

103^D CONGRESS
1ST SESSION

H. R. 33

To amend the Public Health Service Act to establish standards for the certification of laboratories engaged in urine drug testing, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 5, 1993

Mr. DINGELL (for himself and Mr. BLILEY) introduced the following bill;
which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to establish standards for the certification of laboratories engaged in urine drug testing, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Drug Testing Quality
5 Act”.

6 **SEC. 2. STANDARDS FOR CERTIFICATION OF LABORA-**
7 **TORIES ENGAGED IN DRUG TESTING.**

8 Title V of the Public Health Service Act is amended
9 by adding at the end the following:

“PART F—DRUG TESTING**2 “SEC. 571. CERTIFICATION PROGRAM.**

3 “(a) IN GENERAL.—Not later than one year after the
4 date of enactment of this part, the Secretary shall, by reg-
5 ulation, establish a program (hereinafter referred to in
6 this part as the ‘certification program’) for the certifi-
7 cation of laboratories for the performance of toxicological
8 urinalysis conducted for drug testing programs. The cer-
9 tification program shall, except as provided in subsection
10 (b), conform, to the maximum extent practicable, to sub-
11 part C of the mandatory guidelines for Federal workplace
12 drug testing programs published on April 11, 1988, by
13 the Department of Health and Human Services at 53 Fed.
14 Reg. 11979 and any amendments to such guidelines (here-
15 inafter referred to in this part as the ‘HHS guidelines’).

16 “(b) SPECIFIC PROVISION.—The certification pro-
17 gram established by the Secretary under subsection (a)
18 shall, with respect to laboratory inspection, the monitoring
19 of laboratory performance, and the conduct of quality con-
20 trol and performance testing programs, be consistent with
21 the consensus of expert scientific and medical opinion on
22 such matters as determined by the Secretary.

23 “(c) ADDITIONAL REGULATIONS.—

24 “(1) The certification program established by
25 the Secretary under subsection (a) shall, in addition
26 to the requirements of subsections (a) and (b)—

1 “(A) provide that the Secretary shall, in
2 considering applications for certification under
3 the certification program, consider whether the
4 applicant has, directly or indirectly, owned or
5 operated a laboratory which has had its certifi-
6 cation suspended or revoked under the pro-
7 gram, and

8 “(B)(i) include criteria for recognition by
9 the Secretary of—

10 “(I) State agencies and private non-
11 profit accrediting bodies to certify labora-
12 tories in accordance with the requirements
13 of this section if such agencies and bodies
14 meet such criteria, and

15 “(II) State agencies and private non-
16 profit accrediting bodies to act on the Sec-
17 retary’s behalf in certifying laboratories in
18 accordance with the requirements of this
19 section if such agencies and bodies meet
20 such criteria,

21 “(ii) provide that the Secretary shall over-
22 see and review the performance of any agency
23 or accrediting body recognized by the Secretary
24 as meeting the criteria described in clause (i) to

1 ensure its compliance with the requirements of
2 the certification program, and

3 “(iii) provide that the Secretary shall have
4 the right to obtain from an agency or accredi-
5 ting body described in clause (ii) and from any
6 laboratory that may be certified by such an
7 agency or accrediting body all records and ma-
8 terials that are necessary in the Secretary’s
9 judgment for the oversight and review required
10 by clause (ii).

11 “(2) A laboratory may not be certified to per-
12 form drug testing under the certification program
13 established under subsection (a) unless the labora-
14 tory is certified under section 353, except that a lab-
15 oratory which only performs toxicological urinalyses
16 is not required to be certified under section 353 to
17 be certified under the certification program.

18 “(3)(A) A laboratory may not be certified to
19 perform drug testing under the certification program
20 established under subsection (a) unless it dem-
21 onstrates to the Secretary its competence to perform
22 toxicological urinalyses in accordance with the re-
23 quirements of this section and section 572 for the
24 following drugs and drug classes;

1 “(i) the drugs and drug classes for which
2 test methods and cutoff levels are provided
3 under subpart B of the HHS guidelines;

4 “(ii) barbiturates listed in schedules I and
5 II under the Controlled Substances Act (21
6 U.S.C. 801 et seq.); and

7 “(iii) oxazepam and alprazolam.

8 “(B) Notwithstanding subparagraph (A), a lab-
9 oratory certified under subpart C of the HHS guide-
10 lines prior to the date the Secretary establishes the
11 certification program under subsection (a) shall be
12 deemed by the Secretary to be competent to perform
13 toxicological urinalyses for the drugs and drug class-
14 es described in subparagraph (A) and shall be cer-
15 tified by the Secretary to do so for drug testing pro-
16 grams as of such date.

17 “(4) A laboratory certified to perform drug
18 testing under the certification program established
19 under subsection (a), shall, in order to retain such
20 certification, require its scientific, technical, and an-
21 alytical personnel involved in such drug testing to
22 participate in continuing education programs of a
23 nature and at a frequency (not less than annually)
24 specified by the Secretary in regulations.

1 barbiturates listed in schedules I and II under the
2 Controlled Substances Act, oxazepam and
3 alprazolam, anabolic steroids, and such other drugs
4 or drug classes as the Secretary determines under
5 subsection (c) may be appropriate,

6 “(3)(A) neither require nor prohibit the estab-
7 lishment of a drug testing program by any person,
8 and

9 “(B) neither require any person to test nor pro-
10 hibit any person from testing for any particular drug
11 or class of drugs described in paragraph (2) or sub-
12 part B of the HHS guidelines,

13 “(4) provide no specimen collection procedures
14 other than those necessary to establish and maintain
15 a proper chain of custody and to provide for trans-
16 portation of specimens to the laboratory,

17 “(5) consistent with the consensus of expert
18 medical and scientific opinion as determined by the
19 Secretary, establish appropriate cutoff levels for each
20 drug or class of drugs described in paragraph (2) or
21 subpart B of the HHS guidelines for both initial and
22 confirmatory tests,

23 “(6)(A) establish requirements to ensure the in-
24 tegrity and validity of blind performance testing of
25 laboratories certified under the certification program

1 established under section 571, including a number or
2 percentage of specimens (or both) to be submitted to
3 a laboratory by a drug testing program for blind
4 performance testing, set at the lowest level consist-
5 ent with the consensus of expert medical and sci-
6 entific opinion as determined by the Secretary and
7 with the need to ensure accuracy, integrity, and pro-
8 tection of the interests of test subjects, and

9 “(B) establish procedures for drug testing pro-
10 grams to notify the Secretary of any false positive
11 results discovered in blind performance testing or by
12 a medical review officer and for the Secretary to
13 take appropriate action on the basis of such notifica-
14 tion,

15 “(7) provide no interim certification procedures,
16 and

17 “(8) allow access by any test subject or any test
18 subject’s authorized representative, upon written re-
19 quest, to any record relevant to the results of such
20 subject’s drug test and to any record relating to the
21 result of any relevant certification, review, suspen-
22 sion, or revocation of certification proceeding, and
23 require a copy of such record to be provided to such
24 test subject or representative upon written request.

1 Paragraphs (3) and (4) shall not be construed to affect
2 the applicability of the requirements of subpart B of the
3 HHS guidelines to drug testing programs conducted by
4 Federal agencies under Executive Order 12564.

5 “(c) ADDITIONAL DRUGS.—

6 “(1)(A) Any person may file with the Secretary
7 a petition proposing the issuance of a regulation
8 under subsection (b)(2) prescribing test methods and
9 cutoff levels for any drug or class of drugs for which
10 such test methods and cutoff levels have not been
11 previously prescribed. Notice of the regulation pro-
12 posed by a petitioner shall be published in the Fed-
13 eral Register within 30 days after filing.

14 “(B) Twelve months following the issuance of
15 regulations under subsection (a), and every 24
16 months thereafter, the Secretary shall publish in the
17 Federal Register a request for public comment on
18 the advisability of and need for including test meth-
19 ods and cutoff levels in such regulations for drugs
20 or classes of drugs for which such test methods and
21 cutoff levels have not been previously prescribed.

22 “(C) A petitioner or commenter under this
23 paragraph shall be required to demonstrate in such
24 person’s petition or comment, as applicable, that—

1 “(i) widespread or otherwise significant
2 abuse of such drug or class in the United
3 States or any region of the United States poses
4 a serious threat to public health or safety,

5 “(ii) there exists a well-documented and re-
6 liable method for toxicological urinalysis of such
7 drug or class and for establishing cutoff levels
8 applicable to such drug or class,

9 “(iii) such test methods and cutoff levels
10 provide specificity and protection of the inter-
11 ests of test subjects equal to or greater than
12 that provided with respect to the drugs or class-
13 es for which test methods and cutoff levels have
14 been previously prescribed by the Secretary,
15 and

16 “(iv) at least one laboratory certified under
17 section 571 has an interest in providing toxi-
18 cological urinalysis for the drug or class de-
19 scribed in the petition or comment and is com-
20 petent to do so.

21 A petitioner or commenter shall also furnish to the
22 Secretary such additional explanatory and support-
23 ing data as the Secretary may require.

24 “(2)(A) Commencing 90 days following publica-
25 tion in the Federal Register of the request for public

1 comment described in paragraph (1)(B), and every
2 24 months thereafter, the Secretary shall review all
3 petitions received and pending under paragraph
4 (1)(A) and all comments received and pending under
5 paragraph (1)(B), together with additional explana-
6 tory and supporting data submitted by petitioners
7 and commenters and shall, with respect to each drug
8 or class of drugs which is the subject of a petition
9 or comment, determine whether the petitioner or
10 commenter has made the demonstration required by
11 paragraph (1)(C) and whether other facts, cir-
12 cumstances, or considerations outweigh the need to
13 prescribe test methods and cutoff levels for such
14 drug or class.

15 “(B)(i) If the Secretary determines under sub-
16 paragraph (A) that a petitioner or commenter has
17 made the demonstration required by paragraph
18 (1)(C) and that no other facts, circumstances, or
19 considerations outweigh the need to prescribe test
20 methods and cutoff levels for such drug or class, the
21 Secretary shall by order issue a regulation prescrib-
22 ing test methods and cutoff levels for such drug or
23 class.

24 “(ii) If the Secretary determines that a peti-
25 tioner has failed to make the demonstration required

1 by paragraph (1)(C) and that other facts, cir-
2 cumstances, or considerations outweigh the need to
3 prescribe test methods and cutoff levels as requested
4 in the petition, the Secretary shall by order deny the
5 petition and within 30 days thereafter notify the pe-
6 titioner of such order and of the reasons for such ac-
7 tion.

8 “(C) The order required by subparagraph (B)
9 shall be issued within 90 days after review by the
10 Secretary commences under paragraph (2)(A), ex-
11 cept that the Secretary may (prior to such 90th
12 day), by written notice to a petitioner in the case of
13 a petition or publication in the Federal Register in
14 the case of a comment, extend such 90-day period
15 to such time (not more than 180 days after com-
16 mencement of such review) as the Secretary deems
17 necessary to permit appropriate study and investiga-
18 tion.

19 “(d) AMATEUR ATHLETICS.—In issuing regulations
20 under subsection (a), the Secretary shall take into consid-
21 eration any special factors or circumstances applicable to
22 the testing of participants in—

23 “(1) organized interscholastic or intercollegiate
24 athletic competition, or

1 “(2) organized athletic competition conducted
2 under the auspices of or sanctioned by the United
3 States Olympic Committee or any member thereof,
4 that warrant separate or different treatment of such test-
5 ing under the regulations.

6 “(e) REVISION.—The Secretary shall, in accordance
7 with section 553 of title 5, United States Code, revise the
8 regulations issued under subsection (a) as necessary to re-
9 flect improvements in drug testing methods for the pur-
10 pose of ensuring the full reliability and accuracy of drug
11 testing, the accurate reporting of results, and the integrity
12 and efficacy of drug testing programs.

13 **“SEC. 573. SPECIMEN COLLECTION PROCEDURES.**

14 “(a) IN GENERAL.—Not later than 1 year after the
15 date of enactment of this part, the Secretary shall issue
16 model specimen collection procedures for the guidance of
17 drug testing programs other than those conducted by Fed-
18 eral agencies under Executive Order 12564. Such model
19 procedures shall include provisions for designation of a
20 collection site, security, personnel access, and privacy in
21 the collection process, and precautions to ensure the integ-
22 rity and identity of specimens. In issuing such model pro-
23 cedures, the Secretary may recommend alternatives to ad-
24 dress appropriate particularized needs or circumstances,
25 including those applicable to athletic competition, and may

1 provide technical assistance to drug testing programs
2 adopting or considering adoption of such model proce-
3 dures.

4 “(b) SAVINGS PROVISION.—Subsection (a) shall not
5 be construed to affect the applicability of the specimen col-
6 lection procedures in subpart B of the HHS guidelines to
7 drug testing programs conducted by Federal agencies
8 under Executive Order 12564.

9 **“SEC. 574. PROHIBITIONS.**

10 “(a) CERTIFICATION REQUIREMENT.—(1) No person
11 may perform any toxicological urinalysis in connection
12 with any drug testing program unless that person is a lab-
13 oratory which is certified under the certification program
14 established under section 571.

15 “(2) It shall be unlawful for any laboratory certified
16 to perform toxicological urinalysis under the certification
17 program established under section 571 to perform toxi-
18 cological urinalyses in connection with any drug testing
19 program for any drug or drug class other than those listed
20 in section 571(c)(3)(A) unless—

21 “(A) in a case where such other drug or drug
22 class is one for which the Secretary has prescribed
23 test methods and cutoff levels under section
24 572(b)(2) or 572(c), such laboratory is certified by

1 the Secretary to perform toxicological urinalyses for
2 such other drug or drug class, or

3 “(B) in the case of any other drug or drug
4 class, such drug testing program provides the lab-
5 oratory with a statement signed by the test subject
6 acknowledging that disclosure of a test for such
7 other drug or drug class has been made and con-
8 senting to the performance of such test.

9 “(b) OTHER VIOLATIONS.—It shall be unlawful for
10 any person—

11 “(1) who is a test subject to knowingly disclose
12 the results of a toxicological urinalysis in connection
13 with any drug testing program which was not per-
14 formed on such person,

15 “(2) who is not a test subject and who has been
16 directly or indirectly involved in a drug testing pro-
17 gram or a toxicological urinalysis under such a pro-
18 gram, to knowingly disclose the results of any toxi-
19 cological urinalysis in connection with any drug test-
20 ing program, except—

21 “(A) as provided in the regulations issued
22 under section 572,

23 “(B) that if the person is authorized to
24 represent—

1 “(i) an educational institution in
2 which a participant described in section
3 572(d) is enrolled,

4 “(ii) an organized interscholastic or
5 intercollegiate athletic team, league, or as-
6 sociation, or

7 “(iii) an organization that conducts
8 organized athletic competition under the
9 auspices of or sanctioned by the United
10 States Olympic Committee or any member
11 thereof,

12 such person may disclose the results of a toxi-
13 cological urinalysis performed on a participant
14 described in section 572(d) in connection with
15 a drug testing program, and

16 “(C) that if the person is authorized to
17 represent a team, league, or association which
18 conducts a drug testing program in which par-
19 ticipants in athletic competitions who are paid
20 for their performance are test subjects, such
21 person may disclose the results of a toxi-
22 cological urinalysis performed on such partici-
23 pant in connection with a drug testing program,

24 “(3) to knowingly—

1 “(A) alter or falsely report the results of a
2 toxicological urinalysis, or

3 “(B) adulterate any urine specimen (other
4 than a specimen spiked for use in performance
5 testing),

6 in connection with any drug testing program or per-
7 formance testing,

8 “(4) except in connection with epidemiological,
9 biomedical, or other medical research in which the
10 identity of the person providing the urine specimen
11 is unknown, to knowingly perform or cause to be
12 performed on a urine specimen a test for any medi-
13 cal condition or any substance, other than alcohol or
14 a drug or drug class for which the Secretary has
15 prescribed test methods and cutoff levels under sec-
16 tion 572(a) or 562(b)(2), without the consent of the
17 person providing the urine specimen following disclo-
18 sure to such person of the medical condition or sub-
19 stance for which testing will be performed,

20 “(5) if the consent of a person providing a
21 urine specimen is required under paragraph (4) be-
22 fore the specimen may be tested, to take any adverse
23 action against such person for refusing to give such
24 consent, unless such person is a participant de-
25 scribed in section 572(d) or is a participant in ath-

1 letic competition who is paid for the participant's
2 performance,

3 “(6) in the case of a toxicological urinalysis, to
4 take any adverse action against any test subject
5 based, in whole or in part, upon a positive result
6 that has not been confirmed by a test—

7 “(A) which uses gas chromatography/mass
8 spectrometry (or, in the case of alprazolam,
9 which uses high-performance liquid chroma-
10 tography), or

11 “(B) which, after the establishment of the
12 certification program under section 571, is per-
13 formed in accordance with the requirements of
14 such program,

15 “(7) in the case of a toxicological urinalysis,
16 where a confirmed positive result has not been veri-
17 fied by a medical review officer because there exists
18 a legitimate medical explanation for the result con-
19 sistent with legal drug use, including use of a drug
20 pursuant to and in accordance with a valid prescrip-
21 tion, or because the result is scientifically insuffi-
22 cient for further action, to take any adverse action
23 against any test subject based in whole or in part
24 upon such result, except that, in the case of a drug
25 testing program conducted in connection with ath-

1 letic competition, a medical review officer may verify
2 a confirmed positive result for any drug described in
3 subsection (a)(2)(B) notwithstanding the existence
4 of a legitimate medical explanation for the result,
5 and adverse action may be taken against any partici-
6 pant in athletic competition based upon such result,
7 or

8 “(8) to knowingly fail to administer or conduct
9 any toxicological urinalysis or drug testing program
10 in accordance with the requirements of the certifi-
11 cation program established under section 571 or the
12 regulations issued under section 572.

13 As used in paragraph (4), the term ‘any medical condition
14 or any substance’ does not include creatinine, pH, or spe-
15 cific gravity.

16 **“SEC. 575. SANCTIONS AND REMEDIES.**

17 “(a) CRIMINAL PENALTY.—A person who violates
18 section 574(a) shall be subject to imprisonment for not
19 more than 3 years, or a fine under title 18, United States
20 Code, or both.

21 “(b) ADMINISTRATIVE REMEDIES.—

22 “(1) A laboratory performing any toxicological
23 urinalysis in connection with any drug testing pro-
24 gram that violates any regulation issued under sec-
25 tion 572 shall be subject to assessment by the Sec-

1 retary of a civil penalty of not less than \$1,000 or
2 more than \$10,000, taking into account the previous
3 record of the laboratory under sections 571 and 572
4 and the gravity of the violation.

5 “(2) If the Secretary discovers a violation of
6 any regulation issued under section 572 by any per-
7 son other than a laboratory, the Secretary shall refer
8 the matter to the Attorney General for further inves-
9 tigation and appropriate action.

10 “(c) INJUNCTION.—The Secretary or the Attorney
11 General, as appropriate, or any aggrieved person, may
12 bring an action to restrain violations of section 574(a) or
13 any regulation issued under section 572. In any action
14 brought under this subsection, the district courts of the
15 United States shall have jurisdiction for cause shown, to
16 issue declaratory relief, temporary restraining orders, and
17 preliminary and permanent injunctions to require compli-
18 ance with such provisions.

19 “(d) CIVIL ACTION.—Any test subject who is tested,
20 or whose test results are handled, in violation of, or is
21 deprived of rights because of a violation under, subsection
22 (a) or paragraphs (1) through (7) of subsection (b) of sec-
23 tion 574, or who is adversely affected by a material breach
24 in an applicable chain of custody under section 572, may
25 institute a civil action in any district court of the United

1 States of competent jurisdiction for appropriate legal and
2 equitable relief, including employment, reinstatement, pro-
3 motion, the payment of lost wages and benefits, and dam-
4 ages. The costs of suit, including a reasonable attorney's
5 fee, shall be allowed to a prevailing party. Such an attor-
6 ney's fee shall be allowed in the manner in which attor-
7 ney's fees are allowed under the last sentence of section
8 722 of the Revised Statutes (42 U.S.C. 1988). It shall
9 not be a defense to such an action that the plaintiff has
10 waived the rights or protections provided for in this sec-
11 tion or has otherwise consented to a violation, deprivation,
12 or breach. No action may be instituted under this sub-
13 section after the expiration of 2 years from the date the
14 person discovers the violation, deprivation, or breach.

15 “(e) INDEMNIFICATION AND CONTRIBUTION.—Any
16 person conducting a drug testing program who takes any
17 adverse action against any test subject based, in whole or
18 in part, upon a report by a laboratory of a positive test
19 result which is thereafter found to have been a false posi-
20 tive result and who consequently is held liable under sub-
21 section (d) for damages or other sums may institute a civil
22 action against such laboratory for indemnification or con-
23 tribution, as appropriate, in any district court of the Unit-
24 ed States of competent jurisdiction. No action may be in-
25 stituted under this subsection after the expiration of one

1 year from the date on which a judgment under subsection
2 (d) becomes final.

3 **“SEC. 576. CONSTRUCTIONS.**

4 “(a) IN GENERAL.—Nothing in this part limits the
5 authority—

6 “(1) of the Secretary under section
7 571(c)(1)(B)(i) to permit an agency or accrediting
8 body described in section 571(c)(1)(B)(ii) to main-
9 tain, or

10 “(2) of any test subject or duly authorized rep-
11 resentative of a test subject to contract for,
12 standards, procedures, or requirements more protective of
13 test subjects than those provided by the certification pro-
14 gram established under section 571 or the regulations is-
15 sued under section 572.

16 “(b) LIMITATION.—Notwithstanding subsection
17 (a)(1), the Secretary shall not permit an agency or accred-
18 iting body described in section 571(c)(1)(B)(ii) to deny
19 certification under section 571 to any laboratory comply-
20 ing with the standards, procedures, and requirements es-
21 tablished by the Secretary under section 571.

22 “(c) CERTIFICATION.—To the extent that this part
23 imposes a more protective standard, procedure, or require-
24 ment on—

25 “(1) the Secretary,

1 “(2) laboratories performing toxicological uri-
2 nalysis, or

3 “(3) a person conducting a drug testing pro-
4 gram, such standard, procedure, or requirement
5 shall supersede and replace that provided by the
6 HHS guidelines and by any statute, rule, regulation,
7 Executive order, or other law in effect on the date
8 on which such standard, procedure, or requirement
9 becomes effective.

10 **“SEC. 577. PREEMPTION.**

11 “(a) IN GENERAL.—No State or local government
12 may adopt or enforce any law, rule, regulation, ordinance,
13 standard, or order relating to—

14 “(1) the certification of laboratories which per-
15 form drug testing, or

16 “(2) requirements for the conduct of drug test-
17 ing under the certification program established
18 under this part,

19 which is different from such certification program.

20 “(b) PROHIBITION.—No State or local government
21 may adopt or enforce any law, rule, regulation, ordinance,
22 standard, or order that permits or requires any act prohib-
23 ited by section 574.

1 **“SEC. 578. FEES.**

2 “The Secretary shall require the payment of fees by
3 a laboratory for certification and recertification in such
4 amounts as the Secretary may, from time to time, deter-
5 mine are necessary to recover the cost of granting or deny-
6 ing such certification or recertification under the certifi-
7 cation program established under section 571. The Sec-
8 retary shall also require the payment thereafter of annual
9 fees by certified laboratories in such amounts as the Sec-
10 retary may, from time to time, determine are necessary
11 to recover the cost of ongoing testing, inspection, inves-
12 tigation, enforcement, and other supervisory activities with
13 respect to certified laboratories under this part and such
14 certification program. Subject to appropriation Acts, the
15 Secretary may use fees collected under this section to ad-
16 minister the certification program under section 571 and
17 to carry out the activities described in the preceding sen-
18 tence.

19 **“SEC. 579. DEFINITIONS.**

20 “As used in this part—

21 “(1) the term ‘blank specimen’ means a urine
22 specimen containing no drug,

23 “(2) the term ‘controlled substance’ has the
24 meaning given to it in section 102(b) of the Con-
25 trolled Substances Act (21 U.S.C. 802(6)),

1 “(3) the term ‘drug’ means any controlled sub-
2 stance and any metabolite of a controlled substance,

3 “(4) the term ‘drug testing program’ means
4 any program or policy under which 2 or more indi-
5 viduals are, or can reasonably be expected to be, re-
6 quired or requested to submit urine specimens for
7 toxicological urinalysis, but such term does not in-
8 clude—

9 “(A) any program for toxicological urinal-
10 ysis—

11 “(i) administered by the armed forces
12 (as defined in section 2101(2) of title 5,
13 United States Code) or the intelligence
14 community (as defined in Executive Order
15 12333 of December 4, 1981), or

16 “(ii) involving the testing of arrestees,
17 detainees, probationers, incarcerated per-
18 sons, or parolees in the criminal justice
19 system, and

20 “(B) the submission to a laboratory of any
21 urine specimen by an individual’s physician if
22 the testing by the laboratory of the specimen is
23 to be conducted as part of the regular course of
24 diagnosis or treatment prescribed by the physi-
25 cian,

1 “(5) the term ‘false positive result’ means a re-
2 port in connection with any toxicological urinalysis
3 of the presence of a drug in a urine specimen in
4 which that drug is not in fact present at or above
5 the cutoff level for that drug established by the
6 Secretary,

7 “(6) the term ‘medical review officer’ has the
8 meaning given such term in subpart A of the HHS
9 guidelines,

10 “(7) the term ‘person’ includes the Federal
11 Government, a State or local government, or any
12 agency of such a government,

13 “(8) the term ‘performance testing’ means test-
14 ing of a laboratory’s ability—

15 “(A) to identify correctly whether a urine
16 specimen contains a quantity of a drug, and

17 “(B) in the case of a spiked specimen, to
18 identify correctly the amount of any drug in
19 that specimen within qualitative threshold levels
20 and quantitative ranges established by the regu-
21 lations issued under section 572,

22 “(9) the term ‘spiked specimen’ means a urine
23 specimen into which a quantity of a drug or drugs
24 has intentionally been placed for use in performance
25 testing,

1 “(10) the term ‘test subject’ means an individ-
2 ual who has been required or requested to submit a
3 urine specimen for toxicological urinalysis in connec-
4 tion with a drug testing program, and

5 “(11) the term ‘toxicological urinalysis’ means
6 the performance of any analytical procedure or set
7 of procedures on a urine specimen to identify the
8 presence in that specimen of any drug and the
9 amount thereof.”.

10 **SEC. 3. EFFECTIVE DATE.**

11 Part F of title V of the Public Health Service Act,
12 added by section 2, shall take effect on the date of the
13 enactment of this Act, except that subsections (a), (b)(2),
14 and (b)(8) of section 574 of such part shall take effect
15 one year after the date the Secretary of Health and
16 Human Services establishes the laboratory certification
17 program under section 571 of such part.

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