CONCENTRA INC.

#04-7984
P.C. 8400109

July 8, 2004

Department of Health and Human Services, SAMHSA
Attn: Walter F. Vogl, Ph. D.
wvogl@samhsa.gov
5600 Fishers Lane
Rockwall II, Suite 815
Rockville, Maryland 20857

Re: Comments regarding Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Program
Docket Number 04-7984

Dear Dr. Vogl,

Please accept these comments prepared by Concentra Inc. (Concentra) in response to the Notice of Proposed Rulemaking (NPRM) published by the Department of Health and Human Services' (Department). We applaud the Department's efforts to expand the Federal Workplace Drug Testing Program. We believe a good faith effort has been made to provide for a more stringent drug testing program and we appreciate the Department's commitment to providing a safe work environment. We agree with the Department's assessment that there have been significant advances in scientific technology relative to alternative specimen testing. However, we do not believe that sufficient research exists at the present time to proceed with the guidelines presented in the proposed revisions relative to alternative specimen testing.

Concentra currently operates two hundred fifty-six (256) occupational health clinics, and one hundred seventy-two (172) on-site medical clinics throughout the United States. All of our clinics perform DOT drug testing and all Federal Agencies are represented. As an organization that is both directly and indirectly impacted by the proposed revisions, we respectfully submit the following comments for your consideration. The comments are organized consistent with the layout and the order of the Proposed Revisions.

Preamble Commentary

GENERAL COMMENTS

As an entity for whom Department of Transportation (DOT) drug screens represent twenty-nine percent (29%) of all drug screens, Concentra highly recommends that the Department collaborate with the DOT where possible in drafting its final notice of proposed rulemaking. Collaboration on behalf of these two agencies will result in a uniform drug testing procedure that will significantly reduce confusion in the drug testing industry and uphold the Program's "gold standard" reputation. The production of a uniform drug testing procedure will also eliminate the conflicting standards that arise when drug testing facilities develop their own policies and procedures.

SUPPLEMENTARY INFORMATION

The Added Specimens – Major Change

Concentra believes that alternative specimen testing has the potential to greatly enhance the Program. At this time, however, incorporating alternative specimen testing into the Program is grossly premature and will severely compromise the "gold standard" reputation that has been achieved.

Absent from the proposed revisions is an explanation of the relationships between the various specimens. The absence of this type of information is cause alone to delay the incorporation of alternative specimen testing into the Program. For example, what happens when a donor receives a negative drug result on a hair test but a positive urine drug test result? As it stands currently, an employee who receives a positive drug test result on his urine specimen cannot refute this drug test result in court by evidencing a negative drug test result on a hair specimen because the Federal government does not recognize hair specimen testing. In this circumstance, the court will ignore the hair test result. If, however, alternative specimen testing is incorporated into the Program and recognized by the Federal government, then a table of specimen interrelationships will need to be developed. This type of data exists presently for both the Breath Alcohol Test (BAT) and the blood alcohol drug test and should also be established for the alternative specimens prior to incorporating them into the Program. Until these relationships can be explained to the public, Concentra recommends that the Department postpone the implementation of alternative specimen testing.

Alternative Specimens, *Hair*

The Department is proposing to add hair as an optional specimen selection for the Federal Workplace Drug Testing Program. One rationale for the addition is that "hair is easily collected, transported and stored." Concentra disagrees with this statement. There are a number of hair types that would prohibit collection altogether (e.g. donors that are bald, have military cuts, or wear their hair in weaves or dreadlocks). If these donors are held to a different standard (an alternate specimen), there is a potential bias in their favor as their specimen will only show drug ingestion for a 3-5 day interval preceding the collection, rather than a 30-90 day interval. Accordingly, there is a potential bias against donors for whom a hair specimen may be successfully collected. As donors become aware of the advantages to certain hair styles, they may intentionally alter their style when they apply for a new job or are selected for a random test.

We also think it is fair to say that our current society is relatively appearance-conscious and to many, hair plays an important role in appearance. Donors may not readily accept the loss of 100 mg of hair, even if it is cut close to the scalp in an area that is not visible. The collector will likely encounter angry donors resulting in a collection process that is far from easy.

In addition, Concentra harbors some concerns regarding the ability of hair to potentially show drug use extending back ninety (90) days. First, if the proposed revisions are adopted and hair testing is incorporated as an optional specimen selection, we request that guidance be added to address how an MRO can determine whether a prescription drug reasonably justifies the presence of the drug. For example, if the presence of drugs is indicated in the half inch of hair closest to the scalp, can a two-week old prescription be used to justify that presence?

Our second concern involves legal ramifications stemming from the Americans with Disabilities Act (ADA). A "recovering addict" is protected under the ADA; thus, if a recovering addict is denied a job because of a positive drug screen, he/she can seek protection by filing suit under the ADA. As such, Concentra recommends that the Department incorporate provisions into its proposed guidelines that advise an MRO when a recovering addict presents for a drug screen. Fore example, these provisions should address the process for receiving documentation to confirm the enrollment of a donor in a recovery program, defining a "recovery program," and follow-up testing for recovering addict.

Concentra also has some questions and concerns regarding the statement that "sweat can be responsible for drug incorporation at distal segments of hair which does not correspond to the time of drug ingestion." We believe that this property can result in misinformation and ambiguity. For example, if a donor has been taking a prescription drug for two weeks, and the donor's sweat causes drug incorporation in the segment of the hair that represents 60 – 90 days, how will an MRO be able to confirm whether the prescription drug, or some other non-prescription drug, is responsible for that incorporation? In addition, the very fact that some people sweat more than others potentially creates a bias against donors that are prone to sweating.

Concentra appreciates the fact that you have noted in the preamble that there is particular concern relative to the role of hair color. Although we have not conducted, nor are aware of any additional studies on this topic, we do believe that the potential for bias is a significant concern and should not be dismissed lightly.

And, finally, although the Department does not address the impact of chemical treatments on hair, Concentra has some real concerns that such treatments may invalidate a drug test result. Chemical treatments (coloring, perms, etc.) alter the composition of the hair strand. A drug ingesting donor who recently chemically treated his/her hair will potentially receive a false-negative test result. Concentra requests that the Department strongly consider the role of chemical treatments in relative to their effect on the validity of the test.

Alternative Specimens, *Oral Fluid*

The Department is also proposing to add oral fluid as an optional specimen selection. Although Concentra agrees that oral fluid collections can be easily observed and are therefore less likely to be adulterated, we disagree with the statement that "oral fluid is readily accessible," particularly since the guidelines require an unstimulated specimen. "Dry mouth" is not an uncommon condition and should not be disregarded. If the proposed revisions are passed and oral fluid testing is incorporated as an optional specimen selection, we recommend that the Department adopt a specific procedure for "dry mouth" as it has for "shy bladder" under urine. In addition, it is inevitable that adulterants will be developed and will affect the validity of oral specimens as they have with urine.

Concentra agrees with the Department's conclusion relative to marijuana that "further scientific study is needed to be able to differentiate between whether the parent drug was present in the oral cavity due to drug use or environmental contamination." Marijuana is the most common gateway drug ingested by the average drug user. Concentra believes that this limitation is sufficient to altogether prevent the incorporation of oral fluid as an optional specimen selection in the Program. The potential for a false positive is a significant issue and should be carefully considered. If it is determined that an oral fluid

specimen is not a reliable test for marijuana, then it should not be incorporated as an optional specimen selection, particularly since marijuana is the most common gateway drug ingested by the average drug user.

Concentra strongly disagrees with the recommendation that a urine specimen be collected every time an oral fluid specimen is collected. First and foremost, requiring a urine specimen each and every time an oral fluid specimen is provided will ultimately cause many Federal agencies to question the cost-effectiveness and timeliness of even collecting an oral fluid specimen. Furthermore, if each donor is required to produce an oral fluid specimen and a urine specimen, overall wait times at collection sites will drastically increase and ultimately patient satisfaction will decrease. As an example, a typical oral fluid collection takes approximately ten (10) minutes for the collection, and potentially, an additional ten (10) minutes if the donor had anything in his mouth. It then takes approximately fifteen (15) minutes to collect a urine specimen. The paperwork for both tests takes about fifteen (15) minutes to process. This results in a potential total time of 50 minutes to complete the required process for a single donor.

Alternative Specimens, *Sweat*

Relative to incorporating sweat as an optional specimen selection, Concentra agrees that privacy during collection (application of the sweat patch) does not appear to be a concern. However, we do believe there is a significant privacy concern relative to actually wearing the sweat patch for an extended period of time. Although many companies require random drug testing, the fact still remains that there is a negative connotation around being required to have a drug screen, as the Department noted in its statement that "there could be a stigmatizing effect on the wearer." Since the upper arm is the recommended location for the patch, wearers may be uncomfortable dressing in short sleeves, which may present an issue in warm weather months or in climates where the weather is predominantly warm. Privacy has been a rapidly growing concern for at least the past decade, particularly in the health care industry, with the adoption and implementation of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). As such, Concentra recommends that the Department strongly consider the privacy implications inherent in sweat testing.

Concentra also has some concerns and questions relative to possible allergic reactions to the sweat patch. As the Department noted, "skin sensitivity and rash are factors that can only be known after the patch is applied for the first time." We recommend that the Department establish a process whereby any potential allergic reactions on behalf of a donor would be uncovered. This would be, for example, in the form of a series of questions to be asked of the donor when he/she presents for a drug screen. If it is discovered that a donor has an allergic reaction to sweat patches or sweat patch material, then an alternate specimen should be collected. This will not only reduce the occurrence of an allergic reaction but it will also reduce the possibility that an allergic reaction will occur during non-business or weekend hours, as discussed below.

The guidelines also require that a wearer return to the collection site to have the patch removed if an allergic reaction occurs. What should the wearer do if the reaction develops during non-business hours, for example on the weekend? If the wearer removes the patch, should this be considered a "refusal to test"? Potentially, if the wearer removes the patch on Friday evening the rash may subside by Monday morning and it will be impossible to determine if the wearer did indeed experience an allergic reaction. This allows for the opportunity to manipulate the drug test program relative to sweat collections. If the proposed revisions are passed and sweat testing is incorporated as an optional specimen selection, we would request that specific procedures be adopted to address the concerns above.

Concentra agrees with the Department's statement that "sweat patch contamination issues continue to be a concern." These concerns should not be taken lightly, as authorizing the use of sweat as an optional

specimen selection without further investigation and research could result in a plethora of inaccurate test results which would compromise the integrity of the Program.

As noted in the Preamble, currently sweat testing is used in the private sector for monitoring drug use during substance abuse treatment and is also used in the criminal justice system. We believe that these are the only appropriate uses given the nature of how the sweat is collected (through sweat patches) and the inherent problems associated with wearing the patches.

SUPPLEMENTARY INFORMATION - SUBPARTS

Subpart B – Specimens – Major Change
If the proposed revisions are passed and hair, oral fluids, and sweat testing are incorporated as optional specimen selections, Concentra agrees that the reasons for defining and limiting the selection of specimens for the different types of testing are appropriate. However, we disagree with the appropriateness of using hair for return to duty or follow-up, and with using oral fluid for random or pre-employment.

Concentra agrees that routinely collecting more than one type of specimen from a donor should be prohibited except when an oral fluid specimen is collected. Cost, timeliness, and the potential for conflicting results are all considerations when multiple types of specimens are collected.

With regard to the process when a problem occurs during the collection of one type of specimen (e.g. "dry mouth" or "shy bladder") Concentra recommends that either the Department or the Federal Agency be required to list an acceptable alternative specimen, rather than have the collector contact the Federal Agency. This should be specifically noted either in the Guidelines or in the Federal agency's initial request for testing. An appropriate contact at the Federal Agency may not be readily available and may cause extended wait times for the donor and the collector. In addition, as noted previously, if a different specimen is collected than originally requested, the potential for bias exists, for or against the donor depending on which specimen is ultimately collected. This should not be dismissed lightly.

Subpart D – Collectors
Concentra applauds the Department's efforts at creating a more formalized training process for collectors. We ask that the Department recognize the burden that additional training will place on drug testing facilities; and, we recommend that the Department give drug testing facilities one (1) year from the publication date of the final guidelines to train and certify all collectors.

Subpart E – Collection Sites
If the proposed revisions are passed and hair testing is incorporated as an optional specimen selection, Concentra strongly agrees with the Department that head hair is the only type of hair to collect for a hair sample.

Concentra disagrees with the requirement that the collector and the donor are the only individuals present while the specimen is being collected. Collection areas may be designed to accommodate more than one collection at a time by multiple collectors. The Department has noted on several occasions that privacy does not appear to be a concern (other than for urine) and as such should not be a factor here. We agree that potential cross-contamination or specimen mix-ups may be an issue, but we request that the revisions be amended to require that a collector may only collect a specimen from one donor at a time. This would address the above noted concern, but will still allow multiple collections by different collectors in the same area. Many medical facilities are likely to experience significant operational costs if collection areas have to be redesigned or additional areas built. This requirement also appears to conflict with

Subpart E, Section 5.4 of the Guidelines which only prohibits unauthorized personnel to enter the collection site during the collection.

Subpart F – Federal Drug Testing Custody and Control Forms

The Department has requested comments regarding the use of a single Federal CCF versus a multiplicity of forms. Concentra strongly agrees with this proposal. We suggest establishing a uniform and comprehensive form with check boxes reflecting the different specimens (e.g. head hair, urine, oral fluid w/urine, etc.). Having one form would be consistent with the provisions of the OMB Paperwork Reduction Act. It would also assist in the reduction of potential errors made on the CCF and drastically lower the amount of paperwork inherent in creating a multiplicity of forms for each specimen.

Concentra suggests that any new or revised Federal CCF be developed in collaboration with the DOT. Because a significant portion of the drug screening industry is dominated by DOT drug screens, it is only reasonable to collaborate with them prior to developing a new CCF.

We'd also like to recommend that the Department publish the first draft of the revised Federal CCF for review. In doing so, drug testing facilities and industry leaders will be given the opportunity to comment on and recommend changes prior to its adoption. It is important to involve the aforementioned groups in this process as they will be the end users of this form.

The Department has also solicited comments regarding whether it would be useful to add a requirement that the form cannot be altered by the employee or others. Concentra strongly disagrees with this proposal. The urine collection guidelines specifically state that "the collector shall note any unusual behavior or appearance on the Federal CCF." We believe that comments are a vital form of information for the MRO in making decisions as to what questions he or she may ask the donor. Relative to hair collections, a good example would be a case in which the collector can visually determine that the donor has chemically treated hair (colored or permed) or that the donor may be wearing a wig but did not disclose that fact. As such, Concentra strongly recommends that the Department increase the size of the comment box, rather than eliminate it. Because the collection process represents the weakest link in the drug testing process, the size of the comment box/opportunity for commentary should be enhanced, not eliminated.

And, finally, Concentra asks that the Department consider the implementation of a paperless CCF process. From the perspective of the health care industry, electronic transmission or submission of data is becoming a commonplace practice. Allowing the transmission of the Federal CCF from the collection site to the laboratory, for example, will reduce paperwork issues and increase the overall efficiency of the drug testing process.

Subpart G – Collection Device

In this Subpart, the Department proposes the types of collection devices to be used by the Federal agency during the collection process. The Department distinguishes between devices that have been cleared by the Food and Drug Administration (FDA) and those that have not been cleared. For non-FDA approved devices, the Department proposes that Federal agencies must only use a collection device that does not affect the specimen collected. Concentra requests clarification as to how/what standards a Federal agency will use in determining whether or not a collection device affects the specimen collected.

Subpart H – Specimen Collection Procedure

Here the Department establishes the collection procedure for each specimen. In this Subpart, the Department proposes that a Federal agency conduct an annual inspection of each collection site it utilizes for employee drug screens. As mentioned previously, Concentra owns and operates two hundred fifty-six (256) occupational health clinics across the United States and is a fairly large provider of drug screening

services. In 2003, Concentra conducted a little over two (2) million drug screens with only six hundred forty-seven (647) of these representing Federal agencies (not including DOT drug screens). The six-hundred forty-seven (647) drug screens represent approximately seventeen (17) Federal agencies. On the average, this represents only three (3) drug screens per center on behalf of Federal agencies over the course of the entire year. Considering that these three (3) drug screens may come from different Federal agencies, does this number justify the time, effort, and money that each of these Federal agencies would need to invest to meet this requirement?

Subpart L – Point of Collection Test (POCT)
In this Subpart, the Department proposes to add POCT testing to the Program. The rationale behind this is that it will yield immediate test results for those agency employees located in remote areas of the country.

The Department has stated that Federal agencies that choose to participate in POCT testing will bear some of the same responsibilities for ensuring compliance as they do for the laboratory-based drug testing program. As such, the Department proposes that these Federal agencies must meet the following requirements:

1. Use only POCTs that are on the list of SAMHSA-certified devices;
2. Ensure that only trained testers are used and provide them with a standard operating procedures manual;
3. Ensure that the requirements of the regulation are fulfilled;
4. Accomplish the inspection of the POCT test sites;
5. Accomplish proficiency testing;
6. Maintain records on the trainers as well as inspections;
7. Investigate failures;
8. Make available all Federal agency records for the POCT-related activities for periodic inspections by the Secretary; and
9. Other responsibilities.

Relative to requirements 2 and 4 – 6, Concentra harbors some grave concerns regarding both the feasibility and practicality of these requirements. For example, a Federal agency utilizes our Houston, Texas medical center two or three times a year for employee POCT drug screens. Requiring that they conduct an annual inspection of this center is overly burdensome as the volume of drug screens we receive from them does not reasonably justify an inspection. Concentra recommends that the Department consider strongly consider modifying these provisions to reflect these types of circumstances.

Additionally, requirement #2 mandates that Federal agencies ensure that only trained testers are used and that each Federal agency (e.g. Department of Justice, Department of Labor, etc.) provide them with a standard operating procedures manual. Concentra requests clarification regarding who will be performing the training and whether trainers will be required to know and abide by all the procedures outlined in different agency manuals, which may conflict with one another. Specifically, Concentra requests clarification as to whether each Federal agency will be developing a uniform procedure manual, or may be developing individual manuals. Concentra believes that requiring POCT testers to operate under a number of separate manuals is extremely burdensome; and, we encourage the Department to collaborate with impacted Federal agencies (e.g. DOT, NRC) to develop a uniform drug testing manual.

Relative to requirement #6, the Department requests that the Federal agency would be required to retain a record(s) of the collector(s) training. Concentra recommends that this be amended to coincide with the DOT's current policy that requires each collector to retain his/her own training records.

Also in this subpart, the Department discusses the requirement that one of every ten (10) negative samples must be sent to an HHS-certified laboratory for confirmation. Concentra believes this is an unnecessarily burdensome requirement. Concentra would also like the Department to elaborate on the procedure for the selection process and for the logging/tracking of which samples were selected. For example, over the course of a month, Concentra may perform one hundred and six (106) POCTs, only two (2) which are for Federal agency employees. Should Concentra send approximately ten (10) of these samples to an HHS certified lab, or wait until we have conducted ten (10) POCTs for Federal agency employees, which may not occur at any given site over the course of an entire year? In other words, does the one-out-of-ten requirement only apply to Federal agency employee samples or does it apply to all POCT samples? Another significant question is which party incurs the additional cost of the quality control test – the Federal agency whose employee's sample was chosen or the POCT collection site? Concentra requests that the Department address these concerns.

Subpart N – Medical Review Officer – Major Change
Relative to Sections 14.4 – 14.7, the Department has requested comments regarding whether the same type of specimen or one of the other types of specimens should be collected when a specimen is reported as invalid by the lab. First and foremost, Concentra strongly disagrees with the designation of an "invalid" specimen. We believe that designating a specimen as "invalid" will create a loophole in the Program particularly with respect to "random," "return to duty," and "reasonable suspicion/cause" drug tests. If a specimen conducted during one of these tests is designated "invalid" by the laboratory, then the whole objective of this test will have been negated. For example, a "random" drug screen is performed to encourage a drug-free workplace. If the specimen is reported invalid, then the reason for conducting the test in the first place has been voided. Collecting a different or subsequent specimen will not have the same effect because the test can no longer be deemed a "random" drug screen. This is just one instance in which "invalid" specimens will compromise the integrity and force of the Program. As such, Concentra recommends that the Department withdraw the "invalid" drug screen from the proposal; and, for specimens that the laboratory cannot determine the adulterating substance, we suggest that the Department continue to designate these specimens as dilute, adulterated, or substituted.

If the Department proceeds with designation of an "invalid" specimen, MROs utilized by Concentra suggest changes to the procedure. One suggestion is that an observed urine specimen be collected in every instance that a test is reported as invalid. Another recommendation is to collect the same type of specimen be tested in addition to one of the alternative specimens. For example, for an invalid urine test, repeat the urine test and add a hair, saliva, or sweat test. It is important to recognize however, that debate would likely ensue if one specimen came back positive and the other negative. In general, MROs utilized by Concentra did not support the use of alternative specimens.

Concentra would also like to recommend that the Department use DOT's 49 CFR Part 40 as a model for developing provisions governing MROs. Because such provisions already exist, we recommend that the Department use them as a starting point to build from, if necessary. Also, many drug testing facilities have aligned their drug testing policies to the DOT Guidelines, and using them will encourage uniformity throughout the drug testing industry.

Subpart P – Criteria for Rejecting a Specimen for Testing – Major Change
Section 16.3 describes the types of omissions and discrepancies that occasionally occur on the Federal CCF. The Department has requested comments as to whether the MRO should be responsible for tracking these types of errors. MROs used by Concentra recommend that the guidelines permit the MRO to designate a qualified individual to perform this function by including the terminology "or designee".

Relative to Section 16.4, the Department has requested comments on any other errors that must be corrected before the MRO can report a test results or discrepancies that may occur and must be corrected

when the collector transfers the specimen to a POCT tester. MROs utilized by Concentra do not believe they have enough experience with alternative specimens to comment.

Electronic Technology Applications
The Department has requested comments as to whether electronic technology and capabilities should be addressed in the Guidelines. Over the past decade, the health care industry has led both the private and public sectors in incorporating electronic technology into its operational structure. Concentra strongly recommends that the Department contemplate developing policies/guidelines that would facilitate the use of electronic technology in the drug testing industry. As mentioned in our Subpart F discussion, collectors can easily and more efficiently complete and submit an electronic Federal CCF to laboratories. The drug screening industry is eagerly awaiting the Department's permission to implement electronic technology applications into the drug testing process.

SUPPLEMENTARY INFORMATION

Impact of These Guidelines on Government Regulated Industries
Concentra fervently believes that these proposed changes to the Guidelines will impact the DOT and NRC regulated industries. The Omnibus Transportation Employee Testing Act of 1991 (OTETA) requires that the DOT absorb any revisions or guidelines developed by the Department of Health and Human Services. As such, these guidelines will likely be absorbed into 49 CFR Part 40 if adopted.

In addition, Concentra is confident that private industries will be impacted as well, as non-regulated tests tend to be held to a "gold standard" which is typically based on the regulated industries'/Federal guidelines. As a result, these guidelines will likely be applied to millions of donors/tests rather than thousands as considered in the Department's burden analysis. In 2003, Concentra conducted six hundred forty-seven (647) drugs screens for employees of Federal agencies, 585,205 DOT drug screens, and 1,426,452 drug screens on behalf of the private sector – a ratio of approximately 1 : 900 : 2200. It is likely that other entities who offer drug screening services experience the same or similar ratios, and if the guidelines become the "gold standard," the Department's burden analysis will have grossly underestimated the potential impact on the drug screening industry. In order to more realistically project the burden associated with the proposed revisions, projected man hours and all costs should be considered for both regulated and non-regulated testing. Potential bias, discrimination, and privacy concerns should also be considered for both regulated and non-regulated testing. And finally, training requirements should be considered relative to every collection site and every staff member who collects specimens for employees across all industries.

Guideline Commentary

SUBPART B – SPECIMENS

Section 2.1 What Types of Specimens May Be Collected?
As mentioned in the Preamble, Concentra strongly recommends against the use of head hair, oral fluid and sweat as alternative specimens in the Federal Workplace Drug Testing program until further research is conducted, greater justification is provided, and the current technology is updated to ensure greater efficiency and accuracy.

We also feel that, if the primary motivation for introducing these alternative specimens is the potential for adulteration of a urine specimen, the Department must take into consideration the fact that adulterants will almost certainly be developed for these alternative specimens as well. It is only a matter of time before some entrepreneur begins to replicate the sweat patch or that a creative method for adulterating an oral fluid specimen is developed.

Overall, Concentra requests that the Department recognize that certain interest groups or organizations have a financial incentive to see these proposals adopted. The truth is that we all have financial incentives to see these proposals adopted as it will expand our line of services and result in an increase in the number of employers who use us for drug testing, among other services. However, by introducing these alternative specimens at the present time, we all take the risk of jeopardizing the integrity of drug testing as a whole by introducing specimens that can both potentially bias and stigmatize certain ethnic groups and produce an increase in non-negative results because the necessary technology has not been refined. Concentra suggests that the Department strongly consider the potential devastating impact that alternative specimen testing will have on the integrity and "gold standard" reputation of the Program, if adopted.

Section 2.2 Under What Circumstances Can the Different Types of Specimens Be Collected?
In this section, the Department includes a table listing the situations for which the collection of a specific specimen is most appropriate. Concentra questions the appropriateness of using head hair specimens for "return to duty" and "follow up" testing. In light of the fact that head hair captures drug use extending back ninety (90) days, it is possible that drug use extending prior to rehabilitation might be captured; therefore, a recovering addict/donor who has been clean or rehabilitated for the length of his/her absence could be wrongly accused of ingesting drugs. As "recovering addicts" are protected under the ADA, it is possible that a wrongly accused employee/donor will file suit. In light of this, we highly recommend that the Department seriously contemplate the legal ramifications inherent in using head hair as an alternative specimen. We also suggest removing "return to duty" and "follow up" tests from the table as reasons for collecting a head hair specimen.

We also question the suitableness of collecting an oral fluid specimen for a "pre-employment" or "random" drug tests. Because of the short-detection window for oral fluid, this specimen would not be appropriate or useful in capturing recent or previous drug use. As such, Concentra suggests removing "pre-employment" and "random" drug tests from the table as reasons for collecting an oral fluid specimen.

Concentra requests guidance as to the potential situation where a collector inadvertently collects the wrong or incorrect specimen (e.g. collecting a head hair specimen for a post-accident test). Is this specimen still acceptable for testing or must the specimen be thrown out and the appropriate one collected?

Section 2.3 Can More Than One Type of Specimen Be Collected at the Same Time from the Same Donor?
Concentra feels that the Department has developed this subsection in a clear and organized fashion; however, to avoid confusion, we feel that title of this Section needs to be revised. To avoid confusion, we suggest that the Department replace the term "Time" with "Test." The term "test" is more specific and will reduce any ambiguity. Another provision that may cause confusion is the phrase "Yes, more than one type of specimen may be collected..." Concentra feels that this statement can be replaced satisfactorily with "Only in the following circumstances can more than one type of specimen be collected:....." or "The collection of more than one type of specimen is permitted only under the following circumstances.." This will eliminate or circumvent most uncertainty on behalf of those who might read the lead-in as authorizing them to collect more than one specimen in all circumstances.

Subsection (a) requires that a urine specimen be collected each and every time when an oral fluid specimen is collected. As mentioned previously, if each donor is required to produce an oral fluid specimen and a urine specimen, overall wait times at collection sites will drastically increase and ultimately, patient satisfaction will decrease. As an example, a typical oral fluid collection takes approximately ten (10) minutes for the collection, and potentially, an additional ten (10) minutes if the donor had anything in his mouth. It then takes approximately fifteen (15) minutes to collect a urine specimen. The paperwork for both tests takes about fifteen (15) minutes to process. This results in a potential total time of 50 minutes to complete the required process for a single donor. This requirement eliminates any incentive for an employer to request that an oral fluid specimen be collected. If a urine specimen must be collected anyway, it would be much easier, more efficient, and less expensive for a Federal agency to request the collection of a urine specimen in the first place, and, thereby, avoid any unnecessary and redundant collections.

Subsection (b) prompts the collector to contact the Federal agency when a problem occurs during the specimen collection process (e.g. "shy bladder"). As it is often difficult to reach a Federal agency representative, Concentra recommends that the Department establish protocol to deal with these types of situations by mirroring the DOT's procedure relative to "shy bladder."

Section 2.4 How is Each Type of Specimen To Be Collected?
In this section, the Department proposes that each type of specimen be collected as a split specimen.

Concentra requests that the Department consider the increased costs of containers and postage that will be incurred with the collection of a split specimen for all specimens collected. As the HHS standards for drug testing represent the "gold standard" for drug testing in the private industry, the likelihood that testing centers will adopt these procedures industry-wide (to include non-Federal/private drug testing as well) is extremely high.

SUBPART C – DRUG AND VALIDITY TESTS

Subsections 3.19 through 3.22 establish the criteria that must be used to report specimen samples as an invalid result. Concentra strongly advises the Department to reconsider designating a test result as "invalid." As mentioned in the Preamble, "invalid" test results will create a large loophole in the Guidelines that will likely threaten the integrity of the Program. Accordingly, Concentra advises the Department to withdraw the "invalid" drug screen from the proposal; and, for specimens that the laboratory cannot determine the adulterating substance, we suggest that the Department continue to designate these specimens as dilute, adulterated, or substituted.

SUBPART D – COLLECTORS

Section 4.1 Who May Collect a Specimen?

In Subsection (c) of this section, the Department proposes that an employee working for a testing facility not serve as the collector if he/she could link the identity of the donor to the donor's drug test. Concentra applauds the Department's efforts in providing for and maintaining the confidentiality of the donor's test results; however, we feel that this requirement would be extremely difficult to enforce. If adopted, additional guidance will need to be provided as to how testing facilities are expected to ensure compliance with this requirement, simply because it will be very difficult to know or determine in advance whether or not a given collector will remember enough information about a donor that will enable him to link the test result to the donor's identity. For example, who will determine in advance whether or not a link between the donor and test result might occur – the employee himself, the testing facility administrator, the donor, etc.

Relative to POCTs, the current process is that the collector and the test are the same individual and that individual would clearly be able to link the results back to the donor, particularly since the test must be done within a certain period time following the collection. If adopted, this requirement would necessitate significant process change.

Section 4.2 What are the Requirements to Be a Trained Collector for a Federal Agency?

Concentra applauds the Department's attempts to create a more formalized training process for collectors. We do however, have some concerns relative to the training requirements and respectfully request that the Department recognize the tremendous impact that the training requirements would impose on collectors. As such, we recommend that the Department allow time to implement training and certification for all collectors and suggest a "phase in" period of 1 year.

As mentioned previously, Concentra operates two hundred and fifty-six (256) occupational health clinics in thirty-six (36) states and eighty-five (85) markets. Concentra also currently operates one hundred seventy-two (172) on-site clinics. Concentra occupational health clinics alone employ approximately three thousand six-hundred (3,600) employees and all of these employees are cross-trained to serve as collectors. If the proposed revisions were adopted, we would need to provide training for each of our 3,600 employees, with each one performing five (5) consecutive error-free mock collections for four (4) devices (for each type of specimen). We anticipate that we will need at least fifty (50) market trainers to facilitate the training. Considering the costs of travel and training time for both the trainers and the 3,600 collectors, one only has to imagine the concerns that Concentra has significant concerns surrounding these requirements. These concerns will be addressed below by subpart.

Subsection (a) requires that a trained collector have read and understood these Guidelines. Concentra suggests that the Department reword this section to state that collectors only be required to read and understand the Guidelines relevant to their job responsibilities.

The Department states, in subsection (b), that a trained collector will have, among other things, read and understood any "guidance provided by the Federal agency which is consistent with these Guidelines." Concentra requests clarification as to whether all agencies will be developing guidance pertaining to the collection process. If so, this means that testing facilities like Concentra will be inundated with a number of different drug testing standards and policies. As such, Concentra recommends collaboration by all Federal agencies in developing uniform guidance.

Subsection (c) states that collection proficiency is demonstrated by completing five consecutive error-free mock collections for a particular specimen. For reasons mentioned above, we believe that this

requirement would be unduly burdensome to collection sites both financially and from a resource perspective. Taking into account the various alternative specimens, this means that collection sites will incur an additional financial burden to obtain the training supplies, which would be in excess of our standard orders.

A second consideration pertaining to the requirement set forth in subsection (c) is the amount of training time that would be necessitated by this requirement. The amount of time needed to perform this training would significantly interfere with the day-to-day operations of collection sites. In order not to disrupt operations, collection sites might be required to conduct training on weekends, and, as such, would need to compensate employees for overtime.

Finally, relevant to the five error-free mock collections required by subsection (c) , Concentra requests clarification as to how these mock collections should be conducted for the alternative specimens. Will our medical center employees be required to produce oral fluid specimens for each other until they have each completed their five error-free mock collections. For hair, will the use of a wig be required or must our medical center employees continue to cut each other's hair until they have met this requirement?

Subsection (d) requires that all trained collectors successfully complete a training course by an established organization for the particular type(s) of specimen(s) for which the individual is being trained. Concentra requests clarification of the term "established organization" (e.g. who or what is an established organization and what does an organization have to do to become established?). We also request guidance as to what or whose standards or materials should be used to develop the training course (e.g. Federal agency guidance, these Guidelines, protocol established by industry leaders, etc). We also have some serious concerns about the impact of the requirement that all collectors complete a training course for each of the alternative specimens. Because we cross-train all of our medical center employees so that everyone can perform collections if the situation calls for it, this requirement would necessitate that all 3,600 employees take a course for each of the four specimens. We request that the Department recognize this burden by approving a one (1) year "phase in" to fulfill this and other aforementioned training requirements.

Section 4.3 How is a Collector's Training Documented?
In Subsection (b)(2), the trainer is given the option of completing a "train the trainer" course to become qualified. Again, Concentra requests clarification as to both the guidelines and standards that must be used to develop this type of course and the definition of "established organization."

In addition to the individual subsections discussed above, Concentra would like to request clarification pertaining to retraining of employees. Absent from the proposed regulation is how a collector remains proficient in the collection process and how often or frequently retraining must occur. Concentra requests that the Department establish a five (5) year retraining cycle to coincide with the "refresher training" schedule established by the DOT in 49 CFR 40.33 (e). Because a refresher training cycle has already been established by the DOT, Concentra believes it would be reasonable and practicable to adopt this standard.

Concentra would also like to suggest the probability that testing facilities conducting Federal employee drug testing will be prompted to adopt these provisions across the board to include private-sector/non-Federal employee drug testing for two reasons. First, because the HHS Guidelines represent the "gold standard" for drug testing, it is likely that testing facilities will implement the requirements set forth in the Mandatory Guidelines for all drug testing. Second, adopting the Guidelines for all drug testing will also result in the simplification of the collection process for those facilities that perform drug testing for both Federal and private/non-Federal employees.

Concentra believes that the title of this subsection is misleading as it does not actually address how a collector's training is documented. It actually appears to address the responsibilities and qualifications that must be met by the trainer. As such, we recommend that Section 4.3 be entitled, "What Are the Qualifications and Responsibilities of an Approved Trainer?" This revision will more appropriately address the provisions set forth in this section and it will naturally flow from the previous section entitled "What are the Requirements to Be a Trained Collector for a Federal Agency?"

SUBPART E – COLLECTION SITES

Section 5.1 Where Can a Collection for a Drug Test Take Place?
Subsection (b) establishes some examples of an appropriate collection site. These examples do not go far enough, specifically with respect to sweat patches and oral fluid specimens. Concentra requests that the Department clarify appropriate collection sites for these specimens.

Section 5.2 What Are the Requirements for a Collection Site?
In subsections (b) and (f), the Department utilizes the term "secure" to refer to storage conditions. Concentra requests clarification regarding this term and what conditions constitute secure record storage. Specifically, does the Department require that the temporary storage area have a lock or is it sufficient that the storage area be located in an area where other patients would not normally have reasonable access to it?

Absent from this section is a requirement restricting donor access to potential adulterants (e.g. chemicals, contaminants). Concentra recommends that the Department includes provisions to this effect.

Section 5.3 How Long Must Collection Site Records Be Stored?
In this section, the Department establishes a two (2) year retention period for collection site records. Concentra requests that the Department distinguish between original collection site records and the MRO's copy of these records. We are amenable to maintaining original collection site records for two (2) years. We strongly advise, however, that the Department conform to the thirty (30) day retention period set forth in 49 CFR Part 40 for the MRO's copy of these records. It is sufficient that we maintain the original records and not keep two (2) copies of the same document.

Section 5.4 How Does the Collector Ensure the Security of a Specimen at the Collection Site?
In subsection (a)(1), the Department states that no "unauthorized personnel" should be allowed to enter the collection site during the collection. Concentra requests that the Department clarify this term to specify who would be considered authorized personnel – other staff members, other staff members who have been trained to collect specimens, supervisors, etc.? In the preamble, it states that "the collector and the donor are the only individuals present while the specimen is being collected." This statement conflicts with (a)(1) of this section and needs clarification. Concentra recommends revising the Preamble to coincide with this subsection.

Concentra is concerned that subsection (b) makes the assumption that all specimen packaging is tamper-evident. Because the Department has not established this requirement, we feel that the tamper-evident packaging will not always be provided for each specimen. Instead of requiring tamper-evident packaging, Concentra recommends that the Department propose the development of standard kits, similar to those developed by the DOT in 49 CFR Part 40.

Section 5.5 – 5.7 Privacy Requirements
Concentra requests clarification as to specifically what type of privacy is to be afforded to the donor for each type of specimen. Different interpretations as to what constitutes privacy may lead to conflicting collection site standards and consequently a multitude of claims regarding violation of donors' privacy.

Section 5.8 What are the Privacy Requirements When Collecting a Urine Specimen?
Subsection (c) provides that mere suspicion that the donor may tamper with or substitute the specimen is enough to warrant an observed collection. Concentra believes that this section leaves the Department open to a barrage of complaints regarding violation of privacy rights. To avoid potential legal complications, Concentra suggests that the Department develop a list of circumstances or situations that would support a decision to conduct an observed collection.

SUBPART F – FEDERAL DRUG TESTING CUSTODY AND CONTROL FORMS

The Department requested comments on whether or not it would "be preferable, and practical, to have a single Federal CCF that could be used for all the various specimens, rather than a multiplicity of forms." Concentra strongly agrees with this proposal. We suggest establishing a uniform and comprehensive form with check boxes reflecting the different specimens (e.g. head hair, urine, oral fluid w/urine, etc.). Having one form would be consistent with the provisions of the OMB Paperwork Reduction Act. It would also assist in the reduction of potential errors made on the CCF and will drastically lower the amount of paperwork inherent in creating a multiplicity of forms for each specimen.

Concentra suggests that any new or revised Federal CCF be developed in collaboration with the DOT. Because a significant portion of the drug screening industry is dominated by DOT drug screens, it is only reasonable to collaborate with them prior to developing a new CCF.

We'd also like to recommend that the Department publish the first draft of the revised Federal CCF for review. In doing so, drug testing facilities and industry leaders will be given the opportunity to comment on, recommend changes, and bless the form prior to its adoption. It is important to involve the aforementioned groups in this process as they will be the end users of this form.

The Department has also solicited comments regarding whether it would be useful to add a requirement that the form cannot be altered by the employee or others. Concentra strongly disagrees with this proposal. The urine collection guidelines specifically state that "the collector shall note any unusual behavior or appearance on the Federal CCF." We believe that comments are a vital form of information for the MRO in making decisions as to what questions he or she may ask the donor. Relative to hair collections, a good example would be a case in which the collector can visually determine that the donor has chemically treated hair (colored or permed) or that the donor may be wearing a wig but did not disclose that fact. As such, Concentra strongly recommends that the Department increase the size of the comment box, rather than eliminate it. Because the collection process represents the weakest link in the drug testing process, the size of the comment box/opportunity for commentary should be enhanced, not eliminated.

And, finally, Concentra asks that the Department consider the implementation of a paperless CCF process. From the perspective of the health care industry, electronic transmission or submission of data is becoming a commonplace practice. Allowing the transmission of the Federal CCF from the collection site to the laboratory, for example, will reduce paperwork issues and increase the overall efficiency of the drug testing process.

SUBPART G – COLLECTION DEVICE

Section 7.2 Which Collection Devices May Be Used?

The Department requested comments on the proposed requirement that a Federal Agency must only use a collection device that does not affect the specimen collected. Concentra feels that this is an appropriate requirement however we believe the Department needs to elaborate on the subsection (b) which states for non-FDA cleared devices, a "Federal agency must only use a device that does not affect the specimen collected." If the Department is asking Federal agencies to clear non-FDA approved devices, Concentra advocates the development of criteria to assist them in clearing a collection device.

SUBPART H – SPECIMEN COLLECTION PROCEDURE

To promote consistency and uniformity in the drug testing industry, Concentra request that the Department conform as much as possible to DOT guidelines set forth in 49 CFR Part 40. Also in this Subpart, Concentra has suggested the development of a pre-screening policy prior to collecting each alternative specimen.

Section 8.2 What Procedure is Used to Collect a Head Hair Sample?

Please refer to previous comments in the Preamble relative to using head hair as an alternative specimen. Additionally, following please find commentary relative to specific provisions included in this section.

First and foremost, Concentra requests that the Department recognize safety concerns inherent in introducing scissors into the collection process. A belligerent donor or one who is under the influence of an illicit drug(s) may react harshly to the specimen collection. It is not difficult to imagine a donor seizing the scissors from a collector and creating an emergency situation – one that the drug testing facilities may not be equipped to handle. On the other hand, an inept collector could injury a donor during the collection process which could result in a personal injury lawsuit.

In general, this section does not address religious traditions or customs that might interfere with the collection of a head hair specimen. Concentra requests that the Department address this situation. For example, should an alternate specimen be collected or does the refusal to provide a specimen constitute a "refusal to test" in this situation?

Subsection (a)(7) instructs collectors regarding how to collect or cut the head hair specimen. The Department establishes the weight of hair needed for testing at one hundred (100) mg and states that the sample collected must meet that requirement. The proposed guidelines do not instruct the collector as to whether they should cut extremely long hair down to approximately 1.5 inches before they weigh the hair. Our concern is that the difference in the amount of long hair versus the amount of short required to equal 100 mg is significant and will cause confusion when the collector is cutting the hair (i.e. it takes significantly fewer strands of long hair to meet the requirement than it does for short hair.)

Concentra also requests clarification concerning when the specimen collected does not meet the 100 mg requirement. For example, must the collector dispose of the first specimen and start again or can they cut an additional piece from the same region? If the collector must dispose of the first specimen, must they collect the second specimen from the same location or a different one?

Also pertaining to (a)(7), Concentra has some concerns regarding the textural differences of hair (e.g. fine hair, coarse hair). We believe that the amount of hair or number of strands that must be collected to meet the 100 mg requirement will vary depending upon the texture of the donor's hair. A greater sample will need to be collected from a donor with thin/fine hair as opposed to one with thick/coarse hair.

In subsection (a)(8), the process for splitting a head hair specimen is outlined. The process of obtaining a split specimen for head hair is an extremely subjective, time-consuming and intricate process. Furthermore, the likelihood that strands from the specimen will be lost and/or contaminated is extremely high.

Generally speaking, Concentra requests that the Department consider developing a questionnaire to be added the collection procedure. To reveal any contamination concerns, collectors should be instructed to ask, for example, whether or not the donor has chemically treated their hair in the past 60 days. Questions of this nature would occur prior to specimen collection and should be asked to reduce the occurrence of false negative test results. Concentra also requests guidance as to the development of a "next best specimen" policy that would be implemented when an invalidating circumstance (e.g. chemical treatment) is discovered. For example, when it is discovered that the donor has chemically treated her hair, what is the next best specimen for conducting the drug test?

Section 8.3 What Procedure is Used to Collect an Oral Fluid Specimen?
Please refer to previous comments in the Preamble relative to using oral fluid as an alternative specimen. Additionally, following please find commentary relative to specific provisions included in this section.

In subsection (a)(4), the Department requests that "the collector confirm that the donor has not had anything in his or her mouth for ten (10) minutes prior to providing the oral fluid specimen." Concentra requests that the Department elaborate on exactly how a collector is to ensure that a donor has not had anything in his mouth for the past 10minutes. Even if asked, it is possible that a donor will lie to the collector. Does the Department then propose to develop some type of test to confirm this?

If the donor has had something in his mouth in the past 10 minutes, the Department proposes that the collector "wait 10 minutes prior to beginning the collection process." Concentra requests clarification as to how a collector should ensure that the employee does not put anything into his or her mouth. Also, who should be monitoring the donor during this 10 minute timeframe?

Although not discussed, Concentra believes that certain types of prescription and over-the-counter drugs might invalidate the oral fluid specimen. As such, we recommend that the Department develop a questionnaire to be asked prior to the oral fluid collection (e.g. "Have you taken a prescription drug tablet today?"). These questions will help to uncover any factors that could potentially invalidate the specimen and, ultimately, the drug test result. Concentra also requests guidance as to the development of a "next best specimen" policy that would be implemented when an invalidating circumstance (e.g. prescription drug tablet or cough syrup) is discovered. For example, when it is discovered that the donor has recently ingested a prescription drug tablet, what is the next best specimen for conducting the drug test?

Subsection (a)(6) requires that 2 mL of oral fluid be collected over a fifteen (15) minute period of time or "until the appropriate volume of specimen is collected." Concentra requests that the Department develop a maximum timeframe for collecting an oral fluid specimen, much like the three (3) hour timeframe for "shy bladder" adopted by the DOT in 49 CFR 40.193. This will enhance the efficiency of the collection process and foster productivity in the testing facilities. It is also unreasonable to retain a donor for an inordinate length of time.

Subsection (a)(8) specifies how the oral fluid specimen needs to be split. Concentra requests that the Department elaborate on the requirement to mix the specimen prior to splitting the specimen. Why must the specimen be mixed and with what is it being mixed? Generally speaking, splitting an oral fluid specimen can be an exceedingly unpleasant and complicated process. Furthermore, the splitting process for an oral fluid specimen is in its infancy and, as such, needs to be refined.

In subsection (a)(16), the Department requires that the collection of an oral fluid specimen be accompanied by the collection of a urine specimen. Concentra strongly disagrees with the recommendation that a urine specimen be collected every time an oral fluid specimen is collected. This requirement will inherently reduce an agency or employer's desire to collect an oral fluid specimen. If a urine specimen has to be collected whenever an oral fluid specimen is collected, it makes sense that employers will simply elect to collect a urine, sweat, or head hair specimen. Furthermore, if each donor is required to produce an oral fluid specimen and a urine specimen, the collection process could take up to fifty (50) minutes (as mentioned previously). This will drastically increase and ultimately patient satisfaction and employer satisfaction will decrease.

Section 8.4 What Procedure is Used to Collect a Sweat Patch Sample?
Please refer to previous comments in the Preamble relative to the use of sweat as an alternative specimen. Additionally, following please find commentary relative to specific provisions included in this section.

Consistent with recommendations for the other two alternative specimens, Concentra request that the Department develop a questionnaire to be asked prior to the sweat patch application (e.g. "Do you have an allergic reaction to Band-aids or latex?"). These questions will help to uncover any factors (including allergies) that could potentially invalidate the specimen and, ultimately, the drug test result. Concentra also requests guidance as to the development of a "next best specimen" policy that would be implemented when an invalidating circumstance (e.g. history of allergic reaction) is discovered. For example, when it is discovered that the donor has an allergy that could result in the removal of a sweat patch, what is the next best specimen for conducting the drug test?

In (a)(7), the Department states that the sweat patch should be worn for no less than three (3) days and no more than seven (7) days before returning to the collection site. To avoid confusion, Concentra requests that the Department develop a schedule outlining sweat patch application and removal timeframes. By doing this, the Department will have set definitive timeframes for the application and removal of the sweat patch. Please see sample table below.

Patch Application	Patch Removal
Monday	Thursday
Tuesday	Friday
Wednesday	Monday
Thursday	Monday
Friday	Tuesday

The Department states in (a)(8) that the collector will remove the sweat patches from the donor "within several minutes." Concentra requests clarification as to whether this means the two patches should be removed with several minutes of each other or within several minutes of returning to the collection site. If it is intended to mean within several minutes of returning to the collection site, Concentra asks that the Department recognize that, depending upon the time of day, the volume of drug screens or urgent medical care business might prevent the sweat patches from being collected within that timeframe.

Additionally, it is important to note that the integrity of the specimen collection is primarily dependent on the donor. Although subsection (a)(9) instructs the collector to inspect the sweat patch, we feel that stricter measures must be in place to ensure that the donor has not tampered with or replaced the sweat patch. Unfortunately, the technology is such that few safeguards currently exist. As such, we recommend that the use of sweat as an alternative specimen either be postponed until the appropriate technology can be developed or limited to substance abuse programs and the criminal justice system where it is currently being used.

Section 8.5 What Procedure is Used to Collect a Urine Specimen

Subsection (a)(1) requires that there be no other source of water (e.g. no shower or sink) in the enclosure where urination occurs. In the event that drug screens are being conducted on-site, this requirement would likely be impossible to meet. Concentra requests that the requirement be amended to conform with DOT's 49 CFR Part 40 which require that any other source of water be disabled and/or secured before the sample is collected.

Subsection (a)(9) requires that the collector "instruct" the donor to not flush the toilet until the specimen is delivered to the collector. Many facilities have installed sensor-driven toilets that flush automatically. This could represent a complication for onsite drug screens if the facility has installed such toilets. Concentra requests clarification as to whether premature flushing constitutes a refusal to test or if the collector should revert to an observed collection at that point.

Subsection (a)(10)(ii) states that if the donor is unable to provide the required amount of urine, he/she is allowed to have one 8-ounce glass of water every 30 minutes up to a maximum of 24 ounces. Concentra requests that this be revised to coincide with the DOT standard set forth in 49 CFR 40.193 (b)(2). This standard permits a maximum of forty (40) ounces of fluid evenly distributed over a three (3) hour period of time. Also, in this subsection, it states that if the donor drinks the water and then fails to provide 30ml of urine, the collector must contact the appropriate authority to obtain guidance. Concentra recommends that this be amended to state that "if the donor fails for any reason to provide 45ml of urine ....." for consistency purposes. We are concerned that only provided 30ml will not allow for a split specimen.

Subsection (a)(13) instructs the Federal agency to select the observer if there is no collector of the same gender available. Subsection (a)(16) also reiterates this requirement. Concentra has three concerns relative to this obligation. First, it is often difficult to contact the appropriate representative of the Federal agency. Second, how can the Federal agency possibly select the observer without being present at the collection site – can a non-collector be an observer? What if the observer chosen is uncomfortable observing as this is probably not their typical role? And, finally, there are legal ramifications inherent in this requirement. Having a male collector perform an observed urine collection for a female employee and vice versa will leave the testing facility open to sexual harassment claims. Concentra advises the Department to strongly consider both the feasibility and legal ramifications of this requirement.

Generally speaking, we also request that the Department clearly discuss and outline the qualifications and expectations of an observer. For instance, is this a role that will require training or can anyone be an observer?

Subsection (a)(19) requires that Bottle A be sent for testing even if there was not enough urine to split into Bottle B. Concentra disagrees with this requirement. If the donor only provides 30 mL of urine, then a split specimen cannot be created. If there is not enough urine for a split, then none of the urine should be tested (if a split specimen is always required as proposed in these guidelines).

Relative to subsection (a)(24), Concentra disagrees with the requirement that a high level supervisor must review and concur that an observed specimen is needed. Concentra requests that this subsection be amended to coincide with DOT 49 CFR Part 40 which empowers the collector to make the decision to order an observed collection.

Section 8.6 What are the Responsibilities of a Federal Agency That Uses a Collection Site?
Subsection (b) requires that Federal agencies must conduct an annual inspection of each collection site used to collect agency specimens. It also states that these Federal agencies must respond to reports of collector and collection site deficiencies reported to them and must take appropriate action to preclude the recurrence of such deficiencies. While Concentra applauds the Department's efforts in enforcing and ensuring compliance, we question the feasibility of this requirement.

Conducting an annual inspection of each collection site is a significant burden on both the Federal agency and the testing facility. Additional employees may be required depending on the number of collection sites that the Federal agency uses for employee drug testing. It will also drastically increase the amount of paperwork and records needed to document such inspections. Altogether, the burden in terms of man-hours and money required to conduct annual inspections is tremendous. As such, Concentra recommends that a qualifier be added to this requirement. For instance, testing facilities for whom an individual Federal agency accounts for greater than twenty-five percent (25%) of its annual drug testing volume will need to be inspected by a Federal agency.

SUBPART L – POINT OF COLLECTION TEST (POCT)
This subpart establishes the criteria for POCT devices that may be used as part of the Federal Workplace Drug Testing program. It also establishes the criteria for when Federal agencies may use a POCT, what the responsibilities are of a Federal agency that chooses to use a POCT, and the procedures that must be followed when using a POCT.

Section 12.16 What are the Requirements to be a POCT Tester?
Concentra would like to reiterate here comments relative to this section that reflect similar provisions outlined in Subpart D – Collectors. Please refer to Subpart D for our comments and concerns.

Section 12.18 What are the Requirements for Conducting a POCT?
Concentra would like to have the opportunity to comment on the OMB-approved CCF (referenced in Subsections (a) and (e)) for POCT and alternative specimen testing prior to approval. This opportunity is not provided in the Notice of Proposed Rulemaking (NPRM) and we strongly recommend that you make this opportunity available.

Relative to subsection (e), Concentra requests that the Department amend this section to require that all specimens, including the urine specimen, be submitted for analysis. Requiring that the urine split specimen only be sent when an oral fluid specimen is "presumptive positive" for marijuana is unclear and worrisome. If the Department plans to require a urine specimen collection in the first place, then Concentra recommends that the primary specimen be sent along with the split to the lab. Why impose that burden on the collection site if the specimen is not going to be used at all? Second, for validity and assurance purposes, it is highly recommended that the Department send the urine specimen. With the inconsistencies and weaknesses inherent in oral fluid testing, it makes sense that a urine specimen would be tested to validate the result yielded by the oral fluid specimen.

Section 12.19 What are the Quality Control Requirements when Conducting POCTs?
Subsection (a)(1) requires that the collection site test POCT kits each day before donor specimens are tested. Concentra believes that quality control requirements should rest primarily with the manufacturer. We suggest that the Department include provisions to this effect requiring that the manufacturer perform ongoing quality control checks and implementing recalls of POCT devices when necessary. Furthermore, since kits are tested by the manufacturer, are FDA-approved, and have an expiration date, Concentra feels that additional quality control by the collection site is unnecessarily burdensome and redundant. The

collection site's responsibility should be limited to checking the expiration date before proceeding with the collection.

Subsection (a)(2) requires that the collection site test POCT devices with machine-read endpoints each day. Again, Concentra believes that this responsibility primarily rests with the manufacturer. Concentra recommends that the collection site only be required to perform quality control testing once a month unless the manufacturer specifies otherwise.

Subsection (c) requires that at least one of every ten negative samples must be sent to an HHS-certified laboratory for confirmation. Concentra believes this is an unnecessarily burdensome requirement. Concentra would also like the Department to elaborate on the procedure for the selection process and for the logging/tracking of which samples were selected. For example, over the course of a month, Concentra may perform 106 POCTs, only 2 of which are for Federal agency employees. Should Concentra send approximately 10 of these samples to an HHS certified lab, or wait until we have conducted 10 POCTs for Federal agency employees, which may not occur at any given site over the course of an entire year? In other words, does the one-out-of-ten requirement only apply to Federal agency employee samples or does it apply to all POCT samples? Another significant question is which party incurs the additional cost of the quality control test – the Federal agency whose employee's sample was chosen or the POCT collection site?

Section 12.21 What Does a POCT Tester Do With a Specimen After Conducting a POCT?
Subsection (a) states that "each presumptive positive, adulterated, or substituted specimen together with its split is sent to an HHS-certified laboratory for additional testing." Concentra requests clarification regarding the perceived down-time this requirement creates. For example, if a DOT employee's POCT yields a "perceived, positive adulterated or substituted specimen," does a testing facility need to wait for MRO confirmation to contact the employer; or does the testing facility contact the employer and place the employee on a probationary status until the MRO can confirm the results. If waiting for clarification is required, this poses a potential safety risk from the standpoint of placing an at-risk driver on the road who may injure not only himself but others as well. This requirement will also elicit legal ramifications and donor stigmatization if a donor is unjustifiably "stood down" or placed on probationary status. As such the down-time created by this requirement causes concern for legal, operational and safety reasons and should not be dismissed lightly.

Also in this section, Concentra would like to reiterate its concerns with the one tenth requirement that was highlighted in subsection (c) of Section 12.19.

Section 12.22 How is a POCT Negative Result?
Subsection (a) states that a negative result should be reported directly to an MRO within three (on average) working days. Concentra disagrees with the timeframe of three (3) working days. We recommend that the Department conform to the twenty-four (24) hour or next business day timeframe established by the DOT within 49 CFR Part 40.

Concentra also recommends that the Department require that all results be sent to the MRO and not only the negative results.

Section 12.23 How Long Must Records Generated at the POCT Site be Retained?
Concentra requests clarification as to whether the records must be stored on site or may be archived at a storage facility. Furthermore, we request that the Department provide a timeframe for retrieving any records that are archived at a storage facility.

Section 12.24 What POCT Information is Available to the Donor?
This Section outlines the types of information that an employee can obtain relevant to his/her POCT test. This information can be attained only upon the written request by the employee through the MRO or Federal agency. Along with other records, subsection (b) states the POCT tester is required to provide a copy of his/her resume or curriculum vitae. Concentra believes this requirement is unnecessarily burdensome and should be removed from this subsection. We believe it is sufficient to provide the employee with proof of POCT training. We also recommend that the documentation package include a copy of the CCF and both the employees test and test result.

Section 12.25 What Statistical Summary Report Must a Federal Agency Provide to the Secretary?
Subpart (d) states that the Federal agency must make available the POCT tester to testify in a proceeding against a Federal employee when that proceeding is based on a test result that begins with a POCT. Concentra requests clarification as to which party will bear the expense of travel to the proceeding, the Federal agency or the POCT tester. Concentra recommends that the Federal agency be responsible for the expense, and, as such, recommends adding the verbiage "at its own expense."

Section 12.26 What Type of Relationship is Prohibited Between a Manufacturer of a POCT Device or a POCT Site Operation and an MRO?
Concentra requests clarification as to what relationship constitutes a conflict of interest.

Subpart N – Medical Review Officer (MRO)
Where possible, Concentra reiterates its desire to see this section aligned with the provisions established for MROs in 49 CFR Part 40/DOT guidelines.

Relative to Sections 14.4 – 14.7, the Department has requested comments regarding whether the same type of specimen or one of the other types of specimens should be collected when a specimen is reported as invalid by the lab. Generally speaking, Concentra strongly disagrees with the designation of an "invalid" specimen. We believe that designating a specimen as "invalid" will create a loophole in the Program particularly with respect to "random," "return to duty," and "reasonable suspicion/cause" drug tests. If a specimen conducted during one of these tests is designated "invalid" by the laboratory, then the whole objective of this test will have been negated. For example, a "random" drug screen is performed to encourage a drug-free workplace. If the specimen is reported invalid, then the reason for conducting the test in the first place has been voided. Collecting a different or subsequent specimen will not have the same effect because the test can no longer be deemed a "random" drug screen. This is just one instance in which "invalid" specimens will compromise the integrity and force of the Program. As such, Concentra recommends that the Department withdraw the "invalid" drug screen from the proposal; and, for specimens that the laboratory cannot determine the adulterating substance, we suggest that the Department continue to designate these specimens as dilute, adulterated, or substituted.

If the Department proceeds with designation of an "invalid" specimen, MROs utilized by Concentra suggest changes to the procedure. One suggestion is that an observed urine specimen be collected in every instance that a test is reported as invalid. Another recommendation is to collect the same type of specimen be tested in addition to one of the alternative specimens. For example, for an invalid urine test, repeat the urine test and add a hair, saliva, or sweat test. It is important to recognize however, that debate would likely ensue if one specimen came back positive and the other negative. In general, MROs utilized by Concentra did not support the use of alternative specimens.

Section 14.4 What Must an MRO Do When Reviewing a Hair Test Result?
Throughout this section, the Department requires that the MRO contact the donor whenever a positive, adulterated or invalid result is reported. The donor is then asked to provide a valid medical explanation for the result. If a valid explanation is not provided, then appropriate action is taken. Concentra requests

that the Department recognize potential difficulties for the donor in providing a valid medical explanation. It may be unreasonable asking them to remember what happened months ago. Furthermore, an MRO may have difficulty determining whether or not, for example, a prescription obtained forty-five (45) days ago accounts for detected drug use.

Section 14.7 What Must an MRO Do When Reviewing a Urine Test Result?
Subsection (g) would require that a second specimen be collected under direct observation even when the donor is able to provide a valid medical explanation/prescription for the invalid test result. Concentra requests that the Department elaborate upon its rationale for this requirement.

Section 14.9 How Does the MRO Report a Primary Specimen Test Result to an Agency?
Subsection (c) requires that an MRO send a hard copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all non-negative results. Concentra requests clarification as to whether this copy must be an original copy with an original signature or whether it can be a stamped signature. This requirement also appears in Subsection 15.14(c) and should be clarified there as well.

SUBPART O – SPLIT SPECIMEN TESTS

Section 15.1 When May a Split Specimen Be Tested?
Subsection (b) states that the donor must make a written request to have the split specimen tested. Concentra feels that this is an unreasonable burden and a verbal request is sufficient.

Concentra disagrees with subsection (c) which requires that a donor provide a new sample if the second portion of a split specimen cannot be tested (e.g. lost in transit). This seems to be an undue punishment for the donor. The donor has already met his or her responsibility in providing the first specimen and should not be subjected to a second test. Concentra requests that this subsection be revised to coincide with DOT guidelines/49 CFR Part 40 that state that if the split specimen cannot be tested, then the test is simply cancelled. The donor is not required to provide a new specimen.

SUBPART P – CRITERIA FOR REJECTING A SPECIMEN FOR TESTING

Relative to Sections 16.1 and 16.2, Concentra requests that the Department acknowledge the potential for identifying future additional fatal and correctable errors.

Section 16.3 What Discrepancies are Not Sufficient to Require a Laboratory or IITF to Reject a Hair, Oral Fluid, Sweat or Urine Specimen for Testing or for an MRO to Cancel a Test?
This section describes the types of omissions and discrepancies that occasionally occur on the Federal CCF. Concentra recommends that the types of errors identified in Subsection (b) should be corrected in all instances by adding a Memorandum for Record (MFR) or an Affidavit of Correction.

In addition, Concentra recommends that the Department allow for attaching an MFR or an Affidavit of Correction to all copies of the CCF at any point during the collection or testing process when a correctable error is discovered.

The Department has also requested comments as to whether or not the MRO should be responsible for tracking these types of errors. MROs utilized by Concentra recommend that the guidelines permit the MRO to designate a qualified individual to perform this function by including the phrase "or designee".

Relative to Section 16.4, the Department has requested comments on any other errors that must be corrected before the MRO can report a test results or discrepancies that may occur and must be corrected

when the collector transfers the specimen to a POCT tester. MROs providing services for Concentra do not believe they have enough experience with alternative specimens to comment.

Request for Information

There has been much debate as to whether drug screen results are considered protected health information (PHI) as defined by HIPAA. Specifically, does a donor have a right to access (get a copy of) drug screen results and/or the MRO report? Is a HIPAA authorization required in order to release the results back to the employer? If a laboratory is sending results directly to the employer, can the laboratory rely on the fact that the provider secured an authorization? Do drug screen results need to be kept for a minimum of six years? Do disclosures of drug screen results to the employer have to be accounted for if a patient requests an accounting of disclosures? As the addition of alternative specimens is likely to add to the debate, Concentra requests clarification relative to how, if at all, HIPAA applies to drug screen results.

Closing Remarks

In summation, Concentra believes adopting these proposals at the present time would compromise the integrity and threaten the "gold" standard reputation of the Program. We applaud the Department's efforts to point out particular concerns throughout the proposal. However, Concentra believes that until the Department conducts additional research and is able to sufficiently address these concerns, the proposed revisions to the Guidelines should be tabled.

Sincerely,

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