#04-7984
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To: <WVogl@samhsa.gov>
Date: 7/12/04 6:17PM
Subject: FR Docket # 04-7984

Dear Walt,

Attached please find some comments relative to the above referenced docket.

Best regards,
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COMMENTS ON FR DOCKET # 04-7984

POCT Testing

What are the requirements for "kit" validation in a POCT testing facility? Shouldn't the POCT validate every "kit" for all drugs whenever they change suppliers? How about validation of new lots?

Why is POCT testing exempt from QC requirements imposed on laboratory initial testing? To have equivalency I believe the same QC requirements should be imposed on POCT. If not "practical", then this type of testing should not be used.

How is HHS going to monitor certifications of POCT facilities by the agencies? What are the guidelines for the agencies to use in certifying those facilities? And will these requirements be similar to those used in certified laboratories?

Additionally, it is well recognized that the weakest link in the drug testing process today is the collection. Now we are proposing to make collectors also testers with no oversight on that tester. No requirement for supervisory review procedures, no proficiency testing, no blinds, etc... such as required by a laboratory.

Basically by proposing POCT testing we are creating two standards – one very loose (POCT) and one very stringent (lab testing).

Urine Specimens

Reporting requirements for dilute specimens (creatinine 2 to 20 mg/dL and specific gravity 1.0010 to 1.0030) serves no purpose and could create confusion. I suggest removal of this requirement.

The requirement for reconfirming split urine specimen for nitrite at 500 μg/mL should be changed to 200 µg/mL. Nitrite concentration is known to degrade over time and therefore all nitrite positives at the primary lab testing slightly above 500 μg/mL will most likely not reconfirm upon retesting. This recommended change should be in line with criteria for retesting for drugs.

Oral Fluid Testing

The requirement to collect a urine specimen along with oral fluids makes it virtually impossible to use oral fluids as an alternative specimen. If the reason for such a requirement is justified then oral fluid testing technology might not be ready to be proposed in workplace testing. However, data generated in a clinical trial just completed, show that THC levels in oral fluids post smoking marijuana are actually very high and are persistent for 2-8 hours after use. In the mean time data have been reported that passive

exposure to marijuana smoke showed negative results 30 minutes after exposure. This shows that passive exposure might not be an issue in oral fluid testing given the new data.

HHS should examine all available data today before ruling out oral fluids as a viable specimen even for marijuana without the need for collecting a companion urine specimen.

Although the reason for the requirement to collect neat oral fluid samples is understandable, other collection devices might be available to meet that requirement and should be allowed if the manufacturer could demonstrate equivalency.

Oral fluid specimens might also be viable specimens for follow-up and return-to-duty testing.

SVT Testing

The criteria for SVT testing for specimens other than urine are vague with no specific levels to report and therefore should either be made more specific or should be deleted.

Specimens such as hair and oral fluid are observed specimens anyway. Why do we need to test such specimens for adulteration/substitution?