

EMPLOYEE SCREENING SERVICES, INCORPORATED

aka The Supply Source and aka ira jane hurst & associates

#04-7984
P.L 8400185

12 July 2004
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BEFORE THE
SUBSTANCE ABUSE & MENTAL HEALTH SERVICES ADMINISTRATION,
HEALTH AND HUMAN SERVICES
Docket Management System, 5800 Fishers Lane, Rockwall II, Suite 815, Rockville, Maryland 20857

MANDATORY GUIDELINES FOR FEDERAL WORKPLACE
TESTING PROGRAMS
[FR Doc 04-7984]

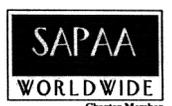
DRUG

COMMENTS OF

EMPLOYEE SCREENING SERVICES, INC.

(A third-party administrator, MRO, collection site which either may provide services to federal employees who fall under drug and alcohol testing regulations.)

Prepared by IRA JANE HURST-ROMERO, C-SAPA, C-SI – PRESIDENT & CEO



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Comment to SAMHSA in reference to FR Doc 04-7984 Continued

INTRODUCTION

This commentary does not address scientific issues as that is not my expertise; it does however address the overall issue of implementation and administration of programs utilizing alternative technology testing programs. It is an undue burden to expect any one person to specifically comment on each and every administrative or implementation detail when the overall concept is in question. My comments include

SPECIFIC COMMENTS IN REFERENCE TO

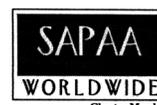
1. THE OVERALL ADMINISTRATIVE AND IMPLEMENTATION CONCEPT PRESENTED IN THE PROPOSED REGULATION
2. INSUFFICIENT CONSIDERATION OF, AND/OR LACK OF INPUT FROM, IMPACTED INDUSTRY (THIRD PARTY ADMINISTRATORS, COLLECTION SITES AND MEDICAL REVIEW OFFICERS) AND/OR FEDERALLY REGULATED EMPLOYERS
3. INSUFFICIENT CONSIDERATION OF INFORMATION REQUIREMENT IMPACT AND EXECUTIVE ORDER 12866: ECONOMIC IMPACT ON INDUSTRY DUE TO REQUIREMENT FOR DEPARTMENT OF TRANSPORTATION (OMNIBUS ACT) TO INCORPORATE ANY FINAL APPLICABLE HHS RULE IN ITS DRUG & ALCOHOL TESTING REGULATIONS

Commentary

Although SAMHSA is responsible for these guidelines, relying on the Drug Testing Advisory Board (DTAB) [which meets at least quarterly] as an important resource and sounding board appears to be shortsighted. The members of that board very rarely, if ever, consist of anyone other than members of SAMHSA and the university or scientific community.

However the rules involve more than science. This rule imposes logistics and practices on third party administrators, collection sites, medical review officers, as well as the manufacturers of POCTs and laboratories. Yet most of the entities involved with logistics, standard operating procedures (other than those used within laboratories and POCT manufacturers) are not represented. It is my belief that the very industry that provides services to the various federal agencies (and individual federal employees) should be involved in providing logistical information as to the means and methods to be used in implementing alternative technologies. After all, the laboratories analyze results; they don't necessarily collect and interpret hair, sweat or oral fluid specimens. Manufacturers understand their products, but not necessarily those of other manufacturers. It can't be successfully argued that understanding a product, maintaining quality control with a manufacturing process or the logistics of supply and demand provides the proper experience and know-how to integrate that product into a successful drug and alcohol testing effort.

Various government representatives, when asked about the lack of industry participation, have long held the option that private industry is only interested in "profit" and therefore, could not or would not provide information in a fair and impartial manner. I must differ with that reasoning! The number of persons who are expert in their fields of endeavor and who volunteer their time and efforts to establish such processes as the Certified Substance Abuse Program Administrator designation as an example are well known. There are persons of character within our industry who would serve in an advisory capacity to bring the



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needed experience to the incorporation of more proper logistics and standard operating procedures for collection sites, TPAs, and MROs than are currently suggested in the NPRM. They should be called upon



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Comment to SAMHSA in reference to FR Doc 04-7984 Continued

associations, which represent the drug and alcohol testing industry (e.g., Substance Abuse Program Administrators Association), are a great resource. These resources are not being tapped by SAMHSA. Unfortunately, scientists and technicians as well as others who do not deal with these issues day after day are the only source for these current proposed regulations. It would be to the program's benefit to implement a 'gold standard' of administration standards and to maintain the integrity of the current drug testing program. This can only be done if persons recognized as experts in the logistics of program administration are consulted in the same manner as the scientists were consulted in the preparation of this proposed rule.

Another example of mis-interpretation is the statement "As the Guidelines received both public and judicial support, the private sector chose to incorporate the requirement to use only a laboratory that has HHS certification under the Guidelines, for employee drug testing." In actuality, it was because so much of the workforce came under DOT regulation (12,135,000 employees) and DOT regulations incorporated HHS guidelines, that private industry undertook to follow a "DOT look-alike" program. Employers who had to test some employees under DOT guidelines, chose to use DOT look-alike programs for the remainder of their workforce in order to forestall accusations of discrimination and to ease the load of day-to-day operations. This then spread to other non-regulated industries. However, it can not be said that all drug testing programs utilize SAMHSA certified laboratories. There is much non-regulated testing which utilizes local, non-certified labs as well as on-site testing devices. While DOT has made a tremendous impact on private industry's drug testing programs, it is not the only version in the public realm. It is critical to understand that only because of the DOT incorporation of SAMHSA laboratory guidelines has HHS had impact on the public sector drug testing programs.

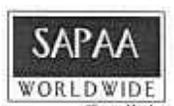
I agree that some information needs collection, however I believe that SAMHSA has once again underestimated the impact. For instance, SAMHSA has based the burden estimates "on the following number of respondents: 38,000 donors who apply for employment in testing designated positions, 100 collectors, 50 urine testing laboratories, 10 hair testing laboratories, 10 oral fluid testing laboratories, 2 sweat testing laboratories, 25 IITFs, 30 POCT manufacturers, 50 POCT testers, and 100 MROs."

Federal employees or applicants live in all corners of the United States and work in many areas of the world. With an estimated 38,000 donors who are applicants, it would be unreasonable to assume that only 100 collection sites would be used. Our firm, in the year 2002, performed 16,121 pre-employment tests utilizing 5,426 collection sites. (I assure you that we are a standard, medium-size TPA.) That's an average of only 3 tests per collection site. Using that same average, it is reasonable that 38,000 federal applicants could use as many as 15,000 collection sites. A 15,000% increase in SAMHSA's estimate of number of collectors or testers would increase to the numbers shown in bold in the table below.

While this rule only cites a requirement to respond in the effect on federal employees, the NPRM itself states that this rule will affect private industry through the Department of Transportation's congressional mandate to utilize DHHS regulations where possible. It is impractical to suggest that a rule which is likely to affect millions of workers not be commented upon in that light. It would also seem to be prudent for HHS to take such comments under consideration as it could be argued that it is critical, when a regulation will affect any other



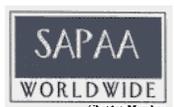
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regulation due to a requirement of law (in this case, the Omnibus Act requiring DOT to utilize



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HHS/SAMHSA standards), that the disclosure for satisfaction of the Paperwork Reduction Act should also include estimates for any rule that will be affected. It is too late to object, change or make comments after the affecting rule forces changes as required by law. The latest estimate of number of employees affected by the DOT regulation is 12, 135,000 which converts to a minimum of a ten thousand (10,000 %) percent increase in the amount of time or cost estimated by HHS. In fact HHS did not estimate a major economic burden to this rule. But if you consider the DOT affect (required by law to adopt) then there is a major cost impact if employers must visit and monitor collection or POCT site compliance especially in light of the fact that DOT regulations affect a minimum of 674,900 employers. And conversely, if the proposed program does not require monitoring, then the integrity of the DOT program comes into question. After all, it is an accepted fact that the collection process (and therefore, the POCT and collection process under this proposed rule) is the main problem area within the current DOT program. Again, expertise from the very industry that this rule will impact would be more than just beneficial. It can make the difference between an unwieldy, litigation promoting, costly regulation and one that carries forward the standards that have evolved within the current federal and DOT programs. Surely it is not the intent of HHS (SAMSHA) to promote one standard for federal employees and another for private industry.

Section	Purpose	No. of Respondents	Responses/Respondent	Hours/Response	Total Hours
4.4(c)	Collector is given name and phone of Federal agency point of contact	100 15,000	1	0.05 (3 min)	5 750
8.2 - 8.5	Collector completes Federal CCF for each type of specimen Collected	100 15,000	380	0.07 (4 min)	2,660 339,000
12.24	Information related to drug test that POCT tester must provide to donor through MRO	50 7,500	10	1	500 75,000



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12.18(c)	POCT tester completes Federal CCF for primary specimen and documents chain of custody for aliquot used for the POCT	50 7,500	100	0.05 (3 min)	250 37,500
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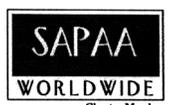
SAMHSA indicates that only 25 Instrument Initial Testing Facilities (IITFs) will “spring up”. Again it is underestimated. In your own words “..it was believed that fewer than 10 laboratories would apply for HHS certification under the Guidelines to conduct Federal employee drug testing, and that the Department would not require even that many to test the urine specimens from all Federal agencies. This situation changed very quickly when the Department of Transportation (DOT) published a final drug testing rule (54 FR 49854) in December 1989 for its regulated transportation industries. DOT required its regulated industries to use drug testing laboratories that were certified by HHS. This requirement began a close relationship between HHS and DOT. Additionally, the Nuclear Regulatory Commission (NRC) in its Fitness for Duty program contained in 10 CFR Part 26 requires its licensees to use drug testing laboratories certified by HHS..... Between July 1988 and early 1990, 50 laboratories had received HHS certification under the Guidelines, while another 100 laboratories were awaiting certification.”

So when HHS states “ Thus the total annual response burden associated with the testing of these alternative specimens by the new laboratories and Instrumented Initial Test Facilities (IITFs) and Point of Collection Test sites is estimated to be 13,888 hours (that is, the sum of the total hours from the above tables). “, it could be underestimating the paperwork impact by 1,826,900 hours. This is more than double the 1,788,089 hours currently approved by OMB under control number 0930-0158 for urine testing under the existing Mandatory Guidelines.

Currently, out of all the certified laboratories in the U.S., two labs that are conglomerates have over two thousand (2,000 patient centers) collection sites between them. It is inconceivable that anyone could be so remiss as to not consider it a possibility those two conglomerates may certify each of these sites as IITFs. After all it could be beneficial to their market share. What number of my estimate of an approximate 15,000 collection sites which may be utilized for the federal program will apply for IITF certification in order to keep their market share? And what number of the over one hundred thousand (100,000) known collection sites currently used by regulated employers will apply for IITF certification in order to perform regulated initial testing via instrumentation. While before HHS only missed the number of certified labs by ninety (90%) percent, you could easily miss the number of IITFs by ten thousand (10,000%) percent

The idea of having federal agencies inspect and keep records for collection sites is expensive, cumbersome and duplicative. If DOT were to take up these regulations, it boggles the imagination to consider over 674,000 private employers inspecting 100,000 collection sites. And how do you consider 674,000 private employers inspecting 15,000 or more IITF's. Who do they report their inspections to? For that matter, how does SAMHSA handle the reports of multiple federal agencies that have inspected the IITF's that they might utilize?

IN SUMMARY, it is not only science that builds a better program, it is the proper implementation of that science and common sense. There are representatives from TPAs, collection sites, MROs and employers who are widely recognized as expert in their various areas of endeavor. This part of the industry which services the federal employee testing programs has not been queried BEFORE THE FACT OF NPRM; therefore, 1) the proposed rule affects a up to 10,000plus percent more people and employers than indicated. 2) the proposed rule does not take into consideration the effect it will have on non-federal



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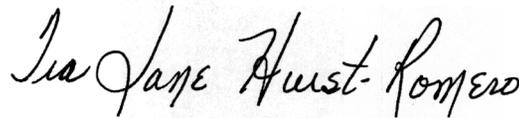
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requirement of law) even though it will have a massive effect on the DOT (and possibly the NRC, NASA rules that affect their contractors' safety sensitive employees); 3) the proposed rule does not effect an information gathering or IITF site monitoring program that can be reasonably implemented yet maintain current standards without undue economic and paperwork burdens; 4) the proposed rule was prepared without industry expertise from the collection site, employer or third-party administrator areas of endeavor (and which is readily available); 5) the proposed rule underestimates the possibility of a new area of industry and its attendant cost to federal employers as well as private employers – the IITF Site Consultant (as happened with the original DOT rule and the appearance of TPAs to administer required programs); 6) the proposed rule more than doubles the impact of additional paperwork and cost when DOT's incorporation of the rule is considered; 7) the proposed rule underestimates the number of respondents; and finally, 8) the proposed rule is unwieldy in the extreme and does not provide an adequate, common sense administrative or administrative system.

While SAMHSA is to be commended for its efforts as well as the thorough scientific investigations that are behind this proposed regulation, it is my opinion that this proposed rule be withdrawn and a new advisory board be convened, not to review scientific issues, but to review and suggest solutions to the methodology used in the operating practices and implementation of alternative testing technologies. This board or panel should also review whether specifying types of occasions when each technology may be used because of detection time limits or whether employers should be allowed to select the one or more technologies they wish to use and accept liability for. After all, for 15 years urine technology has been used effectively with its detection time limits and employers have successfully accepted the liability of those limits. It is my opinion that private industry has found ways to effectively utilize these new technologies. This is experience that needs to be incorporated into these regulations. Inclusion of alternative technologies should go forward and the sooner the better. But it must go forward in a less cumbersome, costly way.

Sincerely,



Ira Jane Hurst-Romero, C-SAPA, C-SI
President and Chief Executive Officer

IJHR:s



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