POLICY

For purposes of this policy, Pennsylvania Hospital includes all off campus licensed facilities, including but not limited to the Surgery Center of Pennsylvania Hospital.

Employees of Pennsylvania Hospital and the University of Pennsylvania Health System (UPHS) endeavors to provide a safe environment for patients, visitors and employees. Pennsylvania Hospital, in accordance with this policy, will test applicants to whom an offer of employment is to be extended for prohibited drug use through pre-employment drug screening.

PURPOSE

The purpose of this policy is to ensure that applicants who are being considered for employment by Pennsylvania Hospital are drug-free when hired.

SCOPE

The requirements and procedures outlined in this policy statement apply to all external candidates hired or rehired at Pennsylvania Hospital on or after 5/1/03.

Outsourced Services Contracts - The procedures outlined in this policy will be negotiated into any new contracts, or re-negotiated into existing contracts.

PROCEDURE – PRE-EMPLOYMENT DRUG SCREENING

Pre-employment drug screening is to be completed on every external individual to whom an offer of employment is to be extended by Pennsylvania Hospital. All offers of employment, including verbal and subsequent written confirmation must include a statement indicating that the offer is conditioned on successful completion of the pre-employment drug screen. This procedure must be completed prior to the start of employment. Information should be secured through the vendor with whom Pennsylvania Hospital Human Resources Department regularly contracts for this purpose (currently, Certiphi Screening, Inc.). Documentation should be maintained in the employee file kept in the Human Resources Department.

A. GENERAL PROVISIONS

1. Pennsylvania Hospital new hires and re-hires will be tested for the following substances:
   a. Marijuana
   b. Cocaine
   c. Opiates
   d. Phencyclidine
   e. Amphetamines
   f. Barbiturates
   g. Benzodiazepines
   h. Methadone
   i. Propoxyphene
2. All applicants must sign a Consent Acknowledgement Form (Appendix A), consenting to urine specimens for Pennsylvania Hospital to consider the applicant for employment.

3. A negative test result is required prior to commencement of employment at Pennsylvania Hospital or any UPHS Entities.

**B. URINE SPECIMEN COLLECTION REQUIREMENTS**

1. The drug testing chain-of-custody (COC) form is to be used as a permanent record on which identifying data on the applicant and on the specimen collection and transfer process are retained. The drug-testing plan requires testing for marijuana, cocaine, opiates, phencyclidine, amphetamines, barbiturates, benzodiazepines, methadone, and propoxyphene.

2. Urine specimens collected under this policy may be used only to test for the prohibited drugs designated or approved for testing as described in this section and shall not be used to conduct any other analysis or tests.

3. This policy does not prohibit procedures reasonably incident to analysis of the specimen for controlled substances (e.g., determination of PH or tests for specific gravity, creatinine, concentration, presence of adulterants or interfering substances).

4. At all times, donors will be treated with respect, insuring the modesty and privacy, as much as practicable, of the donor. Collectors must avoid conduct and/or remarks that might be construed as accusatorial, offensive or inappropriate.

5. The collector shall not leave the collection site during the collection procedure. If it becomes necessary for the collector to leave the site, the collection shall be null and void.

6. If an applicant refuses to cooperate with the collection process, the collector shall inform Certiphi Screening and document on the chain-of-custody form.

7. The collection site shall have all necessary personnel, materials, equipment, facilities, and supervision to provide for the collection, security, temporary storage, and shipping or transportation of urine specimens to a certified drug-testing laboratory designated by Certiphi, Inc. An independent medical facility may also be utilized as a collection site provided the other applicable requirements are met.

8. A designated collection site shall be any suitable location where a specimen can be collected under conditions set forth in the following procedures, including a properly equipped mobile facility.

9. A designated collection site shall give an enclosure within which private urination can occur, a toilet for completion of urination, and a suitable clean surface for writing. The site must also have a source of water for washing hands, which if practicable, should be external to the enclosure where urination occurs.
C. SECURITY

1. The purpose of this paragraph is to prevent unauthorized access, which could compromise the integrity of the specimen during the collection process.

2. The designated collection site is to be secure. If a collection site facility is dedicated solely to urine collection, it shall be secure at all times. If a facility cannot be dedicated solely to drug testing, the portion of the facility used for testing shall be secure during drug testing.

3. A facility normally used for other purposes, such as a public restroom or hospital examining room, may be secured by visual inspection to ensure other persons are not present and undetected access (e.g., through a rear door not in the view of the collection site person) is not possible. Security during collection may be maintained by effective restriction of access to collection materials and specimens. In the case of public restroom, the facility must be posted against access during the entire collection procedure to avoid embarrassment to the applicant or distraction of the collection site person.

4. If it is impractical to maintain continuous physical security of a collection site from the time the specimen is presented until the sealed mailer is transferred for shipment, the following minimum procedures shall apply.

   a) The specimen shall remain under the direct control of the collection site person from delivery to its being sealed in the mailer.

   b) The mailer shall be immediately mailed, maintained in secure storage, or remain under the personal control of the collection site person until mailed.

D. CUSTODY CONTROL

1. The chain-of-custody block of the drug testing custody and control form shall be properly executed by authorized collection site personnel upon receipt of specimens. A chain-of-custody form shall be used for maintaining control and accountability of each specimen from the point of collection to the final disposition of the specimen.

2. Since specimens are sealed in packages that would indicate any tampering during transit to the laboratory and couriers, express carriers and postal service personnel do not have access to the chain-of-custody forms, there is no requirement that such personnel document chain-of-custody for the package during transit.

E. ACCESS TO AUTHORIZED PERSONNEL ONLY

1. No unauthorized personnel shall be permitted in any part of the designated collection site when urine specimens are collected and stored. Only the collection site person may handle specimens prior to their security in the mailing container or monitor or observe a specimen collection.
2. To promote security of specimens, avoid distraction of the collection site person, and ensure against any confusion in the identification of specimens, the collection site person shall have only one donor under supervision at any given time.

3. For this purpose, a collection procedure is complete when the urine bottle has been sealed and initialed, the drug testing custody and control form has been executed, and the applicant has departed the site; or, in the case of an applicant who was unable to provide a complete specimen, has entered a waiting area.

F. DONOR PRIVACY

1. Procedures for collecting urine specimens shall allow individual privacy unless there is a reason to believe that a particular individual may alter or substitute the specimen to be provided.

2. The following circumstances are the exclusive grounds constituting a reason to believe that the individual may alter or substitute the specimen:

   a) The applicant has presented a urine specimen that registers outside the normal temperature range of 32 to 38 degrees Centigrade or 90 to 100 degrees Fahrenheit, and

      (1) the applicant declines to provide a measurement of oral body temperature;
      or,
      (2) The oral body temperature varies by more than 1 degree Centigrade or 1.8 degrees Fahrenheit from the temperature of the specimen.

   b) The last urine specimen provided by the applicant was determined by the laboratory to have a specific gravity of less than 1.003 and a creatinine concentration below 0.2g/L.

   c) The collection site person observes conduct clearly and unequivocally indicating an attempt to substitute or adulterate the specimen.

   d) The applicant has previously been determined to have used a controlled substance without medical authorization.

3. A higher-level supervisor of the collection site person shall review and concur in advance with any decision by a collection site person to obtain a specimen under the direct observation of a same gender collection site person.

G. INTEGRITY AND IDENTIFICATION

The collection site person shall take precautions to ensure that a urine specimen is not adulterated or diluted during the collection procedure and that information on the urine bottle and on the urine custody and control form can identify the individual from whom the specimen was collected. The following minimum precautions shall be taken to ensure the unadulterated specimens are obtained and correctly identified.
1. To deter dilution of specimens at the collection site, toilet-bluing agents shall be placed in
   toilet tanks, wherever possible, so that reservoir of water in the toilet bowl always remains blue.
   If no bluing agent is available to deter specimen dilution, the collector shall instruct the donor
   not to flush until the specimen is delivered to the collector. After the collector has possession
   of the specimen, the individual will be instructed to flush the toilet or urinal to participate in the
   completion of the chain-of-custody. Where practicable, there shall be no other source of water
   in the enclosure when urination occurs. If there is another source of water in the enclosure, it
   shall be effectively secured or monitored to ensure it is not used as a source of diluting the
   specimen.

2. When an individual arrives at the collection site, the collection site person shall ensure that
   the individual is positively identified as the applicant selected for testing, using a picture ID (e.g.,
   through presentation of photo identification or identification by the employer’s representative). If
   the applicant requests, the collection site person shall show proper identification to the
   applicant. The collector will begin to complete the first section of the chain-of-custody form.

3. If the individual fails to arrive at the assigned time, the collection site person shall contact
   Certiphi, Inc. to obtain guidance on the action to be taken.

4. The collection site person shall ask the individual to remove any unnecessary outer
   garments, such as a coat or jacket that might conceal items or substances that could be used to
   tamper with or adulterate the individual’s urine specimen. The collection site person shall
   ensure that all personal belongings, such as a purse or briefcase, will remain with the outer
   garments. The individual may retain his/her wallet. If the applicant requests it, the collection
   site person shall provide the applicant with a receipt for any personal belongings.

5. The donor shall be instructed to wash and dry his/her hands, without soap, prior to voiding.

6. After washing hands, the individual shall remain in the presence of the collector and shall not
   have access to any water fountain, soap dispenser, cleaning agent or any other materials,
   which could be used to adulterate the specimen.

7. The individual may provide their specimen in the privacy of a stall or otherwise partitioned
   area that allows for individual privacy. The collection site person shall instruct the donor to
   choose a collection kit. The collection site person shall note any unusual behavior or
   appearance on the chain-of-custody form under the Collector’s Notes Section. The collector
   can complete the first section of the chain-of-custody form.

8. Pennsylvania Hospital is using the single collection method. The donor may void either
   directly into a specimen bottle or into a separate collection container. If a separate collection
   container is used, the collector will instruct the donor to pour at least thirty (30) ml of urine from
   the collection container to the specimen bottle. This must be done in the presence of the
   collector.

9. Upon receiving the specimen from the donor, the collector shall determine if it has at least
   thirty (30) ml of urine. If the individual is unable to provide the minimum quantity of urine, the
collector shall instruct the donor to drink not more than forty (40) ounces of fluids and, after a period of up to three (3) hours, again attempt to provide a complete specimen, using a fresh collection kit.

10. After the specimen has been provided and submitted to the collector, the donor shall be allowed to wash his/her hands.

11. Within four (4) minutes of collection, the collector must read the temperature of the specimen. The temperature-measuring device used must accurately reflect the temperature without contaminating the specimen. All collection kits provided by a SAMHSA laboratory have a temperature-measuring device on the outside of the collection container or specimen bottle.

12. An out of range specimen temperature constitutes a reason to believe that the donor has altered or substituted the specimen, (as outlined in Section IV.E.2.a.). The donor supplying the specimen may volunteer to have his/her temperature taken to provide evidence to counter the reason to believe the individual may have altered or substituted the specimen.

13. Immediately following the collection, the collector shall inspect the specimen to determine its color and look for signs of contaminants. Any unusual findings must be noted on the chain-of-custody form in the Collector’s Notes Section. All specimens suspected of being adulterated shall be forwarded to the laboratory. Whenever there is a reason to believe that a particular donor has altered or substituted the specimen, (as outlined in Section IV.E.2.), a second specimen shall be obtained, as soon as possible, under the direct observation of a same gender collector.

14. Both the donor and the collector shall keep the specimen in view, at all times, prior to its being sealed and labeled. The specimen must be sealed with a tamper-resistant integrity seal, over the bottle cap and down the sides of the bottle, and labeled. The collector and the donor must be present, at all times, during the following procedures:

   a) If the specimen is transferred from a collection container to a specimen bottle, the collector should instruct the donor to pour the urine and place the cap on the specimen bottle tightly. The donor will then give the specimen to the collector.

   b) The collector will apply the tamper-resistant integrity seal with the specimen identification number, as outlined above, and enter the date. The collector will instruct the donor to initial the seal to certify that the specimen was collected from that donor. The collector will then seal the specimen in the plastic specimen bag.

   c) The collector shall instruct the donor to complete the appropriate donor certification step and the collector will the complete the actual chain.

   d) The collector shall place the appropriate copy of the chain-of-custody form in the plastic specimen bag or the shipping box with the specimen. The sealed specimen bag will be placed in the shipping bag or box and sealed. After the donor is given the donor copy, the specimen is ready for shipment, and the donor is free to leave.
H. TRANSPORTATION TO THE LABORATORY

The collector shall arrange to ship the specimen to the laboratory. The specimens shall be placed in the shipping containers that are designed to minimize the possibility of damage during shipment.

I. DRUG TESTING LABORATORY

1. General

   a) Pennsylvania Hospital shall use a drug-testing laboratory certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), under the Department of Health and Human Services (DHHS).

   b) The laboratory is required, by contract, to maintain test records in confidence and to disclose information relating to the test only to Certiphi, Inc. and the Medical Review Officer.

   c) Each specimen kit received by the laboratory will be inspected for tampering and/or damage, and the chain-of-custody form will be reviewed for any discrepancies. If the specimen and the chain-of-custody form are intact, the specimen will be analyzed to determine if the specified drugs are present.

   d) The laboratory will transmit results to the Certiphi, Inc. by various electronic means; e.g., FTP, facsimile or computer, in a manner designed to ensure confidentiality of the information.

   e) The applicant will be responsible for any and all additional analyses that may be requested. If the additional laboratory analyses analysis proves negative, the applicant will NOT be reimbursed.

2. Laboratory Procedures

   a) Initial Test (Emit Screen) – All specimens will be initially screened for the use of prohibited substances by using an enzyme immunoassay technique (EMIT), which will eliminate negative urine specimens from confirmation testing. Any specimen, which resulted in a positive after the initial screening, will be subject to confirmation testing using a more stringent and precise testing method. The cut-off levels listed below will be used in the initial screening of specimens:

       1) Marijuana metabolites – 50 ng/ml
       2) Cocaine metabolites – 300 ng/ml
       3) Opiate metabolites - 2000 ng/ml
       4) Phencyclidine (PCP) – 25 ng/ml
       5) Amphetamine metabolites – 1000 ng/ml
       6) Barbiturates – 300 ng/ml
7) Benzodiazepines – 300 ng/ml
8) Methadone – 300 ng/ml
9) Propoxyphene – 300 ng/ml

b) Confirmation Test (GC/MS) – All specimens that are identified as positive on the initial test will be confirmed by a second analysis (independent from the initial screen) that uses gas chromatography/mass spectrometry (GC/MS) to confirm the initial positive test result. The cut off levels listed below will be used to determine a confirmed positive test result:

1) Marijuana metabolites – 15 ng/ml (Delta-9-tetrahydrocannabinol-9-carboxylic acid)
2) Cocaine metabolites – 150 ng/ml
3) Opiate metabolites - 2000 ng/ml each
   (a) Morphine
   (b) Codeine
4) Phencyclidine (PCP) – 25 ng/ml
5) Amphetamine metabolites – 500 ng/ml
   (a) Amphetamine
   (b) Methamphetamine
6) Barbiturates – 200 ng/ml
7) Benzodiazepines – 200 ng/ml
8) Methadone – 200 ng/ml
9) Propoxyphene – 300 ng/ml

c) After receipt of the specimen by the laboratory, all results will be reported to Certiphi Inc. after being reviewed and certified as accurate by the certifying scientist.

d) The laboratory shall report as negative all specimens, which are negative on the initial test or negative on the confirmation test. A specific drug(s) will be indicated on the confirmed positive only.

e) The laboratory may provide the quantitative level(s) of the positive test results. Certiphi Inc. shall report the test as negative or positive and the drug metabolite(s) for which it was positive, and shall disclose the quantitative level(s) to UPHS upon request.

f) Reanalysis – When a reanalysis is conducted, it is possible that some analytes may deteriorate during storage; therefore, the results of a retest are to be reported as a confirmation of the original test results if the detected level of the drug(s) are below the established limits and equal to or greater than the sensitivity of the test.

J. MEDICAL REVIEW

1. General
SUBJECT: PRE-EMPLOYMENT DRUG SCREENING

POLICY NUMBER: HR62

a) The MRO shall review confirmed positive drug results and interview the individuals to verify the laboratory results before Pennsylvania Hospital is notified.

b) The MRO has contracted with Certiphi Inc. to provide Pennsylvania Hospital with the medical review services for this drug-testing plan.

2. Reporting and Review of Results

The MRO shall review confirmed positive drug results to verify consistencies in prescriptions and medications as noted on the chain-of-custody form. A confirmed positive test result does not automatically identify an applicant as having used drugs. The MRO shall review the chain-of-custody to ensure that it is complete and sufficient on its face.

3. Qualifications and Responsibilities

a) The MRO shall be a licensed physician with knowledge of substance abuse disorders and retained for this purpose. The MRO shall not be an employee of the laboratory conducting the drug test unless the laboratory establishes a clear separation of functions to prevent any appearance of a conflict of interest including assuring that the MRO has no responsibility for, and is not supervised by or the supervisor of, any person who has responsibility for the drug testing or quality control operations of the laboratory.

b) The role of the MRO is to review and interpret confirmed positive test results obtained through the Pennsylvania Hospital testing program. In carrying out this responsibility, the MRO shall examine alternate medical explanations for any positive test result. This action could include conducting a telephone medical interview with the applicant and telephone review of the applicant's medical history or a telephone review of any other relevant biomedical factors. The MRO may review all medical records made available by the tested applicant when a confirmed positive pre-employment test could have resulted from legally prescribed medication.

4. Positive Test Results

a) Prior to making a final decision on verification of a positive test result, the MRO shall give the applicant an opportunity to discuss the test result.

b) The MRO shall contact the applicant directly, on a confidential basis, to determine whether the applicant wishes to discuss the test result. A staff person under the MRO’s supervision may make the initial contact, and a medically licensed or certified staff person may gather information from the applicant. If the MRO determines there is a legitimate medical explanation for the positive test result, the MRO shall report the test result to Certiphi, Inc. as negative.

c) If, after making reasonable attempts and documenting them, the MRO is unable to reach the applicant directly, the MRO shall contact the Pennsylvania Hospital designee
to direct the applicant to contact the MRO as soon as possible. If it becomes necessary to reach the applicant through the Pennsylvania Hospital designee, such official shall employ procedures that ensure, to the maximum extent practicable, that the requirement of the applicant to contact the MRO is held in the strictest confidence.

d) The MRO may verify a test as positive without having communicated directly with the applicant about the test in two (2) circumstances:

(1) The applicant expressly declines the opportunity to discuss the test.
(2) The Pennsylvania Hospital designee has successfully made a contact with the applicant and instructed him/her to contact the MRO, and more than five (5) days have passed since the date the applicant was successfully contacted by the Pennsylvania Hospital designee.

e) Following verification of a positive test result, the MRO shall refer verification to Certiphi Inc. for UPHS.

DEFINITIONS

1. Chain-of-Custody – procedures to account for the integrity of each urine specimen by tracking its handling and storage from point of specimen collection to final disposition of the specimen. These procedures shall require that an appropriate drug testing custody form from a Substance Abuse and Mental Health Services Administration (SAMHSA) certified laboratory be used from the time of collection to receipt by the laboratory.

2. Collection Site – a designated clinic/facility where applicants may present themselves for the purpose of providing a specimen of their urine to be analyzed for the presence of drugs.

3. Collector – a person who instructs and assists applicants through the specimen collection process

4. Confirmation Drug Test – a second analytical procedure to identify the presence of a specific drug or metabolite which is independent of the initial test and which uses a different technique and chemical principle from that of the initial test in order to ensure reliability and accuracy. Gas chromatography/mass spectrometry (GC/MS) is the authorized confirmation method for marijuana, cocaine, opiates, phencyclidine, amphetamines, barbiturates, benzodiazepines, methadone and propoxyphene.

5. Fail a Drug Test or Test Positive – the confirmation test result shows positive evidence of the presence of a prohibited drug in the applicant’s system.

6. Initial Drug Test – an immunoassay screen to eliminate “negative” urine specimens from further analysis. The Emit Screen is the authorized screening method for marijuana, cocaine, opiates, phencyclidine and amphetamines.
7. Negative Drug Test – a drug test in which a prohibited drug(s) was not detected in the initial drug test (Emit Screen); or, if the specimen screened positive during the Emit Screen, no prohibited drug(s) were detected during the confirmation drug test (GC/MS).

8. Passes Drug Test or Test Negative – the initial testing or confirmation testing does not show evidence of the presence of a prohibited drug in the employee’s or applicant’s system.

9. Positive Drug Test – the confirmation drug test (GC/MS) identified the presence of a prohibited drug(s).


11. Refusal to Submit to a Test – When an applicant fails to provide an adequate urine specimen, without a valid medical explanation, after receiving notice of a drug test requirement, in accordance with the provisions of this policy and engages in conduct that clearly obstructs the testing or collection process.

12. SAMHSA - Substance Abuse and Mental Health Services Administration, a division of the Department of Health and Human Services, established to regulate and certify laboratories that perform analytical drug test on human body fluids (formerly NIDA, National Institute on Drug Abuse)

13. Verified Negative Drug Test Result – a positive test result in which the Medical Review Officer was provided with a legitimate medical explanation.

14. Verified Positive Drug Test Result – a positive test result in which the Medical Review Officer was not provided with a legitimate medical explanation.

/s/Kathleen Kinslow  06/26/08
Kathleen Kinslow, CRNA, EdD, MBA  Date
Executive Director

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