

**WEST VIRGINIA
SECRETARY OF STATE
BETTY IRELAND
ADMINISTRATIVE LAW DIVISION**

Form #7

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2008 SEP 10 AM 9:38

OFFICE WEST VIRGINIA
SECRETARY OF STATE

Effective Date

NOTICE OF AN EMERGENCY RULE

AGENCY: West Virginia Board of Medicine TITLE NUMBER: 11

CITE AUTHORITY: West Virginia Code §29A-3-15, §30-3-10(e) and (f)

EMERGENCY AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 11 CSR 2

TITLE OF RULE BEING PROPOSED: Establishment and Regulation of Restricted License Issued to an Applicant in
Extraordinary Circumstances

THE ABOVE RULE IS BEING FILED AS AN EMERGENCY RULE TO BECOME EFFECTIVE AFTER APPROVAL BY SECRETARY OF STATE OR 42ND DAY AFTER FILING, WHICHEVER OCCURS FIRST.

THE FACTS AND CIRCUMSTANCES CONSTITUTING THE EMERGENCY ARE AS FOLLOWS:

See Attachment

Use additional sheets if necessary


Authorized Signature

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State of West Virginia

West Virginia Board of Medicine

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STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE PROPOSED RULE ON AN EMERGENCY BASIS AND SUMMARY OF CONTENT OF PROPOSED RULE

In 2008, during the Regular Legislative Session, Senate Bill 317 was passed, which updated the licensing requirements in the Medical Practice Act for physicians and podiatrists. The bill, as passed, included an amendment allowing restricted licensure for certain physicians and podiatrists in extraordinary circumstances who do not meet the standard requirements for licensure. The amendment requires the Board to propose rules that establish and regulate the restricted license issued in extraordinary circumstances.

The proposed rule defines "extraordinary circumstances" and "restricted license", and repeats and elaborates upon the statutory provisions under girding the provisions here. The proposed rule does not allow for an applicant to be issued a restricted license in extraordinary circumstances if the applicant has been the subject of disciplinary action or has been convicted of various crimes. The proposed rule provides that a licensee is subject to all the provisions of the Medical Practice Act and rules, and specifies that whatever restrictions are imposed by the Board may be altered if appropriate, necessary, and in the public interest.

The Board of Medicine has unanimously determined at its regular meeting on September 8, 2008, that the proposed rule should be filed on an emergency basis. The possibility exists that the only kidney transplant program in West Virginia may be lost unless this proposed rule is enacted now on an emergency basis, rather than nine months from now as the rule makes its way through the standard legislative process. Providing the option for licensure in extraordinary circumstances now is essential, as it means that an otherwise unqualified candidate for licensure may apply now and the Board of Medicine will have to the opportunity to determine if he or she is qualified under the extraordinary circumstances definition. This is an effort to prevent substantial harm to the public interest and is for the immediate preservation of the public health and welfare.

PRESIDENT
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Deborah Lewis Rodecker
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APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Establishment and Regulation of Restricted License Issued to an Applicant in Extraordinary Circumstances

Type of Rule: Legislative Interpretive Procedural

Agency: West Virginia Board of Medicine

Address: 101 Dee Drive Suite 103
Charleston WV 25311

Phone Number: 304-558-2921 Email: deborahrodecker@wvdhhr.org

Fiscal Note Summary

Summarize in a clear and concise manner what impact this measure will have on costs and revenues of state government.

No impact on costs and revenues of state government.

Fiscal Note Detail

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

FISCAL YEAR			
Effect of Proposal	Current Increase/Decrease (use "--")	Next Increase/Decrease (use "--")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0.00	0.00	0.00
Personal Services			
Current Expenses			
Repairs & Alterations			
Assets			
Other			
2. Estimated Total Revenues	0.00	0.00	0.00

Rule Title: _____

Rule Title: Establishment and Regulation of Restricted License issued to an applicant in Extra

3. **Explanation of above estimates (including long-range effect):**
Please include any increase or decrease in fees in your estimated total revenues.

N/A

MEMORANDUM

Please identify any areas of vagueness, technical defects, reasons the proposed rule would not have a fiscal impact, and/or any special issues not captured elsewhere on this form.

N/A

Date: May 20, 2008

Signature of Agency Head or Authorized Representative

P. J. Knittle



EMERGENCY RULE QUESTIONNAIRE

DATE: September 10, 2008

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: *(Agency Name, Address & Phone No.)* West Virginia Board of Medicine
101 Dee Drive, Suite 103
Charleston, WV 25311

EMERGENCY RULE TITLE: Establishment and Regulation of Restricted License Issued to an Applicant in Extraordinary Circumstances

1. Date of filing September 10, 2008

2. Statutory authority for promulgating emergency rule:
West Virginia Code §29A-3-15, §30-3-10(e) and (f)

3. Date of filing of proposed legislative rule: September 10, 2008

4. Does the emergency rule adopt new language or does it amend or appeal a current legislative rule? The emergency rule adopts new language.

5. Has the same or similar emergency rule previously been filed and expired?
No.

6. State, with particularity, those facts and circumstances which make the emergency rule necessary for the **immediate** preservation of public peace, health, safety or welfare.

If the proposed rule is not enacted on an emergency basis the only Kidney Transplant Program in West Virginia (at CAMC) will be seriously jeopardized because two transplant surgeons are needed to fill vacancies which CAMC has been unable to fill even with extensive international recruitment efforts. There is a possibility that persons who do not qualify for a license under the standard requirements might qualify for licensure under the Extraordinary Circumstances Rule. If the CAMC Kidney Transplant

Program is forced to close, the priority West Virginians have enjoyed in receiving donated kidneys will be lost.

7. If the emergency rule was promulgated in order to comply with a time limit established by the Code or federal statute or regulation, cite the Code provision, federal statute or regulation and time limit established therein.

N/A

8. State, with particularity, those facts and circumstances which make the emergency rule necessary to prevent substantial harm to the public interest.

If the CAMC Kidney Transplant Program is shut down, West Virginia citizens in need of kidney transplants will be forced to travel to Pennsylvania, Virginia or Ohio to obtain kidneys, and the volume of candidates on their waiting lists (for example Pennsylvania has over 5,000 candidates compared to under 200 in WV) far exceeds that in West Virginia. The longer an eligible patient waits for a kidney transplant, the more negative the morbidity and mortality outcome.

As West Virginia leads the Nation in poor health status leading to more kidney disease, enacting the rule on an emergency basis may prevent substantial harm to the public interest because a physician who is not qualified for licensure under standard requirements may qualify under the "Extraordinary Circumstances" definition.

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TITLE II

LEGISLATIVE RULE

2008 SEP 10 AM 9: 38

WEST VIRGINIA BOARD OF MEDICINE

OFFICE WEST VIRGINIA
SECRETARY OF STATE

SERIES 2

ESTABLISHMENT AND REGULATION OF RESTRICTED LICENSE
ISSUED TO AN APPLICANT IN EXTRAORDINARY CIRCUMSTANCES

11-2-1. General.

1.1. Scope.- W. Va. Code §30-3-10(e) provides for the issuance of a restricted license by the Board to an applicant in extraordinary circumstances under certain specific conditions and W. Va. Code §30-3-10(f) requires that rules be promulgated that establish and regulate the restricted license issued to an applicant in extraordinary circumstances.

1.2 Authority.- W.Va. Code §30-3-10(f).

1.3. Filing date.-

1.4. Effective date.

11-2-2. Definitions.

2.1. For purposes of this rule, the following definitions apply:

- a. "extraordinary circumstances" means circumstances where the physician has achieved a high level of academic or professional recognition for excellence in research, teaching, or the practice of medicine, as evidenced by objective factors, including academic appointments, length of time in a profession, scholarly publications and presentations, professional accomplishments, and awards. Consideration of need for the specialty shall be included.
- b. "restricted license" means a license which contains restrictions, limitations, or conditions which may include but are not limited to any or all of the following:
 - 1. practice location;
 - 2. practice setting;
 - 3. specialty area of practice;
 - 4. practice procedures;
 - 5. hours and length of practice;
 - 6. type of patients;
 - 7. sitting for and successful completion of examination(s);
 - 8. evaluations and treatment;

- 9. education;
- 10. monitoring and supervision.

11-2-3. Issuance of License in Extraordinary Circumstances.

3.1. An applicant for issuance of a restricted license in extraordinary circumstances is subject to all the requirements of the provisions of W. Va. Code §30-3-10 and Board rules 11CSR4 pertaining to fees, and 11CSR 1A pertaining to licensure, except insofar as the applicant is unable to satisfy the standard requirements. In such case, the Board, in its discretion, may require additional information to be submitted as part of the application. The Board shall require a personal appearance by the applicant before Board members, and the Board, in its discretion, may issue a restricted license in extraordinary circumstances, provided that the extraordinary circumstances are specified in writing and that written findings are made that:

- a. based on the applicant's exceptional education, training and practice credentials, the applicant's practice in the state would be beneficial to the public welfare;
- b. the applicant's education, training and practice credentials are substantially equivalent to the requirements of licensure established in W. Va. Code §30-3-10; and
- c. the applicant received his/her post-graduate medical training outside of the United States and its territories.

3.2. The burden of satisfying the Board as to whatever additional information is required by the Board, and of the extraordinary circumstances and that the Board is justified in making such written findings is on the applicant.

3.3. The applicant is not eligible for a temporary license pursuant to W. Va. Code §30-3-11.

3.4. The applicant is not eligible for a restricted license in extraordinary circumstances if he/she has been the subject of disciplinary action by any other state or jurisdiction, the uniformed services of the United States or other jurisdiction, or the applicant's peers in a local, regional, state, national, or other professional medical association or staff of a hospital: Provided, that a hospital's temporary suspension for failure to maintain records on a timely basis, failure to attend staff or section meetings, or voluntary cessation of hospital privileges for reasons unrelated to professional competence or ethics shall not be considered to be disciplinary action for purposes of this section.

3.5. The applicant is not eligible for a restricted license in extraordinary circumstances if he/she has been convicted of or entered a plea of guilty to, or pled nolo contendere, to a felony, or placed on deferred adjudication, community supervision, or deferred disposition for a felony, a misdemeanor connected with the practice of medicine or with moral turpitude.

3.6. The restricted license issued in extraordinary circumstances must be approved by a vote of three fourths of the members of the Board.

3.7. Orders denying applications for a restricted license in extraordinary circumstances are not appealable.

3.8. The Board shall report to the President of the Senate and the Speaker of the House of Delegates all decisions made regarding requests for a restricted license under extraordinary circumstances.

11-2-4. Regulation of Restricted License in Extraordinary Circumstances.

4.1. In addition to adhering to the requirements of the restricted license issued, the licensee is subject to all the provisions of the West Virginia Medical Practice Act, W.Va. Code §30-3-1 et seq. and all implementing rules.

11-2-5. Change in Restricted License.

5.1. At the option of the Board or the holder of a restricted license issued pursuant to this rule, changes in restrictions may be authorized by a vote of three fourths of the members of the Board if the Board deems them to be appropriate, necessary and in the public interest.

11-2-6. Conversion of Restricted License to Standard License.

6.1. The Board may convert the restricted license to a standard license upon application of the licensee with a restricted license who later meets the requirements for a standard license.



**Charleston Area
Medical Center**

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2008 SEP 19 AM 10:29

OFFICE WEST VIRGINIA
SECRETARY OF STATE

GLENN CROTTY, JR., MD, FACP
EXECUTIVE VICE PRESIDENT AND
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September 12, 2008

COPY

Honorable Betty Ireland
Secretary of State
Bldg. 1, Suite 157-K
1900 Kanawha Blvd. East
Charleston, WV 25305-0770

Dear Secretary Ireland:

I want to commend the West Virginia Board of Medicine for its unanimous vote on September 8, 2008 to request the Secretary of State to implement on an emergency basis proposed Permanent Legislative Rule 11 CSR 2 for the "Establishment and Regulation of Restricted License Issued to an Applicant in Extraordinary Circumstances."

As you know, that proposed Permanent Legislative Rule was filed with the West Virginia Secretary of State on July 18, 2008 and the Notice of an Emergency Rule was filed with your office on September 10, 2008. Both filings contained a Statement of Circumstances which reads in pertinent part:

"In 2008, during the Regular legislative session, Senate Bill 317 was passed, which updated the licensing requirements in the Medical Practice Act for physicians and podiatrists. The bill, as passed, included an amendment allowing restricted licensure for certain physicians and podiatrists in extraordinary circumstances who do not meet the standard requirements for licensure. The amendment requires the Board to propose rules that establish and regulate the restricted license issued in extraordinary circumstances."

On behalf of Charleston Area Medical Center and the Cleveland Clinic, we applaud the action by the Board of Medicine to implement this proposed new rule in a Permanent Rule, but more importantly to implement it now under the Emergency Rule provisions. We do understand that under the statutory process for proposed legislative rules of this nature, it may not be until sometime next year before the Permanent Rule actually becomes effective, and that is why your determination of the Emergency Rule is so important at this time.

I am writing now to bring to your attention an urgent matter that could seriously jeopardize the future of the only Kidney Transplant Program in West Virginia and to request that the Secretary of State take immediate action to help keep this important health care program alive.

Honorable Betty Ireland
September 12, 2008
Page Two

As you know, an Emergency Rule may be promulgated by a state agency such as the Board of Medicine only when an emergency exists, or when the law specifically authorizes an emergency rule to allow implementation of a law before the next legislative session. West Virginia Code §29A-3-15(f) defines emergency narrowly:

"For the purposes of this section, an emergency exists when the promulgation of an emergency rule is necessary (1) for the immediate preservation of the public peace, health, safety or welfare, (2) to comply with a time limitation established by this code or by a federal statute or regulation, or (3) to prevent substantial harm to the public interest."

The test we all must address is "does an emergency exist" and this must be affirmed by the Board of Medicine and then also by the Secretary of State and the Attorney General. This is not a task that should be taken lightly.

However, the case may be easily made under the statutory guidelines of Code §29A-3-15(f) by substantiating the fact that an emergency does exist because of "the immediate preservation of the public peace, health, safety or welfare," and "to prevent substantial harm to the public interest" if the CAMC Kidney Transplant Program is allowed to shut down. We urge you to help us to keep that from occurring.

There is no doubt that the closing of the CAMC Kidney Transplant Program will cause substantial harm to the public interest and by keeping it open through an Emergency Rule, we can preserve the public health, safety and welfare.

That is because organ transplantation is a public health issue and is in crisis. Nationally there are 99,390 patients awaiting a solid organ transplant and 18 die everyday due to the lack of an available organ. In 2008, we continue to see a great gap between the number of transplants and the number of donors. This is reflective of the 9,029 transplants performed from January 1, 2008 through April 30th 2008 and the 4,478 donors.

West Virginia has been fortunate to have a premier transplant program to try to combat this public health crisis. The CAMC Kidney Transplant Program has been providing kidney transplants to patients with end-stage renal disease for 22 years. This treatment modality provides patients the freedom from dialysis and the opportunity to return to work and to productive life styles.

I would like to make you aware of an emergency situation that will significantly impact the preservation of health and cause substantial harm to our West Virginia dialysis patients. A true emergency currently exists because if we are unable to provide kidney transplants for our patients in West Virginia, we know that the patients will be faced with serious health status and availability obstacles such as:

1. Difficult access to a kidney transplant program as patients will be required to travel at least to Pennsylvania, Virginia or Ohio. It is often very difficult and cost prohibitive for these patients and their families to travel out of state for transplantation and post transplant medical procedure follow up.

2. Many of these states have longer waiting times due to the volume of candidates on their waiting list. For example, Pennsylvania has 5,075 kidney candidates compared to the CAMC waiting list of 183 candidates. Medical evidence tells us the longer an eligible patient for kidney transplant has to wait, then the more negative the morbidity and mortality outcome.

3. When the Center for Organ Recovery and Education began servicing the transplant programs of West Virginia in 1994, they were successful in securing from the United Network of Organ Sharing (UNOS) a special alternative local unit (ALU) for organ allocation in their area. This ALU in the past was rarely granted and today is almost never granted. The purpose of this ALU was to assure that kidneys recovered in the CORE service area within West Virginia are preferentially distributed among patients on the CAMC transplant waiting list, using established Organ Procurement Transplant Network (OPTN) criteria. This has greatly advantaged the transplant candidates awaiting a life-saving kidney transplant. If there is even a temporary closing of the CAMC Kidney Transplant Program, we would be subject to losing the ALU, meaning the priority of West Virginia donated kidneys to West Virginians needing kidney transplants could be lost.

General Statistics on West Virginia Kidney Transplants

Year	Died Awaiting a Kidney Transplant	Transplant Performed
2006	13	51
2007	16	48
2008 (Jan – June)	7	27

The need for an Emergency Rule is further justified because of the lack nationally of available qualified transplant surgeons to work here to continue the CAMC Kidney Transplant Program. An attachment of "CAMC Kidney Transplant Program Facts" is included for your reference.

Our program is in dire need of two new transplant surgeons to fill current vacancies. Despite concentrated extensive international recruitment efforts by the Cleveland Clinic, replacement transplant surgeons qualified and available for the CAMC Kidney Transplant Program are not currently available. At least two candidates who would have qualified under the "extraordinary circumstances" rule were not able to apply and, therefore, have chosen to go to other states. CAMC and the Cleveland Clinic have two potential candidates interested in applying that may qualify under this emergency rule. CAMC would not be asking for this assistance had we been successful in our efforts to recruit candidates who could have been licensed in the traditional manner.

Honorable Betty Ireland
September 12, 2008
Page Four

The Emergency Rule would provide the opportunity right now for qualified transplant surgeons to make application to the Board of Medicine for restricted licensure under "extraordinary circumstances." Without the availability of the Emergency Rule, the CAMC Kidney Transplant Program may be lost.

We are not asking the Secretary of State to do anything other than to grant the opportunity for application by physicians under the "extraordinary circumstances" provision to be able to do so immediately. The same procedures would govern now as already approved by the Board of Medicine in the Permanent Legislative Rule.

We do request that the Secretary of State join us in protecting the valuable continuation of the CAMC Transplant Program by taking action on implementing the Emergency Rule as soon as possible.

In conclusion, let me reiterate the importance of the unanimous vote taken by the Board of Medicine to save a program now on life support. Please help CAMC and the Cleveland Clinic to save this program from termination. The action by the Secretary of State to protect this program will save lives of those needing kidney transplants. An emergency does exist under the statutory guidelines, and an Emergency Rule by the Board of Medicine is certainly justified.

Please contact me if you require any additional information and documentation from CAMC, the Cleveland Clinic, or the Center for Organ Recovery and Education.

Respectfully Submitted,



Glenn Crotty, Jr., M.D., FACP
Executive Vice President and
Chief Operating Officer

c: The Honorable Joe Manchin III, Governor
The Honorable Bonnie Brown, Chair, WV Legislative Rule Making Review Committee
The Honorable Joseph M. Minard, Chair, WV Legislative Rule Making Review Committee
Debra Graham, Chief Counsel, WV Legislative Rule Making Review Committee
John A. Wade, Jr., MD, President, West Virginia Board of Medicine
Robert C. Knittle, M. S., Executive Director, West Virginia Board of Medicine
Deborah Lewis Rodecker, J. D., Counsel, West Virginia Board of Medicine
David L. Ramsey, President and CEO, Charleston Area Medical Center
J. Stephen Jones, M. D., Chair, Regional Urology, Cleveland Clinic
Susan A. Stuart, R.N., Executive Director, Center for Organ Recovery and Education
Judy Cooper, Manager, Administrative Law Division, Office of Secretary of State

CAMC Kidney Transplant Program Facts

Administered Through a Collaborative Agreement With The Cleveland Clinic

CAMC Kidney Transplant Program Is The Only One In West Virginia

Number of Patients on the Transplant List =	184
Number of Patients in Workup = (Workup; defined as patient with renal failure actively trying to get on the transplant list)	300+
Number of Transplants since the program started in 1987 =	849
Number of Transplants YTD 2008 =	35

The United Network of Organ Sharing (UNOS) has designated a special alternative local unit (ALU) for organ allocation which assures that kidneys recovered in the CORE service area within West Virginia are preferentially distributed among patients on the CAMC transplant waiting list using established Organ Procurement Transplant Network (OPTN) criteria. This has greatly advantaged the transplant candidates awaiting a life saving kidney transplant. Even a temporary closing of the CAMC Kidney Transplant Program would jeopardize losing the ALU, meaning the priority of West Virginia donated kidneys to West Virginians needing kidney transplants could be lost.

CAMC Kidney Transplant Program Is The Only Follow-Up Care In West Virginia

Number of Post Transplants currently being followed =	446
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Patients receiving renal transplantation at a specific transplant center must travel back to that center for follow-up care and transplant related hospitalizations. It may be very difficult and cost prohibitive for these patients and their families to travel out of state for post-transplant medical procedure follow-up if treatment is not available at the CAMC Kidney Transplant Program.

WV Leads The Nation In Poor Health Status Leading to More Kidney Disease

Diabetes Rates, % adults (2005-2007 avg)	11.1%	Ranks #1 nationally
Hypertension Rates, % adults (2003-2007 avg)	33.2%	Ranks #3 nationally
Obesity Rates, % adults (2005-2007 avg)	30.6%	Ranks #2 nationally

As the rate of kidney disease advances due to West Virginia leading the nation in related poor health status, particularly in diabetes and hypertension, it is even more important not to lose the CAMC Kidney Transplant Program.

The number of dialysis patients in West Virginia increased 75% from 1993 to 2004. In 2004 almost half of these patients had a primary diagnosis of diabetes and another quarter had a primary diagnosis of hypertension.

In 2004, 3,076 West Virginians were hospitalized with a diagnosis of kidney disease.

83 new cases of End Stage Renal Disease (ESRD) due to diabetes are diagnosed annually in West Virginia.

32.1% of the patients in the CAMC Kidney Transplant Program are Diabetic.