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725 17th Street NW
Washington, DC 20502

ATTENTION: Desk Officer for SAMHSA
REGARDING: FR DOC 04-7984
DATE: June 28, 2004

The attached document provides comments from the International Paruresis Association (IPA) in response to the Health and Human Services (HHS) proposed guideline changes for drug testing procedures (FR DOC 04-7984). We offer these comments on behalf of the millions of Americans afflicted with paruresis, better known as shy-bladder syndrome, who are physically unable to comply with SAMHSA's proposed guidelines for drug testing procedures. Inasmuch as shy-bladder syndrome is a misunderstood, humiliating disorder, its victims rarely discuss its devastating effects, particularly with employers, for fear of retribution. The IPA seeks reasonable accommodation for these persons through means indicated in the attached comments.

Due to lack of public awareness and significant misinformation about shy-bladder syndrome we have incorporated background information with our comments. The IPA is convinced, after reading drug testing guidelines from both HHS and DOT, that the special needs of paruretics have not been taken into account when drug testing guidelines have been formulated. Over the past several years, the IPA has conducted numerous workshops throughout the United States and several other countries to help people overcome this disorder. We have helped people from all walks of life: psychiatrists, psychologists, police officers, commercial pilots, Armed Forces personnel, lawyers, managers, engineers, scientists, truck drivers, entrepreneurs, artists, and so forth. Many of these people are not drug users, but are unemployed or underemployed simply because they are unable to provide a urine specimen under current drug testing procedures.

The IPA believes this situation is a grave injustice. Existing drug testing rules present a virtually impossible hurdle for those who suffer from shy-bladder syndrome and too often these rules have resulted in drug-free workers losing long-term careers or not being able to enter the labor pool. This practice is unfair for those people who have never taken illegal drugs but simply cannot prove their innocence by providing a urine sample under the current or proposed guidelines. We would be remiss not to mention the large volume of phone calls, letters, email, and posts on our Web site from persons in this category. We believe that current drug testing rules shortchange workers and employers and do not allow for reasonable accommodation. As a result, many organizations now face legal proceedings that would be unnecessary if drug testing guidelines were written with an understanding of shy-bladder syndrome. The need for better written rules is all the more essential as increasing numbers of public schools are mandating drug testing as a condition for participation in extracurricular activities.

In reading our comments, please keep in mind that as an organization the International Paruresis Association is neither for nor against drug testing. Our issue centers on how drug testing is done, not whether it is done. Now is the time to promote drug testing rules that are fair to all.

We thank you for the opportunity to provide our comments and hope that you will take them into account when making final revisions to the drug testing guidelines. Please contact us if further information is needed.

Best regards,

Thomas Achatz, IPA President Steven Soifer, IPA Executive Director

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DATE: June 28, 2004

TO: DEPARTMENT OF HEALTH AND HUMAN SERVICES
Substance Abuse and Mental Health Services Administration

SUBJECT: Public Comment on: FR Doc 04-7984, Mandatory Guidelines for Federal Workplace Drug Testing Programs

FROM: Dr. Steven Soifer, IPA Executive Director
Thomas Achatz, IPA President
Philip Baumgaertner, Drug Testing Committee Chairperson

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PREAMBLE: BACKGROUND AND THE FUTURE OF SHY BLADDER DRUG TESTING

BACKGROUND

The International Paruresis Association (IPA) is a 501(c)(3) non-profit organization whose purpose is to help those afflicted with paruresis overcome the stigma, embarrassment, and isolation associated with the condition by educating the public, advocating effective treatments, and advancing related research. Since the founding of IPA in 1996, we have grown to 800 members within the USA. Approximately 43 IPA Support Groups are operating in the United States. The United States IPA was the first paruresis organization in the world, but since 1996, paruresis organizations have formed in 11 foreign countries. A 10-member Board of Directors, and a 26-member Advisory Board, presently govern. Eight members of these Boards are physicians specializing in urology and psychiatry. Ten members of these Boards are doctoral-level or equivalent psychologists. Other members of both Boards are professional therapists, scientists, engineers, attorneys, and laypersons who are in recovery from shy bladder disorder.

Paruresis is a term meaning abnormal urination. Paruresis has been used in medical journals as the technical medical term for shy bladder. In this document, we will generally use the common terminology of the drug testing industry, "shy bladder." We use the term, “paruretic,” to refer to someone who suffers from paruresis or shy bladder.

Shy bladder is estimated to afflict 7% of the population or upwards of 17 million people in the United States. One and one half million Americans (1/2 % of the population) suffer from a severe form of shy bladder that limits their social and occupational choices (1-3). Moderate forms of shy bladder often become temporarily severe when the sufferer must produce urine specimens on demand for employment drug testing purposes. Mild forms of the disorder have been known to worsen dramatically as a result of badly implemented and flawed shy bladder, urine collection protocols. As a result, many otherwise employable people are unable to join the workforce, remain underemployed, or elect to be self-employed.

Far from being a new disorder, reports of shy bladder go back to the 1920s in professional journals, much earlier than that in literary works, and even in biblical tractates. Shy bladder causes people to keep it a secret because of shame associated with a private body function. Shy bladder is becoming more known because of anxiety treatment organizations such as the IPA, and because urine drug testing is expanding at a tremendous rate into the correctional system, pre-employment applicant screening, employee monitoring, athletics, and recently even into school systems. Until a short while ago, it was possible for a person with shy bladder to hide the condition from others, and thus it only affected the sufferer. Today, that is rapidly becoming impossible and many people with this disorder as well as their families face life-altering consequences such as loss of a job, denial of benefits, or exclusion from school activities.

Shy bladder is a very misunderstood disorder. Unfortunately, ignorance of the syndrome is widespread, even within the medical community, and most surprisingly, within the urology community. Indeed, one objective of IPA is to work with medical doctors and therapists who have experience in treating shy bladder so awareness can be increased and treatment can be optimized.

> *Shy bladder seems to be due to an excessive inhibition of micturition by the brain's centers, and by an overactivity of the orthosympathetic system (stress), which relaxes the detrusor and tightens the sphincters. The psychological background of the disorder is evident: it has characteristics of a social phobia. And underlying organic trouble is indeed quite seldom found (4)*

In essence, shy bladder is a social phobia with true mind-body characteristics. Shy bladder is probably a learned voiding dysfunction similar to, but not identical with, non-neurogenic neurogenic bladder, which is sometimes referred to as the Hinman syndrome. With Hinman’s, there is a psychogenic urinary retention that centers on inability of the bladder to perceive that it has not been fully emptied, as with true urinary retention. In

shy bladder the dysfunction involves both of the sphincters and the bladder. There is a known 2% prevalence rate for learned voiding dysfunction among adults, but the actual prevalence is undoubtedly somewhat higher (5). Thus, paruresis is also a medical condition, and can be classified as a chronic pelvic floor dysfunction too.

The neurophysiological and neuromuscular coordination between mind and body necessary to initiate and maintain micturition are incompletely understood, exceedingly complex, and not under voluntary control. The major flaw in current drug testing is the false assumption that control of urination is entirely voluntary. Of course, it is not. (12). In a typical shy bladder scenario, a person who suffers from shy bladder finds that they are unable to void, often notwithstanding an extreme sense of urgency. Indeed, urgency may trigger a vicious cycle of abnormal hyperreflexia of external and internal sphincters, and reflex relaxation of the bladder muscle (to reduce the sense of urgency) which render voiding impossible. In some very rare instances this hyperreflexia of the sphincters may be severe enough that it will prevent the passage of a urinary catheter resulting in a true medical emergency (personal experience of one of the authors of this document).

Those with shy bladder symptoms are only a fraction of the population who cannot reliably control their urination. Those persons with multiple sclerosis, diabetes mellitus, paraplegia, quadriplegia, prostate enlargement, urethral strictures, herniated discs, and strokes are also often unable to control their urination. It is very likely that some individuals labeled as "shy bladder" by collectors belong to these other medical categories. Indeed, one of our dedicated IPA members learned, about a year after joining IPA, that his real medical problem was multiple sclerosis. Governmental reliance on urine as the "gold standard" for drug testing therefore sometimes results in outright employment discrimination for those with disabilities. A robust drug-testing program *must* not rely on a single drug testing method, e.g. urine, to test all personnel, if such reliance results in discrimination against people who do not use drugs.

It does no good to insist that the paruretic drink to excess, as it is a widespread fiction that drinking enough water will cause anyone to urinate. Such thinking has in the past sent more than one paruretic to an emergency room, a situation in which the drug testing company and perhaps, SAMHSA itself may be liable for damages. Threats to a paruretic's employment or career do not help to mitigate the hyperreflexia. Indeed, under such stress, the lock-up becomes impossible to overcome. Only when the paruretic is removed from the source of anxiety (usually to a place of complete privacy), and/or upon removal of time pressure of any sort (e.g., the three-hour rule in shy bladder regulations), and/or with the removal of visual or auditory cues, can the paruretic void. These conditions are seldom achieved (nor are they achievable) within the context of present urine drug testing procedures.

Employment drug testing of paruretics based on urine sample collection methods has produced a litany of horror stories, brought to our attention by people who have been disciplined merely for their inability to produce a urine specimen on demand, with no evidence whatsoever that they were drug abusers. Even clear proof that the applicant or employee was drug free at the time a sample was demanded (and drug free their entire

life), has often been rejected by Human Resource Personnel, and MROs uneducated and naïve in their knowledge of shy bladder, and determined to back up a company's disciplinary policies. Then, punitive steps have followed. It amazes us that production of a urine specimen has become a more important factor in employment considerations than clear evidence that the tested individual is not a drug user.

Currently, there are no objective physiological tests for shy bladder, and this fact has complicated the situation when it comes to policy making with respect to mandatory urine-based drug testing and reasonable accommodation for paruretics. Some urologists and many Medical Review Officers erroneously believe that there are objective tests for shy bladder. **There are currently none.** This fact neither stopped a group of Medical Review Officers from posting upon their Website erroneous information that shy bladder could be diagnosed by cystoscopy, nor has it prevented periodic claims that it can be diagnosed by urodynamic evaluation. Indeed, to the contrary, Rosario et al. (4) found, "The contribution of ambulatory urodynamic monitoring compared to more conventional evaluation in men younger than 48 years of age is NEGLIGIBLE." (Our emphasis.)

Since the implementation of SAMHSA regulations for drug testing of Federal employees and job applicants more than 15 years ago, SAMHSA's regulations have become a standard for employment drug testing in the private sector, and some in Congress are now proposing their use in schools. Therefore, SAMHSA regulations, which generally make no provision for the accommodation of applicants and employees who suffer from shy bladder, adversely influence employment opportunities of shy bladder Americans throughout the entire population, and may affect our children in the future. SAMHSA regulations on drug testing for the Federal Workplace, especially as applied by the private sector, have resulted in numerous incidents of outright unlawful discrimination, job loss, violation of the Americans with Disabilities Act (ADA), violations of the Rehabilitation Act, and violations of individual state law as demonstrated below, with an example from a New Mexico court case in which the jury found for the paruretic plaintiff and awarded substantial punitive damages (7).

Too often, the conduct of urine collectors and MROs towards us has been, to say the least, "peculiar." Emotional distress is deliberately or negligently inflicted on those paruretics who hold or attempt to apply for positions where testing is conducted under SAMHSA regulations or under rules the private sector claim are consistent with SAMHSA regulations (6). Further, denial of employment, threats of dismissal, and actual firing when urine samples are not produced, and institutional refusal to grant requests for accommodation, inflict emotional and economic harm on us and are wrongful.

Those of us with shy bladder used to lead quiet secretive lives, often not telling spouses, relatives, doctors and certainly not employers about our secret social phobia. In the 1980s changes in national policy were made resulting in more commonplace use of urine samples to test job applicants and existing employees for illegal drug use. This implementation of national drug testing put a spotlight on those with shy bladder syndrome.

Suddenly, we found that fewer companies would hire anyone without a urine test. Those of us who acquired jobs before the 1980s suddenly found ourselves subject to firing if we could not provide a urine sample at the next random drug test. Those of us with long-term Federal positions and no history of illegal drug use, who thought we were secure, suddenly found our positions threatened by random urine testing. It was not just our own welfare that was at stake, it also threatened our family's welfare, all for the sake of a cup of urine.

We realized that somehow we had become an unwelcome obstacle in the nation's war on illegal drugs. Urine testing would be so much easier for companies and testing contractors if there were not 'these difficult people' who come out of the restrooms with empty sample bottles and 'wimpy excuses.' Many times we receive sarcastic comments at testing stations that imply those of us with shy bladder are either troublemakers or illegal drug takers that do not want to be tested.

This is the harsh reality for those suffering from shy bladder, even if it differs from what SAMHSA intended, or what people of good will at SAMHSA would have wanted. We wonder if anyone with a background in medical sciences has reviewed the literature on shy bladder for SAMHSA with a view toward actually understanding how to make testing a possibility for us, rather than shunting us off as uncooperative test takers. There are at least 60 relevant manuscripts, going back several decades, on the subject in the medical and social science literature. One reference, "Fears Phobias and Rituals: Panic, Anxiety and their Disorders," by Isaac Meyer Marks, pp.388-389, describes a woman who routinely held her urine for as long as 48 hours. We have a nearly complete bibliography, Enclosure (2), at the end of this document.

How disheartening that despite attendance by IPA at DATIA and other relevant meetings in the last few years, the latest proposed guidelines were prepared without anyone from SAMHSA taking the simple step of inviting IPA staff to provide assistance. IPA currently has the highest shy bladder membership, 800, of any organization in the nation (and for that matter, the world) and offers its consultation and experience free to any government agency.

We understand that SAMHSA has no direct control over the behavior of the private sector, but historically SAMHSA's regulations have been adopted for use by DOT for testing in the private sector of the transportation industry, and elsewhere in the private sector. Hence, SAMHSA's rules are applied in situations where reasonable accommodation is legally required. Soon Congress may mandate the use of SAMHSA rules in school testing. Accordingly, SAMHSA has a special responsibility to make certain that regulations promulgated by it for the Federal workplace also provide "reasonable accommodation" for shy bladder as legally required for the application of its regulations to the private sector. Therefore, the rules need to be changed to eliminate drug testing discrimination practices as described in the Comment section below.

For shy bladder donors, the most vexing aspects of current SAMHSA regulations are:

1) The unjust insistence by SAMHSA, employers, and MROs that failure to provide a specimen equates with refusal, and that such "refusal" is grounds for not hiring or for firing.
2) The "shy bladder protocols" which require shy bladder donors to remain at a testing site for three hours, even though in many cases the testees are in severe pain of urgency and cannot produce a sample. Many paruretics find this physically arduous and mentally devastating, in short—barbaric.
3) Failure of SAMHSA to provide for the mandatory use of alternative testing technology to any applicant who requests accommodation for a shy bladder condition.
4) Failure of SAMHSA to provide for medical evaluation of a paruretic, at which time a nurse or physician could obtain blood or urine samples.
5) Absence of specific regulations permitting people to provide urine samples by self-catheterization, which is how many paruretics routinely empty their bladders.
6) Failure to accept reasonable documentation or written statement from personal. physicians that: a) the employee or applicant suffers from shy bladder; b) the employee or applicant has been examined and is not believed to be a user based on clinical criteria.
7) An unfortunate institutional mindset at SAMHSA (and certainly within the MRO community) that has for the most part been very skeptical of the validity of shy bladder syndrome.
8) Inadequate training requirements for urine collectors. [see details below]
9) Lack of adequate, if any, administrative appeal process and redress.
10) High false positive testing rate for shy bladder donors. [see details below}

With regard to #1 in the preceding list, the insistence by SAMHSA that inability to provide a urine specimen is grounds for not hiring or for firing is logically absurd. This policy is the single most offensive provision to those who suffer from shy bladder. It is, to be plain, unjust!

With regard to #1, #2, #3 and #4, SAMHSA and others have confused an "inability to provide a sample" with "refusal" to provide a sample. As a practical matter, SAMHSA regulations provide inadequate avenues for the paruretic to explain the situation, to have the case reviewed by a physician who is knowledgeable about shy bladder, or to provide basic documentation, which many paruretics lack because they are too ashamed of their condition to seek medical help. As best we can determine, no provision for administrative review has been made. What makes the situation even worse is the fact that many paruretics hold an erroneous belief that they are the only person in the world so afflicted, and therefore they do not seek medical help. Hence, when they are caught in a situation where a urine sample is mandated, they can neither provide the sample nor provide prior documentation of their condition. SAMHSA's regulations have caused many experienced employees to be fired, and a number of these incidents have been reported in the popular press. We mention this because it is illustrative of an unthinking approach to testing which utterly fails to provide reasonable accommodation for disability of a major bodily function in violation of ADA, numerous state laws, and the Rehabilitation Act.

With regard to #8, at the recent April 2004 DATIA Convention in Seattle, the IPA Representative, Phil Baumgaertner, asked the assembled DATIA Board of Directors (BOD) if he would be allowed to catheterize himself to provide a urine sample. One of the BOD members, a Medical Doctor, replied that this would be allowed, since it often comes up with disabled people at her company. Another BOD member replied that his company would not allow an individual to use a catheter. A member of the DATIA audience then replied that her company allows the use of urinary catheters by disabled persons. One of our IPA members, who is an 18-year DOT employee, states that in his actual attempts to use a catheter, some drug testing sites will allow the use of urinary catheters and others will not. (IPA has since found limited catheter guidance in DOT Regulation Title 49 CFR Part 40 Section 40.61 Paragraph (b) 3 which allows the use of a urinary catheter for DOT- related testing.) It is clear that training of collectors is inconsistent regarding the treatment of Americans with disabilities. In any case, we see no specific provisions for individuals to provide samples by catheterizing themselves within the proposed SAMHSA rules. Since self-catheterization is a useful technique that would enable people with a variety of health issues to participate in testing, uniform rules to insure that catheters can be used are essential.

With regard to #9 and #10, we are struck by the commendable care used by SAMHSA in the detailed quality requirements imposed on record keepers and testing labs to reduce false positives. We saw that same care again in the proposed changes over the concern regarding the effect of environmental THC on oral fluid testing. But we are at a loss to explain why SAMHSA does not see shy bladder as a huge false positive issue for the industry.

> *A real life example: On Thursday, 13 May, 2004 in Las Vegas, Nevada, two female collectors stood 4 feet outside the stall in a men's restroom, reportedly waiting impatiently for a man (we will call him Tom, not his real name) to produce a urine sample. Tom was just 1 of 7 male job applicants that day who were all tested in the men's public restroom by two female urine collectors. Two of those 7 male job applicants for a DOT job were unable to provide a urine sample under test site privacy conditions, and verbally complained to the collectors within hearing of each other. The Nevada company refused to give us any information on the second man, but Tom was told that his contingent job offer was withdrawn. Tom's complaints are that female collectors were used to monitor his urine test in a public men's restroom, which is prohibited by HHS and DOT regulations. He was not offered the opportunity to get a medical evaluation as required by DOT regulations, but paid $75 himself to a local drug testing lab for a hair test, which was negative. Neither Tom nor IPA know of any governmental agency that deals administratively with testing complaints. IPA calculates that the false positive rate for the transit company's drug testing that day was 2 divided by 7 or 29%. A 29% error rate for employment testing is an unacceptable level of false positives. (13)*

Our opinion on the above issues has very recently been bolstered by a jury verdict against Presbyterian Health Services Inc. in the State of New Mexico in March 2004. Briefly,

this hospital was sued after it fired a paruretic physician for failing to provide a urine specimen for mandatory drug testing. The jury found: a) that shy bladder is a serious medical condition, b) the hospital acted negligently in a manner that deliberately inflicted emotional distress, c) the hospital violated the New Mexico Human Rights Act. The jury awarded the plaintiff actual damages of $156,000 plus $100,000 in punitive damages (7). Similar cases are pending against other defendants. One incident at Caterpillar has received a fair amount of attention in the press and is being litigated (8). Caterpillar, Inc, chose to ignore three clinical tests that showed no drug use by a shy bladder employee, and instead fired the employee and requested the state not to provide unemployment insurance. A judge overruled Caterpillar's request not to provide unemployment insurance, and the dismissal is being litigated under the ADA. We believe that rational people operate Caterpillar Corporation. If we ask ourselves, "Why do rational people feel that they should punish shy bladder donors for failure to produce a urine sample?" we are left with just one explanation. Caterpillar Corporation managers must consider that shy bladder donors are troublemakers who are deliberately choosing not to provide a urine specimen. That is the crux of the problem facing IPA members in many areas of life. How do we convince the majority of the population that can urinate freely, and under their own volition, that a small percentage of the population, perhaps 7 %, are not fortunate enough to have that same natural ability? We provide Enclosure (2), which includes 60 research papers going back to 1922 as solid evidence for SAMHSA that shy bladder is not a fad, but a real, troubling disorder for many of us. We deserve the opportunity to apply for and accept jobs like anyone else in our free country.

It is possible that SAMHSA regulations preempt state human rights laws when testing is done for Federal agency employees. It is also quite clear that Federal agencies conducting testing under SAMHSA regulations are not bound by the Federal Americans with Disabilities Act. IPA notes that Section 504 of the Rehabilitation Act of 1973 prohibits discrimination against an otherwise qualified individual with a disability, solely on the basis of the disability, in any program or activity that receives federal financial assistance, the executive agencies, or the U. S. Postal Service. Certainly the moral intent of both laws, the ADA and the Rehabilitation Act, to remove discriminatory acts from the employment arena has been overlooked when promulgating previous urine-based drug testing rules. And, when private testing companies rely on Federal regulations and attempt to use SAMHSA procedures in the private unregulated sector, they set themselves up for inevitable ADA suits and other claims that the Federal agencies would be immune from.

Therefore, SAMHSA has special responsibilities to transcend the narrowest of these loopholes and promulgate regulations that will not put employers in legal jeopardy, and disabled employees in impossible situations. We think that SAMHSA has an ethical obligation, if not an affirmative legal requirement, to promulgate shy bladder policy and drug testing regulations that are accommodating, consistent with the goals of the Americans with Disabilities Act, and not in violation of state statutes that protect worker rights. At the same time SAMHSA regulations should not be in conflict with ordinary common sense, ordinary understanding of fairness, or ordinary decency, and they should not be illogical with respect to failure to provide specimens, as the present regulations

appear to be. We sincerely hope that SAMHSA will work with IPA to utilize SAMHSA's new Alternative Tests, especially oral fluid tests, to relieve the discriminating effect of urine testing on shy bladder donors.

SAMHSA's own website proclaims,

> *The Substance Abuse and Mental Health Services Administration: Promoting a Life in the Community for Everyone*

Nonetheless, existing drug testing policies slam the door to employment on those who suffer from shy bladder, which is a real mental health problem (9) and a serious if not devastating difficulty within the context of urine testing.

How ironic it is that SAMHSA, whose mission is,

> *Built on the principle that people of all ages, with or at risk for mental or substance use disorders, should have the opportunity for a fulfilling life that includes a job, a home, and meaningful relationships with family and friends* (10),

is now indirectly engaged in KEEPING people from employment by continuing to allow agencies to use urine testing for shy bladder donors.

How ironic it is that while SAMHSA operates The Center for Mental Health Services (CMHS) with the stated mission to

> *head efforts to speed the application of mental health treatments for persons with mental illness* (10),

SAMHSA has operated with near total indifference to the needs of those who suffer from shy bladder disorder.

Present and proposed SAMHSA drug testing regulations actually encourage Federal agencies and private employers to discriminate in hiring and retention against those who suffer from shy bladder. How, we ask, do these policies promote "a life in the community for everyone?" They do not. They do the opposite.

How ironic it is that under SAMHSA protocols, NO accommodation is provided, and worse, according to the proposed rules,

> *…if a donor tells the collector, upon arrival at the collection site, that he or she <u>cannot provide a specimen</u>, the collector must begin the collection procedure [ANYWAY] regardless of the reason given. …Once these procedures have identified a "Shy Bladder" applicant, the*

agency is to ***drop employment efforts for any shy bladder applicants*** *(11).* (emphasis added)

What we have is a Government agency that is authorizing and promoting employment discrimination against those who suffer from a fairly benign mental disorder, a social phobia, because it interferes with the smooth operation of urine testing procedures.

The proposed SAMHSA guidelines discuss the problems of (a) allergic reactions to sweat patches, (b) insufficient saliva (dry mouth), and (c) insufficient head hair, (d) and even issues related to passive presence of marijuana in oral fluid. The approach to these matters is relatively simple and objective. What is it about shy bladder that justifies the present logically flawed, almost obsessive, insistence that a urine specimen must be produced when there now exist several reasonably acceptable and effective alternative tests?

It would not compromise testing to mandate that when a person can produce documentation to support a medical condition which compromises their ability to produce an adequate volume of urine, the test should be cancelled, and an alternative testing method then must be used. In fact, a more general set of rules could say, "If an individual cannot perform one particular type of test, then another test must be used." Such a change in regulations could be made easily, would apply to all regardless of their particular problem, and would not compromise testing integrity.

THE FUTURE OF SHY BLADDER DRUG TESTING

IPA exists as a service and resource to the shy bladder community. We have a lot of work ahead of us to increase public and governmental awareness of this disorder, to research the specific nature of shy bladder, and to develop optimal treatment methods for the disorder. Yet, about one- third of our time and resources are being diverted in order to deal with drug testing complaints from our members. As a nonprofit organization, we would much rather spend our very limited resources doing other things. We are currently seeing three trends: (1) more lawsuits this year than ever before, (2) increased discontent by members with shy bladder employment discrimination, and (3) a steadily increasing membership and website hits (1000 hits per day). As a result, IPA staff are increasingly being called on to act as expert witnesses in shy bladder employment lawsuits.

IPA would strongly prefer to work with HHS, SAMHSA and DOT to develop regulations designed to eliminate shy bladder employment discrimination, and thus end the emerging trend of these lawsuits. We have experienced professional staff, and psychiatrists, psychologists, and lawyers capable and willing to work with HHS and DOT in a *cooperative* manner to eliminate the regulation problem areas. Some of these staff have previously worked or are currently working as Federal employees and are experienced in drafting policies and regulations, and include scientists capable of understanding the intricacies of forensic toxicology. The decision to collaborate with the IPA is in the hands of HHS, SAMHSA and DOT.

Fortunately, the future is not as bleak for paruretics as it once was. The following are good indicators:

a. The DOT Title 49 Part 40 Regulations in paragraph 40.193 and 40.195 cover shy bladder by referring such cases to a medical office or properly qualified MRO. At a medical office, someone with a "urinary system dysfunction" can receive "an alternate test (e.g. blood)". Jim Swart, acting Director of the HHS ODAPC office, indicated at the April 2004 DATIA Conference that blood, or any other alternate test such as saliva, sweat, or hair could be used in a medical office and that was OK to his staff.

b. HHS and SAMHSA's issue of the Notice of Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs, in the Federal Register dated 13 April 2004, provides a strategically important step (the technology of alternate tests) that *could* allow shy bladder donors a way to participate in drug testing. We still have several concerns about how this technology is deployed and those comments are provided in the Formal Comment section below.

c. Recent positive decisions from judges and juries indicate that America's legal system understands that "shy bladder" does not equal being a "drug user".

The International Paruresis Association applauds many of the proposed regulatory changes to which we are responding. As an organization, we in no way oppose drug testing or the goal of drug-free working environments. We are gratified to see that alternative drug tests using hair, sweat, or saliva would be allowed under limited conditions. Our goal is to expand the use of non-urine based alternative tests to enable shy bladder donors to participate in drug testing at normal collection sites without the need for unnecessary, inconvenient visits to medical clinics. IPA has provided a suggested Shy bladder Protocol in Enclosure (1). This approach is seen by IPA as the surest way to avoid employment discrimination against shy bladder donors. [Presently, some testing companies do not even tell shy bladder donors that they have a right to a medical evaluation, and this needs to change.]

The new proposed revised regulations need to be changed before we can accept them without court challenge, before they are fair to all, before they are legal when applied in the private sector (as they surely will be), before they are humane and decent especially when applied in school testing, and before they are consistent with the moral intent (if not legal intent) of ADA and the Rehabilitation Act. Among other things, on pages 29, 61, and 106 it is written that under shy bladder situations, permission can be obtained from the agency for an alternative sample. Nothing is proposed that says the agencies MUST use alternative tests, nor is anything said about the type of documentation or evidence needed before the alternative test will be granted. These issues need clarification, and we do not believe that putting paruretics through a three-hour ordeal, which seems to be the present initial step in determining shy bladder, is an appropriate approach.

We now respond to the proposed regulatory changes and to Mr. Currie's preamble in detail.

FORMAL COMMENTS

NOTES:
(1) Wherever possible, IPA has put new suggested wording in italics so that changes are easier to find.

(2) The page numbers used below are from the PDF file(2004/pdf/04-7984.pdf) that was provided on the SAMHSA website. These page numbers may not be identical to the pagination in the Federal Register.

(3) For clarifying discussions to these comments, IPA provides contact information in Enclosure (3) to this letter. We have a Drug Testing Committee and we will respond as quickly as possible to all questions and comments.

IPA COMMENT 1

HEADING: Oral Fluid

Paragraph from Heading: 5th

Page: 14

Current Wording:
In order to protect Federal workers from incorrect test results for marijuana, the Department proposes that a second biological specimen, a urine specimen, will need to be collected under the current guidelines....

New Wording OR COMMENT: (Delete the above proposal for a second biologic specimen)

Justification:
IPA believes that no second biologic specimen to saliva testing is required based on a review of ORASURE data and the current scientific literature on the subject. It is undesirable to require a second biologic sample since it would double the drug test cost and the proposed urine specimen will rule out the use of oral fluid testing by shy bladder donors who need this test in order to participate in drug testing. Employers will regard the second biologic sample requirement as a disincentive to accommodate shy bladder sufferers because processing two samples involves extra time and money. We have considered the technical issues raised concerning alleged problems with oral fluid testing and "second hand" contamination of the oral cavity with marijuana during social situations. A way to address this concern would be to require a second sample only in the rare event that the saliva sample tests positive for THC. This procedure would eliminate

most of the extra cost because it would be applied only rarely. This sample would need to be blood, hair, or sweat if the applicant has shy bladder. A number of private sector companies are switching their drug testing programs entirely to saliva.

If the Department insists on a second biologic sample to back up oral fluid, then SAMHSA should mandate agencies to use a second biological specimen other than urine for donors demonstrating or asserting that they suffer from shy bladder. Hair and sweat tests have deterrent attributes to them that should discourage donors faking shy bladder. Hair (90-day effective monitoring) and sweat (7-day monitoring or as long as the patch is worn) tests monitor illegal drug use by donors for a longer period of time than urine (3 - 5 day effectively) testing and therefore donors falsely claiming shy bladders are putting themselves more at risk of discovery. In addition, the effect of hair specimens on one's cosmetic appearance and the need for continuous wearing of a sweat patch will deter false shy bladder claims. In unusual situations (e.g. accident investigation), the agency may send the donor to a medical site for a blood test. Any of these options are preferable to a shy bladder donor than not obtaining or losing employment.

IPA COMMENT 2

Heading: Oral Fluid

Paragraph from Heading: 8

Page: 15

Current Wording:
The Department finds that the collection difficulties associated with oral fluid collection procedures are not functionally different than other specimen collection difficulties currently encountered with urine. Therefore, despite these known limitations, the Department proposes to incorporate this new technology as an optional selection for Federal agencies because oral fluid testing may be useful in certain missions and tasks that only individual Federal agencies can identify.

New Wording:
The Department finds that the collection difficulties associated with oral fluid collection procedures are not functionally different *from* other specimen collection difficulties currently encountered with urine. Therefore, despite these known limitations, the Department proposes to incorporate this new technology as an optional selection for Federal Agencies. *However, the use of oral fluid is MANDATORY for Federal agencies when examining job applicants and employees who claim to suffer from shy bladder, other learned voiding disorders, or other ailments that would make collection of urine difficult or impossible.* Oral fluid may be useful in certain missions and tasks that only individual Federal agencies can identify and they may substitute oral fluid for urine as appropriate to their missions.

Justification:
Shy bladder donors and others who suffer from learned voiding dysfunctions and certain patho-physiological processes typically cannot provide a urine sample. Therefore, oral fluid tests must be available for that portion of the population that cannot reliably provide a urine sample under testing conditions. Allowing agencies an option to choose only urine samples effectively discriminates against shy bladder job applicants. Even though DOT currently has the most shy bladder friendly regulations in the nation, with its option to send a shy bladder applicant for medical clinic evaluation, we are getting complaints that collectors and DERs are not informing job applicants of this option.

The best way to end job discrimination against shy bladder job applicants based on experience with the 2001 DOT regulations is to end the practice of requiring shy bladder donors to go to a distant medical clinic. Instead, Federal departments must provide alternate tests (e.g. oral fluid) such that shy bladder donors can participate in drug testing at the collection site, along with everyone else.

IPA COMMENT 3

Heading: Sweat

Paragraph from Heading: 5

Page: 17

Current Wording:
Despite these known limitations, the Department proposes to incorporate this new technology as an optional selection for Federal agencies because sweat testing may be useful in certain missions and tasks that only individual Federal agencies can identify.

New Wording:
Despite these known limitations, the Department proposes to incorporate this new technology as an optional selection for Federal agencies because sweat testing may be useful in certain missions and tasks. *Sweat is proposed as a MANDATORY option in situations where urine, oral fluid, or hair either cannot be obtained (e.g., shy bladder and similar conditions; baldness, reasonable cosmetic concerns) and when oral fluid does not detect the agent(s) or metabolites of primary interest to the examining agency.*

Justification:
Shy bladder donors and others who suffer from learned voiding dysfunctions and certain patho-physiological processes cannot typically provide a urine sample, therefore choosing urine as the biological sample discriminates against employment of shy bladder donors. Agencies cannot be left the choice to discriminate, and therefore sweat testing must be one of the mandatory options agencies must choose for applicants and employees who cannot provide other types of specimens or who choose to refuse to provide hair specimens for cosmetic or health reasons.

IPA COMMENT 4

Heading: Sweat

Paragraph from Heading: 10

Page: 18

Current Wording:
Sweat also appears to be well suited for return-to-duty and follow-up testing for workplace testing.

New Wording:
Sweat also appears to be well suited for return-to-duty, follow-up testing, *and for shy bladder donors who are not able to produce a urine sample*.

Justification:
Under the existing regulations shy bladder donors, through no fault of their own, have been unable to get or retain jobs under existing urine testing rules. Existing discriminatory rules need to be changed to provide reasonable accommodation for shy bladder donors.

IPA COMMENT 5

Heading: Advantages of POCT's

Paragraph from Heading: 3

Page: 22

Current Wording: In order to protect Federal workers from incorrect test results for marijuana, a second biological specimen, a urine specimen, will need to be collected at the same time the oral fluid specimen is obtained.

New Wording: (Delete the above wording)

Justification:
IPA considers that no second biologic specimen to saliva testing is required based on a review of ORASURE data and the open scientific literature. It is undesirable to require a second biologic sample since this will require greater cost and rule out the use of the saliva test for the shy bladder donors who need such a test in order to participate in drug testing. We have considered the technical issues raised concerning alleged problems with oral fluid testing and passive contamination of the oral cavity with marijuana during social situations.

If the Department insists on a second biologic sample, then IPA requests that the Department MANDATE agencies to choose a second biologic specimen other than urine for donors demonstrating or claiming shy bladder. Hair and sweat tests have deterrent attributes to them that should discourage donors faking shy bladder. Hair (90-day effective monitoring) and sweat (7-day monitoring or as long as the patch is worn) tests monitor illegal drug use by donors for a longer period of time than urine (3 - 5 day effectively) testing and therefore donors falsely claiming shy bladders are putting themselves more at risk. In addition, the effect of hair specimens on one's cosmetic appearance and the need for continuous wearing of a sweat patch will deter false shy bladder status claims. In unusual situations (e.g. accident investigation), the agency may send the donor to a medical site for a blood test. Any of these options are preferable to a shy bladder donor as opposed to not obtaining or losing employment.

Under the existing regulations shy bladder donors, through no fault of their own, have been unable to get or retain jobs under existing urine testing rules. Existing discriminatory rules need to be changed to allow shy bladder donors and others with disordered micturition to qualify for jobs.

IPA COMMENT 6

Heading: Subpart B - Specimens - Major Change

Paragraph from Heading: 1

Page: 26

Current Wording:
In Section 2.1, the Department proposes to expand the urine drug-testing program for Federal agencies to permit testing head hair, oral fluid, and sweat specimens. The Department wants to make it clear to agencies that there is no requirement that they use hair, saliva, or sweat as part of their drug testing program, but rather, that agencies may use those specimens.

New Wording:
In section 2.1, the Department proposes to expand the urine drug-testing program for Federal agencies to permit testing head hair, oral fluid, and sweat specimens. The Department wants to make it clear to agencies *that there is A MANDATORY requirement that they use hair, saliva or sweat as part of their drug-testing program for disabled donors who cannot provide urine samples. These situations may arise when applicants or employees are afflicted by a wide variety of disabilities and/or disease, including but not limited to: paralysis, multiple sclerosis, diabetes mellitus, stroke, prostate enlargement, and shy bladder. It is not even necessary for the donor to know the exact medical reason for their inability to provide a urine sample, and in fact, many disabilities/diseases such as MS, shy bladder, and prostate enlargement are often not promptly or properly diagnosed. Where the donor cannot provide urine samples, the*

collector's duty must be to offer an alternative specimen collection so that everyone can participate in a drug test. Collectors must remember that a donor's failure to provide a urine sample does not equate with "refusal to test."

Justification:
There are all manner of disorders, disfigurement, cosmetic or esthetic concerns that affect the ability of applicants and employees to participate in urine testing, specifically, and in any testing, in general. In order to avoid any appearance of callousness, and to avoid violating anti-discrimination laws, agencies must accommodate donor needs to avoid employment discrimination. Shy bladder donors and others who suffer from psychological and certain patho-physiological processes typically cannot provide a urine samples. Therefore choosing urine as the only acceptable biological sample leads directly to discrimination against employment of shy bladder donors, and others afflicted by disordered micturition.

IPA COMMENT 7

Heading: Urine

Paragraph from Heading: 2

Page: 27

Current Wording:
Drug ingestion for a 3-5 day interval preceding the specimen collection can usually be identified in urine. Based on the detection window, urine is most suited for random, return to duty and follow-up testing.

New Wording: (Add the following sentence after the ones above)
For donors demonstrating or claiming to suffer from shy bladder, the agency must choose an alternate test to urine testing since shy bladder donors typically cannot provide a urine specimen.

Justification:
Under the existing regulations, the shy bladder donors, through no fault of their own, have been unable to get or retain jobs under existing urine testing rules. Existing discriminatory rules need to be changed to allow paruretic donors to participate in testing.

IPA COMMENT 8

Heading: Oral Fluid

Paragraph from Heading: 1

Page: 27

Current Wording:
In order to protect Federal workers from incorrect test results for marijuana, a second biological specimen, a urine specimen, will need to be collected at the same time the oral fluid specimen is obtained.

New Wording: (Delete the above wording)

Justification:
IPA believes that no second biological specimen to saliva testing is required based on a review of ORASURE data and the open scientific literature. It is undesirable to require a second biologic sample since this will require greater cost and rule out the use of the saliva test for the shy bladder donors who need such a test in order to participate in drug testing.

If the Department insists on a second biologic sample, then IPA requests that the Department allow agencies to choose a second biologic specimen other than urine for donors demonstrating or stating shy bladder. Hair and sweat tests have deterrent attributes to them that should discourage donors faking shy bladder. Hair (90-day effective monitoring) and sweat (7-day monitoring or as long as the patch is worn) tests monitor illegal drug use by donors for a longer period of time than urine (3 - 5 day effectively) testing and therefore donors falsely claiming shy bladders are putting themselves more at risk. In addition, the effect of hair specimens on one's cosmetic appearance and the need for continuous wearing of a sweat patch will deter false shy bladder status claims. In unusual situations (e.g. accident investigation), the Agency may send the donor to a medical site for a blood test. Any of these options are preferable to a shy bladder donor as opposed to not obtaining or losing employment.

Under the existing regulations, shy bladder donors, through no fault of their own, have been unable to get or retain jobs under existing urine testing rules. Existing discriminatory rules need to be changed to allow paruretic donors to qualify for and keep jobs.

While passive THC in oral fluid might, in very rare circumstance, be a problem when testing law enforcement officials whose duties take them, to places where marijuana is used immediately prior to a drug test, typical law-abiding applicants and employees should not be expected to be in places where they will acquire THC in their oral cavities at detectable levels. Given the rapidity with which THC clears from the oral cavity, less than 1 hour, the relatively low level of THC acquired passively will be a non-issue if oral fluid is collected mid-shift, or mid-afternoon. Considering the relative impacts and benefits of accommodating shy bladder sufferers versus taking into account secondhand THC errors in testing, IPA strongly believes there is a far greater public benefit in changing regulations to fairly treat people with shy bladder.

IPA COMMENT 9

Heading: Sweat Patch

Paragraph from Heading: 3

Page: 28

Current Wording:
In section 2.3, the Department proposes to prohibit routinely collecting more than one type of specimen from a donor at the same time except when an oral fluid specimen is collected.

New Wording:
In section 2.3, the Department proposes to discourage routinely collecting more than one type of specimen from a donor at the same time unless doing so is necessary to cover the full range of active compounds and metabolites that must be tested to meet agency mission, or if urine cannot be collected because applicants or employees are afflicted by a voiding dysfunction.

Justification:
Under the existing regulations, the shy bladder donors, through no fault of their own, have been unable to get or retain jobs under existing urine testing rules. Existing discriminatory rules need to be changed to allow shy bladder donors to qualify for jobs.

IPA COMMENT 10

Heading: Subpart B - Specimens - Major Change

Paragraph from Heading: 10

Page: Bottom of 28, top of 29

Current Wording:
If a problem occurs during the collection of one type of specimen (e.g. shy bladder for a urine specimen, insufficient specimen available), permission can be obtained from the Federal agency to collect an alternative specimen.

New Wording:
If shy bladder donors are unable to provide urine samples or adequately sized urine samples, then testing personnel shall automatically provide an opportunity for shy bladder donors to take an alternative test such as hair, saliva, or sweat. Shy bladder and other disabled donors may choose, at their option, to use self-applied catheterization if qualified on that procedure.

Justification:

Individual permission from a Federal agency might work for a rare infrequent situation, but shy bladder disorder is not rare. In a Harvard study, 6.7% of those surveyed were judged to have this social phobia. Requiring individual permission from a Federal agency to proceed with an alternative specimen collection begs the question: what is the alternative? The alternative is simply not to hire shy bladder applicants or to fire existing employees. This blatant job discrimination is immoral, and quite possibly illegal.

It cannot be left up to agencies to have the option to choose to discriminate against shy bladder donors. Many millions of shy bladder donors are gainfully employed, often doing outstanding work, for Federal as well as private agencies and companies.

With regard to the use of self-applied catheterization, wording is contained in DOT Regulation Title 49 CFR Part 40 Paragraph 40.61 (b)(3) and (b)(4) to allow the use of urinary catheters. Various groups of disabled donors (paralyzed, severe shy bladder, multiple sclerosis among others) routinely use these devices to empty their bladders. To not permit these devices to provide urine is tantamount to employment discrimination. Current proposals by SAMHSA are unfortunately silent on this subject.

IPA COMMENT 11

Heading: Sweat Patch

Paragraph from Heading: 4

Page: 29

Current Wording:
In section 2.4, the Department proposes to establish the requirement for all specimens to be collected as split specimens, and in section 2.5 to establish a minimum quantity that must be collected for each type of specimen. For hair, 100 mg of head hair was the quantity recommended by the hair testing industry. For oral fluid, the Department is proposing that 2 mL be collected in a collection tube rather than allowing oral fluid to be collected directly into a collection device that does not provide an accurate measurement of the volume of oral fluid collected.

New Wording: None

Justification: (COMMENT)
The International Paruresis Association wishes to encourage the development and use of a wide range of alternative testing. In order to allow for the rapid incorporation of new technology, and permit a wider range of existing technology to be used, we think that these mandatory quantities of hair and saliva should not be codified. New developments and new technology will certainly arrive that require smaller samples. By codifying the specific quantities mentioned above, SAMHSA would inhibit development of new testing methodology. We think such a policy is unwise. The requirement that oral fluid be collected into a collection device may discourage the development and widespread use of

POC oral fluid tests. One hundred milligrams of hair may be a substantial amount in bald or shorthaired people and it may not be cosmetically acceptable for some to part with this amount. Drug Testing will have a more positive reception with the general population if an environment is created which accommodates a wide range of the population, and does not result in employment discrimination. Promulgation of rules that encourage technological development and do not artificially place limitations on such developments is essential. What would happen if tomorrow a test were developed that for example required only a buccal swab, or a few microliters of saliva? With the present regulatory wording collectors would still be locked in to a 2 ml sample collection.

IPA COMMENT 12

Heading: Subpart L - Point of Collection Test (POCT) - Major Change

Paragraph from Heading: Last Paragraph

Page: 49

Current Wording:
If a Federal agency chooses to use POCT, then it must use only POCTs that are on the list of SAMHSA-certified devices, ensure that only trained testers are used and provide them with a standard operating procedures manual, ensure that the requirements of the regulation are fulfilled, accomplish the inspection of the POCT test sites, accomplish proficiency testing…

New Wording:
If a Federal agency chooses to use POCT, then it must use only POCTs that are on the list of SAMHSA-certified devices, or apply for a waiver, which may be granted in order to facilitate Agency mission and expand the scope of available alternative testing.

Justification:
The IPA believes that it is important to encourage the development and use of a wide range of testing devices, so that no one suffers from any discrimination or unwelcome personal intrusion during the course of testing. To further these goals, we think it would be wise for agencies to be able to experiment as they see fit—provided that no disciplinary action, or failure to hire, would be based solely on such tests results. It may be necessary to promulgate some regulations that cover such expanded use of alternative devices. We think broad latitude is appropriate with regard to applicant screening for all but the most safety-sensitive positions. Present policy stands in the way of product and process development and furthers the financial goals of existing service providers at the expense of innovation.

IPA COMMENT 13

Heading: Subpart N - Medical Review Officer (MRO) - Major Change

Paragraph from Heading: 1

Page: 54

Current Wording:
In Section 14.1, the Department establishes who may serve as an MRO, including the requirement that the individual successfully complete an examination administered by a nationally recognized entity that certifies MROs or subspecialty board for physicians performing a review of Federal employee drug test results, which has been approved by the Secretary. This section also establishes the requirements for nationally recognized entities that seek approval by the Secretary to certify MROs or for subspecialty boards for physicians performing a review of Federal employee drug test results to submit their qualifications and sample examination.

New Wording:
In Section 14.1, the Department establishes who may serve as an MRO, including the requirement that the individual successfully complete an examination administered by a nationally recognized entity that certifies MROs or subspecialty board for physicians performing a review of Federal employee drug test results, which has been approved by the Secretary. *A change is made to require at least 2 hours of specialized training in learned voiding dysfunctions such as Hinman's and shy bladder, which will emphasize the psychological nature of the disorder, and emphasize that shy bladder is a real disorder, and those afflicted by it are human beings deserving of proper treatment by medical professionals, and are to be treated respectfully as any disabled person would be treated. MROs must be licensed in the State in which testing takes place. Tested applicants and employees must be provided with the name, telephone number, email address, and business street address of the MRO who will review and certify their laboratory results.*

Justification: Comment
The IPA receives frequent complaints about "attitude" issues of urine collectors and MROs, which we believe is the result of insufficient training. The MROs in particular, through some of the posting on the websites of their organizations and through presentations made at DATIA meetings, have consistently shown an ignorance of, or even disbelief in, shy bladder. MROs should be required to complete at least 2 hours of specialized training in learned voiding dysfunctions such as Hinman's and shy bladder, to include not only patho-physiology, but also relevant psychological viewpoints. Too many MROs seem to have contempt for those afflicted by shy bladder. Proper training would go a long way toward resolving this difficulty. (In our background statement we cited two specific examples of incorrect notions commonly held by MROs. Education and training are desperately needed.)

The present Guidelines do not consider the medical licensing of MROs, but elsewhere we have read that they need not be licensed in the United States. We believe that any MRO must be licensed in the State where testing is conducted, that the identity of the MRO should be provided to donors at the time of sample collection, and that contact

information should be provided too. This would allow applicants and employees who have special problems to communicate them directly in a manner that protects medical information and confidentiality. The suggested openness will go along way toward ensuring accountability of the MROs.

IPA COMMENT 14

Heading: Subpart N - Medical Review Officer (MRO) - Major Change

Paragraph from Heading: last paragraph

Page: 55

Current Wording:
Section 14.10 describes the relationship that is prohibited between an MRO and a…

New Wording: (Request for additional requirement)
An additional requirement must be put on the MROs, e.g., a limited physician-patient relationship should be required wherein the MRO must serve both the needs of the agency and the health needs of the tested individual.

Justification: (Comment)
MROs have at the very least a moral duty to be certain of a situation before they label someone as a user of illegal drugs. We are aware that some courts have held MROs responsible for negligent reports to employers. They have a duty of care, and that should extend to a limited one-on-one doctor-patient relationship if such is necessary to properly evaluate a case. We believe that much heartache could be averted if this group was held to the highest ethical and legal standards**.**

IPA COMMENT 15

Heading: Issues of Special Interest

Paragraph from Heading: 3

Page: 60

Current Wording:
To ensure that a THC result on an oral fluid specimen is from active exposure, the Department is proposing to always collect a urine specimen with an oral fluid specimen that would be available if the oral fluid specimen was positive for THC.

New Wording: (Delete the proposal for a second biologic urine specimen)

Justification:

IPA recommends that no second biologic specimen to saliva testing is required based on a review of ORASURE data and the open scientific literature. It is undesirable to require a second biologic sample since this will require greater cost and rule out the use of the saliva test for the shy bladder donors who need such a test in order to participate in drug testing.

If the Department insists on a second biologic sample, then IPA requests that the Department require agencies to choose a second biologic specimen other than urine for donors demonstrating or claiming shy bladder. Hair and sweat tests have deterrent attributes to them that should discourage donors faking shy bladder. Hair (90-day effective monitoring) and sweat (7-day monitoring or as long as the patch is worn) tests monitor illegal drug use by donors for a longer period of time than urine (3 - 5 day effectively) testing and therefore donors falsely claiming shy bladders are putting themselves more at risk. In addition, the effect of hair specimens on one's cosmetic appearance and the need for continuous wearing of a sweat patch will deter false shy bladder status claims. In unusual situations (e.g. accident investigation), the Agency may send the donor to a medical site for a blood test. Any of these options are preferable to a shy bladder donor as opposed to not obtaining or losing employment.

Under the existing regulations, shy bladder donors, through no fault of their own, have been unable to get or retain jobs under existing urine testing rules. Existing discriminatory rules need to be changed to allow paruretics and others who suffer from voiding disorders to qualify for jobs.

IPA COMMENT 16

Heading: Section 1.5 What do the terms used in these Guidelines mean?

Paragraph from Heading: NA

Page: 103

Current Wording: NA

New Wording: (Add the Following Definition)
Shy Bladder: For purposes of this Guideline, a donor who for any of several mental or physiological reasons is unable to supply a urine sample and who is to be treated with respect

Justification:
Inadequate research has been accomplished to determine the exact causes of Shy bladder Disorder. The typical shy bladder donor can urinate in safe environments (e.g. their own home) as determined by their subconscious but not typically in public restrooms, with or without other persons being present, where others are waiting to use the facility, or where urine samples are demanded such as in doctor's offices, hospitals and drug testing facilities. DSM-IV 300.23 currently classifies this disorder as a Social Anxiety Disorder

with contributing genetic, physiological, and environmental factors. There is no known method to allow a shy bladder sufferer to urinate in a place they consider threatening, unless the person has been taught self-intermittent catheterization (SIC).

Other disorders and diseases can mimic shy bladder disorder. We had one member who thought he had shy bladder disorder for one year until a doctor did some more tests and changed his diagnosis to a mild form of multiple sclerosis. Physicians have found urethral strictures, a form of obstruction, in a few shy bladder patients. Until governmental agencies or private foundations provide grant money to research this disorder, we will not have definitive standards for shy bladder. It does not make sense that any Federal agency is going to want to pay for extensive medical testing of job applicants or current employees to determine the exact nature of each person's urinary problem.

Our proposed definition accepts the reality of today's situation, that is, a number of donors are going to be unable to provide a urine sample. The drug testing community must deal with this situation in a way that does not trample on the rights of this group to apply for and retain jobs in the absence of illegal drug use. Thankfully, the answer is simple and available. The answer is to authorize increased use of alternate drug tests to replace urine testing for shy bladder donors.

IPA COMMENT 17

Heading: Section 1.5 What do the terms used in these Guidelines mean?

Paragraph from Heading: last entry

Page: 104

Current Wording:
Substituted. A specimen that could not have been derived from the donor’s body at the time of collection because it is inconsistent with normal physiology.

New Wording:
Substituted. A specimen that could not have been derived from the donor’s body at the time of collection because it is inconsistent with normal physiology *and would not occur in an ambulatory donor.*

Justification:
Paruretics who have been compelled to drink 40 oz of fluid have sometimes been accused of substitution due to the dilute nature of their urine. Sometimes paruretics have taken a lot of water before arriving for the test in the hopes that urgency will enable them to provide a urine specimen, only to be asked to drink more at the test site. We have had at least one posting of this problem on our bulletin board. Perhaps the specific gravity specifications are adequate and appropriate, but we would like for SAMHSA to be certain

that specific gravity below the proposed cut-off cannot be obtained from an ambulatory donor. (We suspect, but do not know, that it actually can.)

IPA COMMENT 18

Heading: Subpart B - Specimens, Section 2.2 Under what circumstances can the different types of specimens be collected

Paragraph from Heading: Table

Page: 105

Current Wording: The table currently provides a list of reasons for which the Hair, Oral Fluid, Sweat (patch), or Urine tests can be used.

New Wording: Add the following wording to the Hair, Oral Fluid, and Sweat (patch) categories:

Shy bladder donor in any situation

Justification:
IPA recommends no second biologic sample for oral fluid based on a review of ORASURE data and the open scientific literature. If the Department continues to insist on a second biologic urine sample, then shy bladder donors, through no fault of their own, will be unable to get or retain jobs under urine testing rules. Existing discriminatory rules need to be changed to allow those afflicted by shy bladder or other voiding dysfunction to fairly participate in drug testing, and thereby qualify for jobs.

IPA COMMENT 19

Heading: Section 3.15 What criteria are used to report a urine specimen as adulterated?

Paragraph from Heading: 2

Page: 118

Current Wording:
(b) The nitrite concentration is greater than or equal to 500 mcg/mL using either a nitrite colorimetric test or a general oxidant colorimetric test for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on the second aliquot;

New Wording: (Question on the above wording)
The IPA has a tangential interest in this matter. Many of our constituents routinely use self-catheterization for voiding and may from time to time have an inapparent infection.

We are aware that nitrite, when present in urine, is an indicator of infection. Has anyone involved in this rulemaking process considered if the threshold level specified here is well above that which might occur naturally during the course of an infection?

We feel certain that some applicants and employees selected at random may have asymptomatic infections. It is bound to come up with time. It is our understanding that typical clinical dipstick tests for nitrite do not determine the actual amount of nitrite present. We have not researched the known upper limits of nitrite accumulation during infection. Has this issue been investigated by SAMHSA? Have any persons been identified as having an adulterated specimen on the basis of nitrite been falsely accused? Does SAMHSA have any means to determine if this has occurred?

Justification: NA

IPA COMMENT 20

Heading: Section 3.15 What criteria are used to report a urine specimen as adulterated?

Paragraph from Heading: last

Page: 119

Current Wording:
(h) The presence of any other adulterant not specified in (c) through (g) of this section is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot.

New Wording: (Add the following sentence after the ones above)
Except that normal components of lubricating materials such as K-Y™ Jelly, which might be used by those who provide urine samples by catheterization, will not be considered adulterants. Neither will iodine be considered an adulterant if it is used as a cleansing agent prior to catheterization. (It might be helpful to keep sterile collection containers that can attach to the funnel end of catheters present at testing sites to facilitate collection via catheter.)

Justification:
The IPA has several constituents who would want to provide a urine specimen by self-catheterization. Although we prefer that most testing would be done in the future with non-urine based tests, we recognize that there may be situations where urine is the only acceptable choice. In these cases, shy bladder employees must be permitted to provide a specimen by catheterization, and as the correct use of catheterization requires lubricating the catheter with a lubricant such as surgical or K-Y™ Jelly, the components of such lubricating materials must not be considered adulterants. Additionally, though it is unlikely that iodine used for cleansing purposes would appear in urine, iodine-containing cleansing wipes must be permitted in the toilet area (urine collection room), and it might

be necessary to reconsider portions of these regulations which deal with adulteration of urine by halogens.

IPA COMMENT 21

Heading: Section 4.2 What are the requirements to be a trained collector for a Federal agency?

Paragraph from Heading: (d)

Page: 124

Current Wording:
(d) Successfully completed a training course …

New Wording: (Add the following sentences after the ones above)
(e) An individual trained for urine specimens, must include 30 minutes of lecture or an appropriate equivalent reading assignment on shy bladder, with emphasis on the special sensitivities of paruretics with regard to external stimuli that trigger the "lock up." Urine collectors must be trained to recognize a paruretic, to deal with them in a sensitive manner, and assist them by taking steps to remove time-pressure, unwelcome sound, and other external stimuli that invade their personal space making it impossible for them to void. They must be taught how to handle situations in which donors produce specimens by insertion of a catheter.

Justification:
The IPA receives frequent reports about a wide variety of conduct on the part of urine collectors, ranging from compassionate and understanding to some very poor attitudes on the part of collectors, infliction of emotional distress by collectors, and an unwillingness to take even the most minimal steps to aid the paruretic through his/her attempt to provide a sample. In fact, it seems to us from the many comments we have received that some collectors delight in giving paruretics a hard time. We are aware of one very egregious case involving a transportation employee. No one should be compelled to suffer such abuse. Proper training of urine collectors is a must.

On a related theme, many people who present for urine collection erroneously believe that the collector is medically trained. We often hear from our constituents about the conduct of "the nurse." Urine collectors must be required to make it immediately clear to all donors that they are not medical personnel, unless they hold an appropriate degree in nursing or medical technology. We also think it would be advisable that they be required to provide their full name and the full name of their immediate supervisor, and the name of the company conducting the test, if it differs from the employer, as a matter of course.

IPA COMMENT 22

Heading: Section 4.2 What are the requirements to be a trained collector for a Federal agency?

Paragraph from Heading: (d)

Page: 124

Current Wording:
(d) Successfully completed a training course by an established organization …

New Wording: (Add the following sentences after the ones above)
(f) Will understand how collection of urine specimens is accomplished with disabled donors, e.g. paraplegics and shy bladder donors who may use urinary catheters. Will have seen physical samples of both Foley catheters with collection bags and catheters used for intermittent catheterization, and will know how donors use these devices to empty their bladder. Collectors will be able to explain how urine samples will be collected from donors who routinely use these devices. Training will also be provided in the necessary sensitivity to be shown by collectors when dealing with disabled donors.

Justification:
The IPA representative at the April 2004 DATIA Convention in Seattle asked the assembled Board of Directors (BOD) if he would be allowed to use a catheter as a shy bladder donor. One medically trained BOD member, an M.D. explained that: yes, urine collection from a donor using an intermittent catheter was allowed, and it was done in a similar manner as to someone using a Foley catheter in a wheelchair. Another BOD member said his company would not allow it since his collectors were not medically trained (displaying a lack of knowledge concerning the nature of self catheterization). A DATIA member from the audience said that her company allows self-catheterization collections. During lunchtime, a DATIA member from Alabama told the IPA representative that he was not even aware that people could use a urinary catheter on themselves. Subsequently, an 18-year career employee of DOT who has shy bladder mentioned to the IPA representative that some DOT collection sites have permitted him to use a urinary catheter for urine collections, and other sites have not, depending on the company.

It is clear that some drug testing companies are providing training to their collectors regarding urinary catheters and others do not include the subject of disabled people in their training. This lack of training is likely already the cause of some job discrimination judging by the DOT employee comments discussed above.

It is crucial that SAMHSA require some elementary training by drug testing companies of their collectors regarding the use of urinary catheters by disabled people, including paraplegics and shy bladder donors, among many others. Let us make ourselves clear, WE ARE NOT SUGGESTING THAT COLLECTORS ATTEMPT TO CATHETERIZE

DONORS. We are only saying that collectors must be aware that; a) some individuals will provide urine samples by catheter, b) both Foley and SIC catheter methods are in common use, and c) specific steps are needed to collect urine from disabled donors.

IPA COMMENT 23

Heading: Section 5.2 What are the requirements for a collection site?

Paragraph from Heading: (c)

Page: 126

Current Wording:
(c) The ability to provide the donor privacy that is appropriate for the specimen being collected;

New Wording: (Add the following sentence after the ones above)
(c) The ability to provide the donor privacy that is appropriate for the specimen being collected*; privacy needs vary among individuals, and as paruretics have a peculiar need for privacy in providing a urine specimen, the restroom must be at least 15 feet from a common area and the collector must stand at least 15 feet from the door to the restroom, unless there is a special need for observed collection.*

Justification:
Paruretics have a special need for visual, spatial, and auditory privacy. When this need is not met, they are unable to void volitionally. Many of our constituents have commented that they could have, or might have, been able to provide a specimen "if only" the collector's desk were further away from the restroom door, "if only" others waiting to be tested were kept a decent distance from the restroom door, "if only" the collector had stopped reminding them that they faced a time limit, "if only" the noise level had been higher, or lower, or different.

In order to avoid discriminatory hiring and retention practices that inevitably are part of a urine testing program, the IPA would much prefer that urine testing not be applied to shy bladder donors. But if it must be, then collectors (individuals and organizations) have a moral and legal obligation to provide reasonable accommodation in the design standards of collection facilities. It seems reasonable to require (particularly) high-volume testing companies to design their facilities in an appropriate manner.

IPA COMMENT 24

Heading: Section 8.5 What procedure is used to collect a urine specimen

Paragraph from Heading: Paragraph a. (4)

Page: 139

Current Wording:
The paragraph starting with: The collector shall ask the donor to remove any unnecessary outer garments….

New Wording: (Add the following sentence somewhere in the above paragraph)
For those donors who state that they wish to provide the urine sample by self-intermittent catheterization (SIC), they will be asked to verbally confirm that they have been medically trained to accomplish the procedure and that they do so on a routine basis to empty their bladder. These donors will be permitted to carry a rubber or plastic catheter in a sterile unopened package or a used but clean catheter in a transparent plastic bag into the collection site. No catheter should be handled by any collector at anytime. A collector may visually inspect both clean and sterile catheters through transparent areas of their containers for the presence of foreign particles. If a collector is concerned about the cleanliness of the catheter, he may ask the donor to pour clean tap water through the catheter, and observe, but this should rarely be necessary. The donor may bring, small foil packets or plastic squeeze bottles of water-soluble surgical lubricant or KY™ lubricant for use with the catheter. Catheter users may also need to bring small sterile cleaning pads impregnated with antiseptic with them into the collection site. These pads may contain iodine. Use of such wipes must not be prohibited. Donors may also use lubricants that contain anesthetic agents, but when this is done, the collector should report the situation so there is no confusion between the anesthetic agent and an adulterant.

Justification:
People with moderate to severe forms of shy bladder have often found it beneficial to learn how to use self-intermittent catheterization (SIC) to drain their bladders. Self-intermittent catheterization is a technique of draining your bladder when one cannot urinate properly. Shy bladder donors have learned this from urology offices, women's clinics, or general practice medical offices. Typically, it takes less than 5 minutes to provide a urine sample by SIC. These methods are discussed in the books: "Conquering Bladder and Prostate Problems" by Jerry Blaivas, MD, ISBN 0-306-45864-0, Copyright 1998 by Plenum Press, and "Shy bladder Syndrome, Your Step-by-Step Guide to Overcoming Paruresis" by Steven Soifer, George D. Zgourides, Joseph Himle, Nancy L. Pickering, and are specifically mentioned as an approach to the management of Shy bladder at a Website operated by the University of Maryland Medical School, http://www.umm.edu/ency/article/003972.htm.

The modern practice of patients using clean (not sterile) self-intermittent catheters (SIC) to lead a full life was introduced after research published by Dr. Jack Lapides, former Chairman of Urology at the University of Michigan, in 1971. Many disabled groups, in addition to the shy bladder population, use SIC but in addition, some disabled groups use Foley catheters with collection bags too.

Employment discrimination against disabled people, especially for purposes of urine testing, cannot be permitted to stand. Employers are required to make "reasonable

accommodation" for disabled people under the ADA law. Agencies may be required to accommodate under the Rehabilitation Act. Judges and juries will understand that the use of alternate tests, or use of catheters for urine collection procedures, is essential for "reasonable accommodation". It is clear from events at DATIA conventions that a select few companies are accommodating the disabled well, while others do not. In any case, SAMHSA rules do not address catheter use at all. This needs to change.

IPA COMMENT 25

Heading: Section 8.5 What procedure is used to collect a urine specimen

Paragraph from Heading: Paragraph a (6)

Page: 139

Current Wording:
(6) After washing hands, the donor must remain in the presence of the collector and must not have access to any water fountain, faucet, soap dispenser, cleaning agent, or any other materials which could be used to adulterate the specimen.

New Wording: (Add the following sentence after the ones above)
(6) After washing hands, the donor must remain in the presence of the collector and must not have access to any water fountain, faucet, soap dispenser, cleaning agent, or any other materials that could be used to adulterate the specimen, *except that water must be available for shy bladder applicants or employees who wish to provide their sample by means of self-catheterization with a hydro-phobic catheter such as the LoFric ™ catheter, which must be moistened with tap water. Cleansing wipes containing iodine or halogenated compounds will be permitted in the collection area when samples are to be collected by self-catheterization.*

Justification:
Should it occur that our entreaties to SAMHSA to allow a broad range of alternative testing and donor choice are ignored, some paruretics will chose to provide specimens through LoFric™ brand catheters, and they will require access to a functioning lavatory (running tap water to activate the lubricant coated catheter). Failure to provide such access could be viewed as illegal discrimination as such access is a reasonable accommodation.

IPA COMMENT 26

Heading: Section 14.7 What must an MRO do when reviewing a urine test result?

Paragraph from Heading: Paragraph (c)

Page: 240

Current Wording:
If a laboratory also reports that the specimen is dilute, the MRO directs the agency to have the donor provide another specimen using a direct observed collection procedure

New Wording:
If a laboratory also reports that the specimen is dilute, the MRO directs the agency to have the donor provide another specimen using a direct observed collection procedure, *or an oral fluid test if the donor expresses concern over the loss of privacy or states that he has shy bladder symptoms when urinating under observation.*

Justification:
There is a broad range of shy bladder symptoms from severe to mild among the 800 members of the IPA. Many shy bladder donors with mild symptoms could provide a urine sample quite easily under some privacy conditions like a stall or a single room, but would freeze at a urinal or direct observation. It makes a lot of sense to not accuse someone of drug use for having shy bladder by allowing him or her to receive a saliva test instead of an observed urine test.

IPA COMMENT 27

Heading: Hair

Paragraph from Heading: 2

Page: 10

Current Wording:
The Department is proposing to permit agencies as part of their Federal workplace program to test hair with lengths of about 1.5 inches long, representing a time period of 90 days, and to use these specimens for pre-employment, return-to-duty, or follow-up testing.

New Wording:
The Department is proposing to permit agencies as part of their Federal workplace program to test hair with lengths of about 1.5 inches long, representing a time period of 90 days, and to use these specimens for pre-employment, return-to-duty, follow-up testing, *or for shy bladder donors*.

Justification:

Status as a shy bladder donor should be sufficient justification to employ a hair test, in order to reduce employment discrimination against that donor population.

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3. Labbate L.A. Paruresis and urine drug testing. Depress. Anxiety 4:249-252. 1996.

4. Rosario et al. Urodynamic assessment of the bashful bladder. J. Urology 163:215. 2000.

5. Groutz A., and Blaivas, J.G. Non-neurogenic female voiding dysfunction. Curr. Opin. Urol. 12:311-316. 2002.

6. Based on complaints submitted to us or posted on our web based bulletin board.

7. Miguel Dozier v Presbyterian Healthcare Services, State of New Mexico, County of Rio Arriba, First Judicial District, The Honorable Timothy L. Garcia, Presiding.

8. The International Paruresis Association is providing assistance to the Plaintiff.

9. DSM IV 300.23

10. Taken from the SAMHSA Website.

11. From the Proposed Mandatory Regulations and existing CFR.

12. Allen, T. D. (1972). Psychogenic urinary retention. Southern Medical Journal, 65(3), 302-304.

13. IPA Drug Test Investigation Report 2004-01 Occurrence Date: 13 May 2004, Las Vegas, Nevada

Enclosure (1)

IPA SUGGESTED SHY BLADDER PROTOCOL

IPA has seen three recent trends: (1) Without much effort and no outside sponsorship, the organization is steadily growing. After being founded in 1996 by two people in Baltimore, we now have 800 dues paying members and average 1000 hits a day between our website and discussion board. We have 43 Support Groups across the nation. Shy bladder members subsequently formed associations in 11 foreign countries. (2) Members are becoming more assertive and more willing to stand up for their rights. They are angry about government regulations that prevent a shy bladder donor from getting or keeping a job, as more companies require drug testing. (3) There are 6 lawsuits that we are aware of this year. One of these occurred in New Mexico in March 2004 where a doctor, the shy bladder donor, won a $256,000 judgement against his employer, a hospital that equated shy bladder with being a drug user.

Consequently:
IPA would like to see the following testing protocol used for shy bladder donors (with the understanding that a shy bladder donor has taken on the larger meaning of any donor who has a medical or psychological disorder that prevents the donor from providing a urine specimen);

1. A donor enters the collection site and declares that he (she) has shy bladder, paruresis, or some other voiding dysfunction. and has a signed statement from a medical doctor who states that the patient has no clinical evidence of illegal drug usage and reports shy bladder symptoms. This signed statement would be good for 3 years from date of the doctor's signature. (Go to 3);

2. Any donor who tries and is unable to produce a urine specimen or a urine specimen of adequate volume, within a limited period of time, 35 minutes for adults and 15 minutes or less for children subject to school testing. (Go to 3)

3. Donors from 1 or 2 above are considered to be shy bladder donors. These donors will immediately (i.e. no three-hour wait and no requirement to drink water) be given a hair, sweat, or saliva test at the option of the collector (the collector will be trained to normally specify a saliva test with less frequent random selection of a hair or sweat test).

NOTE: Under specific circumstances, the selection of an alternate test method to be specified in Step 3 will be mandated as follows:

Circumstance	**Type of Specimen**
Return to Duty	Hair or Sweat
Follow-up	Hair or Sweat
Reasonable suspicion	Saliva
Post-Accident	Saliva
Pre-employment	See 3 above

Random See 3 above

ADVANTAGES OF USING THE IPA SUGGESTED PROTOCOL

A. Cost-Effective: Urine testing proponents tout low cost comparisons with alternate tests, but they fail to include inherent urine testing costs such as:

1. Three-hour wait tests after a shy bladder failed to produce a urine sample. This is a significant cost and perusal of the DATIA Discussion Forum reflects a question about what to do if the collector is the only one at the collection site and a shy bladder donor is encountered who requires a three-hour observation period. Time translates into extra cost for that urine test.

2. Agency time spent in drug counseling/negotiating with shy bladder donors, is wasted time because no illegal drug use was involved with a shy bladder donor.

3. Costs of lawsuits and jury damage awards ($256,000 in the latest New Mexico case)

B. Low-risk: SAMHSA may be concerned that donors falsely claiming shy bladder status could abuse the IPA Suggested Protocol. IPA submits the following points:

1. Downside risk is low since all donors will at least get a saliva test; it is not as if an abuser was getting away with not being tested.

2. False claims of shy bladder status could be discouraged if it was published that collectors will randomly use hair or sweat tests in addition to saliva tests on shy bladder donors. Hair (90 day effective monitoring) and sweat (7 day monitoring or as long as the patch is worn) tests monitor illegal drug use by donors for a longer period of time than urine (3 - 5 day detection window) testing and therefore donors falsely claiming shy bladders are putting themselves more at risk. In addition, the effect of hair specimens on one's cosmetic appearance and the need for continuous wearing of a sweat patch will deter significant numbers of false shy bladder status claims.

3. SAMHSA, if they wished, could occasionally monitor the numbers of donors claiming shy bladder status. If counts of those reporting shy bladder status exceeded 30% then further investigation might be warranted. IPA suspects that the Harvard survey report of 6.7% shy bladder donors in the population might be quadrupled by donors who would not be functionally classified by DSM-IV as having paruresis, but nevertheless are intimidated by actions of some drug test collectors. IPA reached this conclusion by recently interviewing a man who experienced severe shy bladder symptoms after his treatment by two female urine specimen collectors (13). During his drug testing experience on 13 May 2004, 2 of 7 males experienced shy bladder symptoms preventing urination. IPA would only expect about 7% shy bladder, but intimidation apparently can increase that

percentage by a factor of 4. Admittedly, IPA only has one investigation like this to work from. We would really be interested in any data available from SAMHSA or DOT relative to the number of drug test donors who are unable to provide sufficient urine samples.

Enclosure (2)

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Enclosure (3)

IPA Contact Information - Drug Testing Comments

1. Formal Correspondence regarding the IPA Drug Testing Comments should be sent to:

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2. Formal Correspondence can also be sent to this IPA FAX number:

410-601-0035 Attention: Drug Testing Committee

3. For informal verbal discussion, please contact:

Phil Baumgaertner, IPA Drug Testing Committee Chairperson
Phone Number 360-385-4528

Or,

Dr. Steven Soifer, Executive Director, IPA
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4. E-mail correspondence should be sent to these addresses:

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