#04-7984
P.L. 8400140

To: Walter Vogl, Department of Health and Human Services (HHS)

From: Employers Drug Program Management, Inc. (EDPM, Inc.)

Date: July 12, 2004

Subject: FR Docket # 04-7984

Public Comment: *Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs*

Summary

EDPM, Inc. has been a third-party administrator of alcohol and drug testing services since 1990. We currently service 2800+ client companies and schools throughout the United States. Our services consists of nearly an equal distribution of DOT and non-DOT testing, including some alternative specimen testing such as hair, oral fluid, and POCT testing. Several of our clients understand that the Proposed Rule, while addressing Federal Agencies specifically, will likely have a broader impact both on DOT and non-DOT testing in the near future.

Based on our experience as well as the expressed concerns of HHS, ***EDPM opposes the Proposed Rule in its current form, especially with respect to the allowance of alternative specimen testing technologies.*** We believe that any substantive changes that would have such a far-reaching and dramatic impact on the Federal government as well as DOT and non-DOT institutions need a much more solid legal, scientific, and administrative foundation.

We articulate several specific concerns about the Proposed Mandatory Guidelines for the Federal Workplace Drug Testing Program below, based on our extensive experience in the industry as well as feedback received from several of our clients.

Alternative Specimen Testing

In general, EDPM is concerned that HHS is proceeding with alternative specimen testing while simultaneously explicitly acknowledging the

problems with these methodologies in the Federal Register. The enormous impact of these guidelines, in terms of implications for future DOT-based testing, warrant that any and all new testing guidelines be as rigorously understood, agreed upon, and accurate as the current "gold standard" of urine testing.

One of the primary concerns that we have (which several of our clients have corroborated) is the equivalency in testing across alternative specimens. By allowing multiple options for specimen testing within a particular Agency (and even within a specific test event for a single donor), HHS is implicitly contending that these alternatives will yield essentially the same level of accuracy, reliability, and results. Companies that do drug testing need to be sure that the testing processes they have in place will be defensible, in the legal arena and in their respective work environments. However, given the very different types of tests (with varying detection windows, etc.) and the lack of primacy of a particular alternative, we believe that enabling multiple options may do more harm than good.

Oral Fluid

Oral fluid testing should not be allowed considering that **even HHS does not trust this testing method**. This is evident in the proposed requirement to concurrently conduct a urine screen with an oral fluid screen. As HHS notes in the Federal Register, the concurrent urine screen is needed "in order to protect Federal workers from incorrect test results for marijuana..."

In fact, the underlying rationale in favor of oral fluid testing appears to be "oral fluid testing may be useful in certain missions and tasks that only individual Federal agencies can identify." It does not make sense for the federal government to allow a new testing technology with fundamental deficiencies if the underlying benefits cannot be readily identified. The dual drug screen requirement fails to add value to the process and simply yields higher expenses for employers.

Hair Testing

While a 90-day window for drug detection may be desirable in some circumstances, HHS needs to consider all the ramifications of its proposal prior to implementation.

First, the limitation of the collection process to head hair only will result in serious difficulties for the employer and employee. In society today, it is not at all unusual for males to not have any head hair or an insufficient amount of head hair to effectively conduct a hair test. This would especially hold true of individuals that may be undergoing medical treatments such as chemotherapy. Under the current proposal, an individual with no head hair would require an alternative specimen test.

The problem is that no other proposed testing alternative offers a 90-day detection window (or anything close). Two potential issues arise: the bias of this testing procedure against women (as they are substantially less likely to not have head hair) and employment discrimination based on drug testing. Employees or prospective employees that take a drug test can easily remove their head hair, knowing that once they do, they have a smaller window of detection with other test types. The lack of consistency in testing expectations and application will increase the opportunities and likelihood of discrimination.

One of our clients has also raised the issue of light versus dark hair. This has certainly been a common objection to hair testing and one which HHS even describes as a "major concern." The federal government has a responsibility to ensure that the example set in its testing process will be fully unencumbered by real or perceived racial bias. Given that HHS believes hair testing has "suspected limitations" for this reason, the prudent course of action would be to wait for definitive, independent studies to completely validate the accuracy, reliability, and the lack of color bias in the testing process.

Point of Collection Testing

The proposed guideline for POCT testing notes that an 80% "success" rate in identifying drugs of abuse is sufficient. An 80% reliability rate seems very low as it applies to a critical employment process with such serious consequences for positive results. While it can be argued that laboratory confirmations can address the balance of the tests, the stigma and anxiety that false positives may create for employees warrant a much higher reliability rate.

Another problem with the POCT testing is found in the greater reliance on collectors. HHS does not offer adequate guidance on specific POCT

collector training and compliance, especially when compared to collector training requirements for urine drug screens and breath alcohol tests. Since the collection has typically been viewed as the most difficult and uncertain element of the drug screen process, greater reliance on the collector without very specific training guidelines and requirements is not a good idea.

A third area of concern with POCT is the lack of specificity in discarding collected urine. While the guidelines reference discarding aliquots, primary and split specimens after a negative result, what are the procedures for doing so? Further guidance is necessary to ensure a reliable process.

Finally, there could be potential issues with the integrity of the collection process. Current proposed guidelines permit the POCT tester to break the seal on the primary specimen "after the donor leaves the collection site." However, if the result is a non-negative and requires laboratory confirmation, the donor would not be able to confirm the re-sealing of the primary specimen prior to shipment to a laboratory. Although the collector would sign the new seal, the inability of the donor to reinforce the validity of the primary specimen may seriously compromise the real and/or perceived integrity of the specimen.

Collections and Quality Assurance

CCF Documentation

The proposed guidelines would require separate Chains-of-Custody forms for each type of specimen. This would be a logistical nightmare to implement effectively. The volume of paperwork management, which has been made worse by the failure to increase reliance on electronic documentation and transmissions, already is a daunting challenge for laboratories, collectors, MROs, and TPAs – and this is only with one type of specimen. If this requirement becomes reality, HHS would be ensuring a huge increase in collection errors.

This level of documentation also runs contrary to the 1995 Paperwork Reduction Act of 1995, the purpose of which was "to minimize the paperwork burden for individuals, small businesses, educational and nonprofit institutions, Federal contractors, State, local and tribal

governments, and other persons resulting from the collection of information by or for the Federal Government.

We ***strongly*** urge HHS to rescind this requirement.

Consistency in Specimen Collection

The proposed guidelines would permit an MRO to direct the client (Agency) to have another specimen collected if the first specimen was reported invalid by the laboratory. We urge the HHS to ensure that the same type of specimen (relative to original collection) is collected should a second specimen collection be necessary. The primary aim is to maintain a degree of consistency in the testing process.

Quality Assurance Testing

We believe that the blind quality sample submission requirement of 20% for each type of specimen should *not* be reduced to 1% or even 3% in the near future, at least for the alternative forms of testing. Given HHS' own concerns about some of the newer technologies and their effectiveness, a higher blind quality sample rate is justified. However, as noted earlier, we seriously question the implementation of alternative specimen types in the first place. It seems that even HHS' consideration of such a high blind sample rate indicates a lack of confidence in the alternative technologies.

A 10% submission rate of POCT negative results for Quality Assurance purposes also seems too high for a process that is seen as reliable enough to warrant legitimacy by HHS. This high submission rate also reinforces the lack of reliability of POCT products in drug testing.

Respectfully submitted,

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Subject: HHS Doc #04-7984: Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs

Attached please find a Public Comment document for Doc # 04-7984.

If you have any questions or need anything further, please let me know.

Thank you.

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