorized. Today, most workplace screening targets all five drug classes.

Now, the HHS Substance Abuse & Mental Health Services Administration (SAMHSA) is proposing major revisions to its mandatory guidelines for workplace drug abuse testing. The changes appear in two notices published in the Apr. 13 *Federal Register*:

- A proposed rule (with 90-day comment period) that would allow testing of head hair, sweat and saliva in addition to urine; establish criteria for point-of-collection testing of urine and oral fluid; allow certification of additional testing sites known as instrumented initial test facilities or IITFs; and add standards for collectors, on-site testers and medical review officers. The rule is expected to be finalized and go into effect in 2005.
- A revision of existing guidelines to ensure uniform standards for urine specimen validity testing and reporting procedures. These standards take effect Nov. 1 of this year, though comments will be accepted through June 14.

The SAMHSA rulemaking reflects scientific advances in drug testing technology. It also is a response to the proliferation of ways to adulterate or substitute urine specimens. Over the past several years, the agency notes, more and more adulterants have been marketed on the Internet and in magazines, including ads on how to substitute a "clean" specimen for a "dirty" one.

Alternative Specimens

Under the newly proposed rule, federal agencies may (but don't have to) test head hair, oral fluid or sweat samples, in addition to urine specimens. A laboratory or IITF must be certified for each specimen type it wants to test since the testing procedures are different for each. SAMHSA offers some guidance on use of the alternative specimen types.

Who's Affected?

The SAMHSA rules largely affect federal employees and job applicants in safety and security-related positions. About 400,000 federal workers in designated positions—those who have security clearances, carry firearms, deal with public safety or national security, or who are presidential appointees—are drug-tested when they apply for jobs. Some are subject to random testing during their employment. Others are tested only if they are involved in a workplace accident or show signs of drug use.

But other federal agencies, as well as many private employers, follow the SAMHSA guidelines and use only SAMHSA-certified labs. The U.S. Department of Transportation, for example, oversees worker drug testing in industries it regulates, in particular the airline and trucking sectors, and requires use of SAMHSA-certified labs. The Nuclear Regulatory Commission requires its licensees to use such labs as well.

Currently, SAMHSA-certified labs test urine specimens from approximately 120 federal agencies that employ 1.6 million civilian federal employees. In all, SAMHSA has responsibility for more than 6.5 million of the 33 million workplace drug tests done each year for U.S. employers.

Hair: Drugs flow from follicular blood into the base of hair shaft, creating a drug-laced band that can be timed based on its distance from the scalp at the time of testing. SAMHSA would allow testing of the first 1.5 inches of head hair, which would correspond to a 90-day sampling period—much longer than for other specimen types. This makes it ideal for pre-employment and random drug testing, the agency says, but not for suspected drug use or post-accident cases since drugs or drug metabolites don't appear in hair for 7-10 days after use.

Compared to urine, hair is easier to collect, transport and store, less likely to transmit bio-organisms and harder to adulterate. Hair tests show drug metabolites as well as the drug itself (at picogram levels), which can disprove claims of mere environmental exposure. But there are caveats: sweat from the scalp can also deposit drugs and their metabolites onto hair in ways that can confuse the timing of drug use. According to some studies, black hair incorporates drugs more readily than blonde hair. Still, the agency will allow hair testing, concluding that drug detection is more important than certainty of the exact amount.

Oral Fluid: The active components of most drugs of abuse pass into oral fluid within an hour of use and remain there as long as 24 hours, making oral-fluid tests most suitable to detect very recent drug use, for example, in reasonable suspicion/cause and post-accident situations. However, the active component of marijuana does not remain. For this reason, SAMHSA proposes that a urine specimen be collected along with every oral-fluid specimen, and that the urine be tested for marijuana if the oral-fluid test result is positive. The agency would allow oral-fluid tests even though test subjects can reduce drug concentrations in oral fluid by chewing gum, which increases salivary pH.

Sweat: There are several wipes and patches on the market for collecting sweat, SAMHSA notes, though only one is FDA-approved. The main distinction of the sweat patch is its ability to detect drug use after it has been applied. Used in the private sector during drug abuse treatment, it "appears to be well suited for return-to-duty and follow-up testing," SAMHSA says. It recommends using the patch for 3-to-8-day periods.

Alternative Testing Facilities

In an effort to shorten the time for reporting negative test results, SAMHSA would allow establishment of instrumented initial test facilities (IITFs). An IITF would perform only initial tests, not confirmatory tests. Positive results would still need to be confirmed by a certified lab. An IITF, SAMHSA says, functions like the screening part of a full-service laboratory, but is established in locations to meet local testing needs more quickly and economically. The Nuclear Regulatory Commission has allowed such sites since 1990. These lab-like facilities would be subject to rigorous certification, performance testing and inspection requirements, with the focus exclusively on initial drug and validity testing.

FDA Reasserts Role Over DOA Screening

In draft guidance issued last December, the Food & Drug Administration alerted device makers that it is stepping up enforcement activities in the marketing of products to screen for drugs of abuse. The agency spelled out new options for companies preparing marketing submissions for such tests and described the types of studies that should be conducted to establish the validity of the tests.

Most striking, however, were FDA's recommendations for cautionary labeling and other controls over possibly inaccurate preliminary results. Because of the potential for both false positives and false negatives from all tests in any setting, the label should specify that positive results be confirmed by a different test method. FDA also recommends that the label explain that the tests are not always accurate and that a variety of factors, including substances that interfere with the test, can influence the reliability of results.

At the same time, the agency sent warning letters to four companies selling systems that test hair samples for illicit drug use, reminding the companies that the tests require FDA clearance.

The SAMHSA contact for more information is Walter Vogl, PhD, 310-443-6014, wvogl@samhsa.gov.

Point-Of-Collection Tests

POCT products include non-instrumented devices with visually-read endpoints and semi-automated or automated instrumented devices with machine-read endpoints. Manufacturers have made POCTs for urine and oral fluid, and SAMHSA expects them to develop tests for other types of specimens as well. The main value of POCT is its ability to test in small, remote locales where there may be a lack of fixed facilities, expensive test equipment and highly trained testing personnel. POCTs also can be used to check samples for adulteration.

Despite their potential to be used almost anywhere, POCT devices have limited utility in certain situations, SAMHSA notes. For example, POCT testing of urine is most suitable for emergency/crisis management and may be least suitable for pre-employment, return to duty and follow-up testing. POCT testing of oral fluid is most suited for emergency/crisis management and for reasonable suspicion/cause and post-accident testing; may be least suited for random testing; and is not suited for testing related to return to duty, follow-up and pre-employment. Currently, no POCT devices have been cleared by FDA to screen hair or sweat for drugs of abuse.

To provide ongoing quality assurance for POCT devices, SAMHSA proposes a certification process under which the device makers would provide tests to be evaluated for placement on the list of SAMHSA-certified devices. Federal agencies that use POCTs would be required to ensure that only trained testers perform the tests; provide standard operating procedure manuals; ensure that regulatory requirements are fulfilled; inspect the test sites; conduct proficiency testing; keep records on trainers and inspections; and investigate failures.

U.S. Drug Testing Market

- 33M screens for employers each year.
- Total 2003 revenue (estimated): $891M.
- Quest Diagnostics has the largest share, 10+M screens for estimated revenue of $150M, followed by Lab Corp with 6M screens, $90M in estimated revenue. Other major players: LabOne, Medtox, Psychemedics and Advanced Toxicology Network.
- Cost per standard 5-drug panel (urine specimens): about $12.
- Collection fees, medical review, program management add about $15 to specimen cost.
- 47 SAMHSA-certified labs at the end of 2003 vs. 71 in 1998.
- Leading hair testing companies (by estimated 2003 test volume): Psychemedics, Quest Diagnostics, U.S. Drug Testing Labs.

Split Samples

SAMHSA would require that all drug testing specimens be collected as split specimens. This would give the donor the right to have a split specimen tested when a primary specimen was reported positive, substituted or adulterated. This also gives a federal agency the option to have a split specimen tested as part of a legal or administrative proceeding to defend an original positive, adulterated or substituted result if a donor chooses not to have the split specimen tested.

Confirmatory Testing

The proposed rule would allow additional analytical procedures for confirmatory drug tests. The traditional method used to test urine specimens has been gas chromatography/mass spectrometry (GC/MS). For some types of specimens, SAMHSA says, the confirmatory work may be performed by LC/MS, GC/MS/MS, and LC/MS/MS in addition to GC/MS.

Other Provisions

- Prohibit collection of two specimen types at once, except with oral fluid specimens.
- Require validity testing of every specimen.
- Lower the cutoff concentration for cocaine metabolites (which would increase positives by 10-20%) and for amphetamine metabolites (increasing positives by 5-24%).
- Require federal agencies to inspect each of their collection sites annually.

California Begins Independent Lab Contracting Initiative

One goal is to get quality testing at favorable prices. Another is to promote a higher level of ethical conduct and to erect an additional hurdle against Medi-Cal lab fraud, a problem that has repeatedly rankled California

The California Department of Health Services has launched a new process for requiring independent clinical laboratories to obtain contracts with DHS if they wish to continue to provide and get paid for services to the state's Medicaid program, called Medi-Cal. The state on Apr. 5 issued a request-for-applications for two-year contracts to provide these services at reduced prices set forth in an attached fee schedule (80% of the Medicare rate).

Initially, DHS will only require labs to apply for contracts if they have active Medi-Cal provider numbers for performance of tests classified as moderate or high complexity under CLIA. At this time, the state is not requesting applications from labs run by licensed clinics or health facilities, or by physicians and physician groups, that bill with their Medi-Cal provider number.

DHS will only consider applications from labs required to compete in the initial round if they first submit non-binding letters of intent to apply by this Apr. 23. DHS will only consider applications it receives by May 17. Labs that fail to submit letters of intent or applications, or that are denied contracts, will lose their ability to seek Medi-Cal reimbursement. However, pathologists and other physicians may still be able to perform tests for them. Physicians who have CLIA certification for waived tests or provider-performed microscopy, and who perform only those levels of test complexity, may continue to do so without a state contract until further notice.

The Department plans to hold pre-application conferences on Apr. 15 in Los Angeles and Apr. 19 in Sacramento. The solicitation sets forth procedures for submitting questions prior to the meetings. See *www.dhs.ca.gov/omcp/html/Clinical%20labs%20download.htm*. DHS intends to post contract awards by Sept. 1, 2004 and start the contracts by Oct. 1.

The contracting will be in stages coordinated with the staggered update of Medi-Cal files, to ensure that all Medi-Cal providers have the requisite CLIA certificates and Medi-Cal clinical lab provider numbers.

Celebrating National Medical Laboratory Week ★ Apr. 18-24

This annual event recognizes the approximately 265,000 medical laboratory professionals and 15,000 board-certified pathologists who play a vital role in every aspect of healthcare.

Laboratory Professionals
Working with You for Better Health

It's an occasion to educate the public, promote the lab professions, recruit students to the field and build morale.

The ***11 sponsors*** for this year's celebration include:

★ American Society for Clinical Pathology
★ American Association for Clinical Chemistry
★ American Association of Blood Banks
★ American Medical Technologists
★ American Society for Clinical Laboratory Science
★ American Society of Cytopathology
★ American Society for Microbiology
★ Association of Public Health Laboratories
★ Clinical Laboratory Management Association
★ College of American Pathologists
★ National Society for Histotechnology

CMS Website To Help Seniors Compare Drug Prices

Beginning Apr. 29, the Centers for Medicare & Medicaid Services will host a Website that seniors can access to compare prescription drug prices offered by sponsors of Medicare-approved drug discount cards, authorized under last year's Medicare Modernization Act. The card program is a transitional step to help seniors save until a full Medicare drug benefit debuts in 2006.

Seniors can begin enrolling in the drug discount program of their choice as soon as May 3 and start receiving benefits by June 1, says CMS. Altogether, 28 entities are offering discount cards to seniors in traditional fee-for-service Medicare, while 43 Medicare managed care plans are offering cards to their members

The government expects the card program will help seniors save 10% to 25% on prescription medications, but Health & Human Services Secretary Tommy Thompson said he believes card sponsors may push prices down even more, as they compete for market share. This competition will be driven in large part by the easy accessibility of discount card drug prices online at *www.medicare.gov* and by telephone at 1-800-MEDICARE.

The Website provides a drop-down box of prescription drugs listed alphabetically, which seniors can use to compare monthly prices for the drugs they take after entering data on their zip code, any other prescription drug coverage they might have, and whether they qualify as low-income beneficiaries (those at or below 135% of the poverty line get a $600 annual credit, an enrollment fee waiver and a reduced co-pay).

Seniors also will be able to shop for cheaper alternatives within a class of drugs. They'll be able to choose from 209 categories of drugs, each of which must include at least three drugs.

G-2 SPECIAL AUDIOCONFERENCES

Don't Miss Our 2 New "Hot Topic" Audioconferences

APR. 29: HOW TO COMPLY WITH FINAL STARK REGULATIONS. A thorough look at how they impact financial ties between referring physicians and healthcare providers, including labs and pathologists. Speaker: attorney S. Craig Holden, Ober/Kaler, Baltimore, MD

MAY 13: NEW RULES FOR MANAGED CARE CONTRACTING. Practical tips to help pathology groups negotiate the best deal. Speakers: Mike Raich, president, Vachette Pathology, Palmyra, MI; Ray Howard, VP, Ray Howard & Associates, Jacksonville, FL.

Both 90-minute sessions run from 2:00-3:30 pm (Eastern). Your single paid registration entitles you to as many listeners per site as you like. To register or get more information, call 1-800-401-5937 ext 3907. To sign up online, go to:

- ❑ Apr. 29 session: *www.ioma.com/products/g2_reg.php?confid=143*
- ❑ May 13 session: *www.ioma.com/products/g2_reg.php?confid=173*

NIR Subscription Order or Renewal Form

❑ *YES*, enter my subscription to *National Intelligence Report* at the rate of $389 for one full year (22 issues). My subscription includes the *National Intelligence Report* newsletter, the in-depth *Focus* insert, news extras as major stories break, and exclusive discounts on other Washington G-2 Reports products.

❑ Check enclosed (payable to Washington G-2 Reports)

❑ American Express ❑ VISA ❑ MasterCard

Card # _____ Exp. Date _____

Cardholder's Signature _____

Name As Appears On Card _____

Name/Title _____

Company/Institution _____

Address _____

City _____ State _____ Zip _____

Phone _____ Fax _____

e-mail address _____

MAIL TO: Washington G-2 Reports, 3 Park Avenue, 30th Floor, New York NY 10016-5902.
Or call 212-629-3679 and order via credit card or fax order to 212-564-0465 04/04B

NATIONAL INTELLIGENCE REPORT (ISSN 0270-6768) is published twice monthly (except August and December which are one-issue months) by Washington G-2 Reports, 1111 14th Street NW, Suite 500, Washington DC 20005-5663. Tel: (202) 789-1034. Fax: (202) 289-4062. Website: www.g2reports.com

Order Line: (212) 629-3679. *Publisher:* Dennis W. Weissman. *Editor:* D.J. Curren. *Managing Editor:* Bowman Cox.

Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 212-244-0360, ext. 200.