# WISCONSIN LEGISLATIVE COUNCIL STAFF



#### RULES CLEARINGHOUSE

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## CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

# CLEARINGHOUSE RULE 00-141

AN ORDER to repeal RL 7.06 (1) (d) and (2) (d); to renumber and amend RL 7.06 (1) (e) and (2) (e); to amend RL 7.04 (1) (e) and 7.05 (1) (d); and to create RL 7.11 and Appendix II of chapter RL 7, relating to standards for approved drug testing programs.

# Submitted by DEPARTMENT OF REGULATION AND LICENSING

09–29–00 RECEIVED BY LEGISLATIVE COUNCIL.

10–19–00 REPORT SENT TO AGENCY.

RS:DD:jal;rv

### LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below: 1. STATUTORY AUTHORITY [s. 227.15 (2) (a)] NO / YES Comment Attached 2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)] Comment Attached YES CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)] YES NO Comment Attached ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS [s. 227.15 (2) (e)] YES / NO Comment Attached 5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)] NO YES Comment Attached POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL REGULATIONS [s. 227.15 (2) (g)] NO / Comment Attached YES COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)] NO / YES Comment Attached

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# **CLEARINGHOUSE RULE 00–141**

### **Comments**

[NOTE: All citations to "Manual" in the comments below are to the Administrative Rules Procedures Manual, prepared by the Revisor of Statutes Bureau and the Legislative Council Staff, dated September 1998.]

# 2. Form, Style and Placement in Administrative Code

- a. The department's analysis explains why the rule is being promulgated and identifies anticipated effects of the rule, but fails to summarize the content of the rule. [See s. 1.02 (2), Manual.]
- b. The entire appendix should be placed in the text of the Wisconsin Administrative Code in the proper format. The language contained in the appendix sets standards, imposes requirements and grants authority to various actors in the drug testing program system. Rule drafting format and norms cannot be avoided by the use of an appendix of this type. Because the appendix has not been prepared properly for placement in Wisconsin Administrative Code text, this report will not contain the usual format comments of a Clearinghouse Report other than to make the following general statements:
  - (1) Use of the terms "shall," "must" and "will" should be reviewed. When a mandate is imposed, the word "shall" should be used.
  - (2) Acronyms should not be used unless defined.
  - (3) Slashed alternatives should not be used.

(4) Unless phrases used are understood terms of art, they should be described or referenced for the reader. For example, see terms such as "medical review officer" and "U.S. Department of Transportation collection protocol."

# 4. Adequacy of References to Related Statutes, Rules and Forms

- a. The statutes referenced in the department's analysis as statutes authorizing promulgation and statutes being interpreted should be compared with statutory references in s. RL 7.01 (1).
- b. In ss. RL 7.04 (1) (e) and 7.05 (1) (d), the underscored language should be expanded by adding the reference "under s. RL 7.11."

# 5. Clarity, Grammar, Punctuation and Use of Plain Language

In Part C. 4. of Appendix 2, will it be clear to users of the rule to what the "department's standard panel" refers? Further, reference to the "attached drug list" is unclear; attached to what?

# STATE OF WISCONSIN DEPARTMENT OF REGULATION AND LICENSING

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE DEPARTMENT OF REGULATION

AND LICENSING

PROPOSED ORDER OF THE DEPARTMENT OF REGULATION AND LICENSING ADOPTING RULES

ADOPTING RULES

(CLEARINGHOUSE RULE 00-)

# PROPOSED ORDER

An order of the Department of Regulation and Licensing to repeal RL 7.06 (1) (d) and (2) (d); to renumber and amend RL 7.06 (1) (e) and (2) (e); to amend RL 7.04 (1) (e) and 7.05 (1) (d), and to create RL 7.11 and Appendix II of Chapter RL 7, relating to standards for approved drug testing programs.

Analysis prepared by the Department of Regulation and Licensing.

# **ANALYSIS**

Statutes authorizing promulgation: ss. 227.11 (2) and 440.03, Stats.

Statutes interpreted: s. 440.03 (1), Stats.

Currently there is no uniformity concerning the collection of specimens, the transfer of specimens to testing laboratories, the integrity of the chain of custody, appropriate drug panels for medical professionals, true randomization of selection of specimen drop occasions and prompt and accurate reporting of test results for drug testing of professionals regulated by the department. The proposed standards would insure that these variables in the testing program are minimized, thus offering greater protection to the public and greater fairness to participants. Just as important, the proposed standards require the professional to contact the testing program on a daily basis without the intermediary of counselors and therapists. This will encourage personal responsibility and avoid inefficiencies and reporting delays which often occur under the present system. Finally, the proposed standards offer the public more protection by allowing the department to enlarge and tailor the drug testing panels in light of the special opportunities available to medical professionals for access and abuse of pharmaceuticals. It is anticipated that economies of scale will also be encouraged by this program which will ease the cost for participants in drug screening programs.

## TEXT OF RULE

SECTION 1. RL 7.04 (1) (e) is amended to read:

RL 7.04 (1) (e) Submit random monitored blood or urine samples for the purpose of screening for alcohol or controlled substances provided by a drug testing program approved by the department, as required.

Draft of September 29, 2000

Page 1

SECTION 2. RL 7.05 (1) (d) is amended to read:

RL 7.05 (1) (d) An agreement to submit to random monitored drug screens provided by a drug testing program approved by the department at the credential holder's expense, if deemed necessary by the board liaison.

SECTION 3. RL 7.06 (1) (d) is repealed.

SECTION 4. RL 7.06 (1) (e) is renumbered RL 7.06 (1) (d) and amended to read:

RL 7.06 (1) (d) The facility, through the credential holder's supervising therapist, agrees to file reports as required, including quarterly progress reports and immediate reports if a credential holder withdraws from therapy, submits a positive blood or urine screen, relapses, or is believed to be in an unsafe condition to practice.

SECTION 5. RL 7.06 (2) (d) is repealed.

SECTION 6. RL 7.06 (2) (e) is renumbered RL 7.06 (2) (d) and amended to read:

RL 7.06 (2) (d) Agrees to file reports as required to the coordinator, including quarterly progress reports and immediate reports if a credential holder withdraws from therapy, submits a positive blood or urine screen, relapses, or is believed to be in an unsafe condition to practice.

SECTION 7. RL 7.11 is created to read:

RL 7.11 Approval of drug testing programs. The department shall approve drug testing programs for use by credential holders who participate in drug and alcohol monitoring programs pursuant to agreements between the department or boards and credential holders, or pursuant to disciplinary orders. The standards for approval of drug testing programs are at Appendix II.

SECTION 8. Appendix II of Chapter RL 7 is created to read:

#### CHAPTER RL 7

#### APPENDIX 2

# DRUG TESTING PROGRAM STANDARDS FOR APPROVAL OF PROGRAMS

To be approved as a drug testing program for the Department of Regulation and Licensing, programs must satisfactorily meet all of the following standards:

A. Program Administration Requirements

- 1. The drug-testing program (program) shall enroll participants (donors) by assigning the donor an account number, a Private Identification Number (PIN) and establish a method of payment with the donor. No costs are to be incurred by the department.
- 2. The program shall provide the donor with an adequate supply of preprinted chain of custody forms and notify the donor when additional forms must be purchased.
- 3. The program shall provide the donor with the address and phone number of the nearest collection site. The program shall assist the donor in locating a qualified collection site when traveling outside their home area.
- 4. Once enrollment is complete, random selection shall begin immediately and the program shall notify the designated department staff person that selection has begun.
- 5. The program shall maintain a nationwide 800 number capable of processing 300-500 department calls per day that is operational 24 hours per day, 7 days per week, including holidays. In the alternative, this requirement may be met by providing random notification to donors through a secure Internet website.
- 6. The 800 number or secure website shall be accessible for donors to contact daily and provides for computer randomization of each participant that automatically designates whether the donor must provide a specimen, based on a frequency determined by the department.
- 7. The program shall maintain data that is updated on a daily basis verifying the date and time each donor was notified, date, time and location each specimen was collected, results of drug screen and whether or not the donor complied as directed?
- 8. The program shall make available through secure Internet access data that is updated on a daily basis such as notification times, noncompliance to notification procedures, day, time and site of each collection performed along with the drug test results.
- 9. The program must utilize appropriate internal (e.g., test call-ins, record audits, off-site computer backups, etc.) and external (e.g., random checks of collection sites, control specimens routed through courier service to laboratory, etc.) quality controls.
- 10. The program shall maintain the confidentiality of donors in accordance with federal confidentiality regulations.
- 11. The program shall not sell or otherwise transfer or transmit names and other personal identification information of the credential holders to other persons or entities without permission from the department. The program will not solicit from credential holders presently in the monitoring program or formerly in the monitoring program or otherwise contact credential holders except for purposes consistent with administering the program and only with permission from the department.

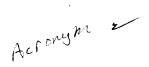
- 12. The program shall provide a detailed inventory of all services and supplies that are included in the standard fee paid by the donor. The program will clearly inform donors of the bundled cost for each drug screen that includes the cost for program administration, collection, transportation, analysis, reporting and confirmation. Cost should not include Medical Review Officer (MRO) review.
- 13. The program shall provide the department with at least three (3) references of current businesses that use its services with the names and phone numbers of contact people.
- 14. The program shall immediately report to the department if the program, laboratory or any collection site fails to meet these standards. The department reserves the right to remove a program from the approved list if the program fails to comply with the standards.
- 15. The program shall make available expert testimony, at a reasonable cost, regarding the drugtesting program. The cost for this service shall be part of the costs of investigation incurred by the department. The program shall make litigation services available for five (5) years after the termination of the agreement.
- 16. The program must agree to protect the contents of all drug panels and not disclose the contents to donors. The program must also obtain agreement from the laboratory to protect the contents of all drug panels and not disclose the contents to donors.

### B. Collection Site Administration

- 1. The program will locate, train and monitor all collection sites per industry standards for drug test collections. The program will locate new collections sites as needed as well as locate sites for donors who travel out of state. The program shall make special effort to locate collection sites open 24 hours per day that utilize the U.S. Department of Transportation collection protocol.
- 2. The program shall provide donors and employers of donors with assistance on a 24-hour/day basis if collection is needed for cause.
- 3. The program shall provide the department with a list of collection sites within Wisconsin that utilize the U.S. Department of Transportation collection protocol.
- 4. The program shall provide the name, address and phone number of a contact person for the courier service used.
- 5. The program shall ensure delivery of specimens within twenty-four hours of sampling.

# C. Laboratory Requirements

1. The program shall identify the laboratory by name, address and phone number of the laboratory's representative and provide a copy of their current contract.



- 2. The program must utilize a laboratory that holds DHHS/SAMHSA certification that has had no adverse/corrective action within the last 3 years. The laboratory must maintain DHHS/SAMHSA certification during the entire time the program is providing drug-testing services to the department.
- 3. The program shall utilize a laboratory that complies with all DHHS/SAMHSA standards, including those related to the handling, processing and storage of specimens.
- 4. The program shall utilize a laboratory that is capable of processing all specimens for the drugs listed in the department's standard panel and additional individual drugs as listed in the attached drug list.
- 5. Testing of participant specimens shall be initiated within 48 hours of pickup by courier.
- 6. Gas Chromatography/Mass Spectrometry (GC/MS), Mass Spectrometry (MS), or another acceptable method shall confirm all positives.
- 7. The laboratory shall allow department personnel to tour its facilities where donor specimens are tested.
- D. Reporting of Results
- 1. The program shall provide results of each specimen to the designated department personnel within 24 hours of processing.
- 2. The program shall be capable of distributing results of drug screens to two or more department personnel.
- 3. The program shall immediately inform the designated department personnel regarding all confirmed positive test results the same day the test results are confirmed or by the next business day if the results are confirmed after hours, on the weekend or on a state or federal holiday.
- 4. Upon request, the program shall fax, email or electronically transmit laboratory copies of drug test results.
- 5. The program shall provide a medical review officer (MRO) upon request and at the donor's expense for MRO review of disputed positive test results.

6. Upon request of the donor or the department, the program shall provide chain-of custody	/
transfer of disputed specimens to an independent laboratory for re-testing.	

(END OF TEXT OF RULE)

The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.22 (2) (intro.), Stats.

Dated	Agency
	Marlene A. Cummings, Secretary
	Department of Regulation and Licensing

## FISCAL ESTIMATE

- 1. The anticipated fiscal effect on the fiscal liability and revenues of any local unit of government of the proposed rule is: \$0.00.
- 2. The projected anticipated state fiscal effect during the current biennium of the proposed rule is: \$0.00.
- 3. The projected net annualized fiscal impact on state funds of the proposed rule is: \$0.00.

# INITIAL REGULATORY FLEXIBILITY ANALYSIS

These proposed rules will be reviewed by the department through its Small Business Review Advisory Committee to determine whether there will be an economic impact on a substantial number of small businesses, as defined in s. 227.114 (1) (a), Stats.

No-16

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# STATE OF WISCONSIN DEPARTMENT OF REGULATION AND LICENSING

IN THE MATTER OF RULE-MAKING

PROPOSED ORDER OF THE

PROCEEDINGS BEFORE THE

: DEPARTMENT OF REGULATION AND

**DEPARTMENT OF REGULATION** 

LICENSING ADOPTING RULES

AND LICENSING

(CLEARINGHOUSE RULE 00-041)

TO: Senator Judy Robson, Senate Co-Chairperson

Joint Committee for the Review of Administrative Rules

Room 15 South, State Capitol Madison, Wisconsin 53702

PLEASE TAKE NOTICE that the DEPARTMENT OF REGULATION AND LICENSING is submitting in final draft form rules relating to standards for approved drug programs.

Please stamp or sign a copy of this letter to acknowledge receipt. If you have any questions concerning the final draft form or desire additional information, please contact Pamela Haack at 266-0495.

# STATE OF WISCONSIN DEPARTMENT OF REGULATION AND LICENSING

IN THE MATTER OF RULE-MAKING: REPORT TO THE LEGISLATURE PROCEEDINGS BEFORE THE: ON CLEARINGHOUSE RULE 00-141

**DEPARTMENT OF REGULATION**: (s. 227.19 (3), Stats.)

AND LICENSING

#### I. THE PROPOSED RULE:

The proposed rule, including the analysis and text, is attached.

#### II. REFERENCE TO APPLICABLE FORMS:

No new or revised forms are required by these rules.

#### III. FISCAL ESTIMATES:

These rules will have no significant impact upon state or local units of government.

#### IV. STATEMENT EXPLAINING NEED:

The Department of Regulation and Licensing or an attached regulatory board may impose drug monitoring requirements after receiving information that a credential holder has used alcohol or other drugs to the extent it has affected professional practice. Monitoring requirements include random drug testing for alcohol and other drugs for participants in the Impaired Professionals Procedure or for those under a disciplinary order issued by the regulatory authorities.

Currently there is no uniformity concerning the collection of specimens, the transfer of specimens to testing laboratories, the integrity of the chain of custody, appropriate drug panels for medical professionals, true randomization of selection of specimen drop occasions and prompt and accurate reporting of test results for drug testing of professionals regulated by the department. The proposed rules would insure that these variables in the testing program are minimized, thus offering greater protection to the public and greater fairness to participants. Just as important, the proposed rules require the professional to contact the testing program on a daily basis without the intermediary of counselors and therapists. This will encourage personal responsibility and avoid inefficiencies and reporting delays which often occur under the present system. Finally, the proposed rules offer the public more protection by allowing the department to test for drugs available to medical professionals. It is anticipated that economies of scale will also be encouraged by this program which will ease the cost for participants in drug screening programs.

# V. NOTICE OF PUBLIC HEARING:

A public hearing was held on October 30, 2000. There were no appearances at the public hearing and no written comments were received.

# VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

All of the recommendations suggested in the Clearinghouse Report were accepted in whole.

# VII. FINAL REGULATORY FLEXIBILITY ANALYSIS:

These rules will have no significant economic impact on small businesses, as defined in s. 227.114 (1) (a), Stats.

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# STATE OF WISCONSIN DEPARTMENT OF REGULATION AND LICENSING

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE DEPARTMENT OF REGULATION AND LICENSING : PROPOSED ORDER OF THE: DEPARTMENT OF REGULATION: AND LICENSING ADOPTING RULES

ADOPTING RULES

(CLEARINGHOUSE RULE 00-141)

#### PROPOSED ORDER

An order of the Department of Regulation and Licensing to repeal RL 7.06 (1) (d) and (2) (d); to renumber and amend RL 7.06 (1) (e) and (2) (e); to amend RL 7.04 (1) (e) and 7.05 (1) (d), and to create RL 7.02 (6) and (8), and RL 7.11, relating to standards for approved drug testing programs.

Analysis prepared by the Department of Regulation and Licensing.

# **ANALYSIS**

Statutes authorizing promulgation: ss. 227.11 (2) and 440.03, Stats.

Statutes interpreted: s. 440.03 (1), Stats.

The Department of Regulation and Licensing or an attached regulatory board may impose drug monitoring requirements after receiving information that a credential holder has used alcohol or other drugs to the extent it has affected professional practice. Monitoring requirements include random drug testing for alcohol and other drugs for participants in the Impaired Professionals Procedure or for those under a disciplinary order issued by the regulatory authorities.

Currently there is no uniformity concerning the collection of specimens, the transfer of specimens to testing laboratories, the integrity of the chain of custody, appropriate drug panels for medical professionals, true randomization of selection of specimen drop occasions and prompt and accurate reporting of test results for drug testing of professionals regulated by the department. The proposed rules would insure that these variables in the testing program are minimized, thus offering greater protection to the public and greater fairness to participants. Just as important, the proposed rules require the professional to contact the testing program on a daily basis without the intermediary of counselors and therapists. This will encourage personal responsibility and avoid inefficiencies and reporting delays which often occur under the present system. Finally, the proposed rules offer the public more protection by allowing the department to test for drugs available to medical professionals. It is anticipated that economies of scale will also be encouraged by this program which will ease the cost for participants in drug screening programs.

The proposed rule describes the requirements that drug-testing programs must meet in the areas of program administration, collection site administration, laboratory management and reporting

requirements. Program administration requires the program to enroll participants by establishing a method of payment and furnishing preprinted chain-of-custody forms. The program is required to provide the name and address of convenient collection sites as well as assist in locating collection sites should the participant travel out of state. The program is required to maintain an 800-number or internet website that is operational 24 hours per day, seven days per week to inform participants when they are selected to provide a specimen for testing. Program administration requires the program to maintain and make available to the department data necessary to verify participant compliance with drug-testing procedures through a internet website. The program is responsible for maintaining internal and external quality controls to ensure the accuracy of test results and other services. The program is required to disclose to participants the cost of each drug screen and prohibits the program from releasing to the participant or the public the specific drugs tested. The rules allow the department to withdraw approval if the program or the laboratory or a collection site fails to comply with the rules. The rules prohibit the program from selling or transferring names of participants without permission from the department.

Collection site administration requires programs to obtain, train and supervise all approved collection sites and requires delivery of specimens within 24 hours of collection.

Laboratory management requires programs to utilize a laboratory that maintains the necessary certification and quality performance. The laboratory is required to analyze specimens for the drugs specified by the department within 48 hours after pickup by courier or mailing. The rules require the laboratory to confirm all positive results utilizing an approved testing methodology.

Finally, reporting requirements requires the laboratory to report results within 24 hours of processing and to notify department personnel of all positive results. The laboratory is required to transmit results of drug screens at the request of the department. The program is responsible for providing a medical review officer upon request to review disputed positive results and to arrange for transfer of disputed specimens to another approved laboratory for retesting.

## **TEXT OF RULE**

SECTION 1. RL 7.02 (6) and 7.02 (8) are created to read:

RL 7.02 (6) "Medical review officer" means a medical doctor or doctor of osteopathy who is a licensed physician and who has knowledge of substance abuse disorders and has appropriate medical training to interpret and evaluate an individual's confirmed positive test result together with an individual's medical history and any other relevant biomedical information.

(8) "Program" means any entity approved by the department to provide the full scope of drug testing services for the department.

SECTION 2. RL 7.04 (1) (e) is amended to read:

RL 7.04 (1) (e) Submit random monitored blood or urine samples for the purpose of screening for alcohol or controlled substances provided by a drug testing program approved by the department under s. RL 7.11, as required.

SECTION 3. RL 7.05 (1) (d) is amended to read:

RL 7.05 (1) (d) An agreement to submit to random monitored drug screens provided by a drug testing program approved by the department under s. RL 7.11 at the credential holder's expense, if deemed necessary by the board liaison.

SECTION 4. RL 7.06 (1) (d) is repealed.

SECTION 5. RL 7.06 (1) (e) is renumbered RL 7.06 (1) (d) and amended to read:

RL 7.06 (1) (d) The facility, through the credential holder's supervising therapist, agrees to file reports as required, including quarterly progress reports and immediate reports if a credential holder withdraws from therapy, submits a positive blood or urine screen, relapses, or is believed to be in an unsafe condition to practice.

SECTION 6. RL 7.06 (2) (d) is repealed.

SECTION 7. RL 7.06 (2) (e) is renumbered RL 7.06 (2) (d) and amended to read:

RL 7.06 (2) (d) Agrees to file reports as required to the coordinator, including quarterly progress reports and immediate reports if a credential holder withdraws from therapy, submits a positive blood or urine screen, relapses, or is believed to be in an unsafe condition to practice.

SECTION 8. RL 7.11 is created to read:

RL 7.11 Approval of drug testing programs. The department shall approve drug testing programs for use by credential holders who participate in drug and alcohol monitoring programs pursuant to agreements between the department or boards and credential holders, or pursuant to disciplinary orders. To be approved as a drug testing program for the department, programs shall satisfactorily meet all of the following standards in the areas of program administration, collection site administration, laboratory requirements and reporting requirements:

# (1) Program administration requirements are:

(a) The program shall enroll participants by setting up an account, establishing a method of payment and supplying preprinted chain-of-custody forms.

- (b) The program shall provide the participant with the address and phone number of the nearest collection sites and shall assist in locating a qualified collection site when traveling outside the local area.
- (c) Random selection of days when participants shall provide specimens shall begin upon enrollment and the program shall notify designated department staff that selection has begun.
- (d) The program shall maintain a nationwide 800 number or a internet website that is operational 24 hours per day, 7 days per week to inform participants of when to provide specimens.
- (e) The program shall maintain and make available to the department through a internet website data that are updated on a daily basis verifying the date and time each participant was notified after random selection to provide a specimen, the date, time and location each specimen was collected, the results of drug screen and whether or not the participant complied as directed.
- (f) The program shall maintain internal and external quality of test results and other services.
- (g) The program shall maintain the confidentiality of participants in accordance with s. 146.82, Stats.
- (h) The program shall inform participants of the total cost for each drug screen including the cost for program administration, collection, transportation, analysis, reporting and confirmation. Total cost shall not include the services of a medical review officer.
- (i) The program shall immediately report to the department if the program, laboratory or any collection site fails to comply with this section. The department may remove a program from the approved list if the program fails to comply with this section.
- (j) The program shall make available to the department experts to support a test result for 5 years after the test results are released to the department.
- (k) The program shall not sell or otherwise transfer or transmit names and other personal identification information of the participants to other persons or entities without permission from the department. The program shall not solicit from participants presently or formerly in the monitoring program or otherwise contact participants except for purposes consistent with administering the program and only with permission from the department.
- (l) The program and laboratory shall not disclose to the participant or the public the specific drugs tested.
  - (2) Collection site administration requirements are:

- (a) The program shall locate, train and monitor collection sites for compliance with the U.S. department of transportation collection protocol under 49 CFR 40.
- (b) The program shall require delivery of specimens to the laboratory within 24 hours of collection.

# (3) Laboratory requirements are:

- (a) The program shall utilize a laboratory that is certified by the U.S. department of health and human services, substance abuse and mental health services administration under 49 CFR 40. If the laboratory has had adverse or corrective action, the department shall evaluate the laboratory's compliance on a case by case basis.
- (b) The program shall utilize a laboratory capable of analyzing specimens for drugs specified by the department.
- (c) Testing of specimens shall be initiated within 48 hours of pickup by courier.
- (d) All positive drug screens shall be confirmed utilizing gas chromatography in combination with mass spectrometry, mass spectrometry, or another approved method.
- (e) The laboratory shall allow department personnel to tour facilities where participant specimens are tested.

# (4) The requirements for reporting of results are:

- (a) The program shall provide results of each specimen to designated department personnel within 24 hours of processing.
- (b) The program shall inform designated department personnel of confirmed positive test results on the same day the test results are confirmed or by the next business day if the results are confirmed after hours, on the weekend or on a state or federal holiday.
- (c) The program shall fax, e-mail or electronically transmit laboratory copies of drug test results at the request of the department.
- (d) The program shall provide a medical review officer upon request and at the expense of the participant, to review disputed positive test results.
- (e) The program shall provide chain-of-custody transfer of disputed specimens to an approved independent laboratory for retesting at the request of the participant or the department.

(END OF TEXT OF RULE)

	ake effect on the first day of the month following trative register, pursuant to s. 227.22 (2) (intro.), Stats.
Dated	Agency Marlene A. Cummings, Secretary Department of Regulation and Licensing

# FISCAL ESTIMATE

- 1. The anticipated fiscal effect on the fiscal liability and revenues of any local unit of government of the proposed rule is: \$0.00.
- 2. The projected anticipated state fiscal effect during the current biennium of the proposed rule is: \$0.00.
- 3. The projected net annualized fiscal impact on state funds of the proposed rule is: \$0.00.

# FINAL REGULATORY FLEXIBILITY ANALYSIS

These rules will have no significant economic impact on small businesses, as defined in s. 227.114 (1) (a), Stats.

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