

CERTIFICATE

STATE OF WISCONSIN

DEPARTMENT OF REGULATION AND LICENSING

TO ALL WHOM THESE PRESENTS SHALL COME, GREETINGS:

I, Marlene A. Cummings, Secretary, Wisconsin Department of Regulation and Licensing and custodian of the official records of the Department of Regulation and Licensing, hereby certify that the annexed rules were duly approved and adopted by the Department of Regulation and Licensing on the 4th day of December, 2000.

I further certify that said copy has been compared by me with the original on file in this office and that the same is a true copy thereof, and of the whole of such original.

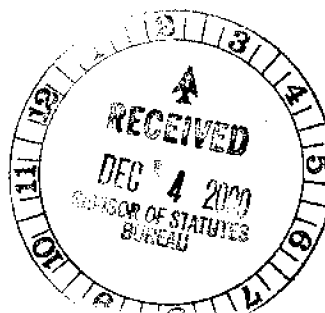
IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the official seal of the department at 1400 East Washington Avenue, Madison, Wisconsin this 4th day of December, 2000.



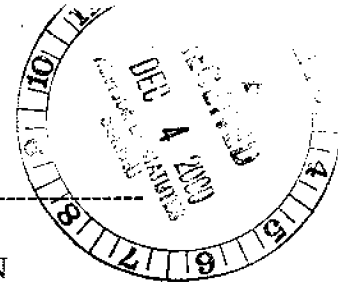
**Marlene A. Cummings, Secretary,
Department of Regulation and
Licensing**

00-141

2-1-01



STATE OF WISCONSIN
DEPARTMENT OF REGULATION AND LICENSING



IN THE MATTER OF RULE-MAKING : ORDER OF THE
PROCEEDINGS BEFORE THE : DEPARTMENT OF REGULATION
DEPARTMENT OF REGULATION : AND LICENSING ADOPTING RULES
AND LICENSING : ADOPTING RULES
: (CLEARINGHOUSE RULE 00-141)

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)

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 12/4/00

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

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12/4/00



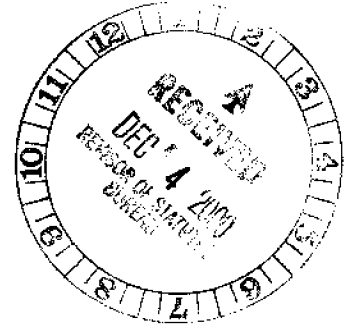
State of Wisconsin
DEPARTMENT OF REGULATION AND LICENSING
CORRESPONDENCE/MEMORANDUM

DATE: December 4, 2000

TO: Gary Poulson
Assistant Revisor of Statutes

FROM: Pamela A. Haack, Paralegal
Department of Regulation and Licensing
Office of Administrative Rules

SUBJECT: Final Order Adopting Rules



Agency: Department of Regulation and Licensing

Clearinghouse Rule 00-141

Attached is a copy and a certified copy of a final order adopting rules relating to standards for approved drug testing programs.

Please stamp or sign a copy of this letter to acknowledge receipt.

Thank you.