FEBRUARY 10

Tuesday, February 10, 2009

9:00 a.m. to 11:00 a.m.

Legislative Rule-Making
Review Committee
(Code §29A-3-10)

Earl Ray Tomblin
ex officio nonvoting member

Richard Thompson
ex officio nonvoting member

Senate		**House**
Minard, Chairman		Brown, Chairman
Fanning, Vice Chair	Absent	Poling, Vice Chair
Prezioso	Absent	Miley
Unger		Talbott
Boley		Overington
Facemyer	Absent	Sobonya

The meeting was called to order by Senator Minard, Chairman.

Delegate Brown moved that the minutes of the January 12, 2009, meeting be approved. The motion was adopted.

Jay Lazell, Associate Counsel, explained his abstract on the rule proposed by the **Office of the Department of Environmental Protection on Air Quality, *Control and Reduction of Nitrogen Oxides from Non-Electric Generating Units as a Means of Mitigate Transport of Ozone Precursors*, 45CSR1.**

Delegate Brown moved that the proposed rule be approved. The motion was adopted.

Mr. Lazell, reviewed his abstract on the rule proposed by the **Office of the Department of Environmental Protection on Air Quality, *Nox Budget Trading Program as a Means of Control and Reduction of Nitrogen Oxides from Electric Generating Units*, 45CSR26.**

Delegate Brown moved that the proposed rule be approved. The motion was adopted.

Rita Pauley, Associate Counsel, explained her abstract on the rule proposed by the **West Virginia Development Office, *Brownfield Economic Development Districts*, 145CSR11**, stated that the Office has agreed to technical modifications, and responded to questions from the committee.

Delegate Brown moved that the proposed rule be approved as

modified. The motion was adopted.

Brian Skinner, Associate Counsel, reviewed his abstract on the rule proposed by the **West Virginia State Fire Commission, *Standards for the Certification and Continuing Education of Municipal, County, and other Public Building Code Officials, Building Code Inspectors and Plans Examiners*, 87CSR7**, stated that the Commission has agreed to technical modifications and responded to questions from the committee.

Anthony Carrico, Deputy State Fire Marshall, responded to questions from the committee.

Delegate Brown moved that the proposed rule be approved as modified. The motion was adopted.

Mr. Skinner, Associate Counsel, explained his abstract on the rule proposed by the **West Virginia State Fire Marshall, *Supervision of Fire Protection Work*, 130CSR3**, stated that the Marshall has agreed to technical modifications and responded to questions.

Delegate Brown moved that the proposed rule be approved as modified. The motion was adopted.

Ms. Pauley, Associate Counsel, reviewed her abstract on the rule proposed by the **Governor's Committee on Crime, Delinquency and Correction, *Law Enforcement Training Standards*, 149CSR2**, stated that the Committee has agreed to technical modifications and answered questions from the committee.

Delegate Brown moved that the proposed rule be approved as modified. The motion was adopted.

Ms. Pauley addressed the committee again about subpoena powers and whether or not to draft a bill specifically stating those powers.

Ms. Pauley, Associate Counsel, explained her abstract on the rule proposed by the **West Virginia Division of Highways, *Use of State Road Rights of Way and Adjacent Areas*, 157CSR6**, and stated that the Division has agreed to technical modifications.

Paul Mattox, Commissioner of Highways, addressed the committee, showed an example of what a memorial sign would look like, and answered questions from the committee.

Ms. Pauley then responded to questions from the committee.

Delegate Brown moved that the proposed rule be approved as modified. The motion was adopted.

Ms. Pauley, Associate Counsel, reviewed her abstract on the

rule proposed by the **West Virginia Division of Highways, *Transportation of Hazardous Wastes Upon the Roads and Highways*, 157CSR7.**

Delegate Brown moved that the proposed rule be approved. The motion was adopted.

Ms. Pauley, Associate Counsel, explained her abstract on the rule proposed by the **West Virginia Insurance Commission, *Coordination of Health Benefits*, 114CSR28,** stated that the Commission has agreed to technical modifications, and responded to questions.

Delegate Brown moved that the proposed rule be approved as modified. The motion was adopted.

Ms. Pauley, Associate Counsel, reviewed her abstract on the rule proposed by the **West Virginia Insurance Commission, *Long-Term Care Insurance*, 114CSR32,** stated that the Commission has agreed to technical modifications and answered questions from the committee.

Tim Murphy, Associate Counsel for the West Virginia Insurance Commission, responded to questions.

Delegate Brown moved that the proposed rule be approved as modified. The motion was adopted.

Ms. Pauley, Associate Counsel, explained her abstract on the rule proposed by the **West Virginia Insurance Commission, *Actuarial Opinion and Memorandum Rule*, 114CSR41,** stated that the Commission has agreed to technical modifications and responded to questions form the committee.

Delegate Brown moved that the proposed rule be approved as modified. The motion was adopted.

Ms. Pauley, Associate Counsel, reviewed her abstract on the rule proposed by the **West Virginia Insurance Commission, *Viatical Settlements*, 114CSR80,** stated that the Commission has agreed to technical modifications and responded to questions from the committee.

Tim Murphy, Associate Counsel for the West Virginia Insurance Commission, answered questions from the committee.

Delegate Brown moved that the proposed rule be approved as modified. The motion was adopted.

Ms. Pauley, Associate Counsel, explained her abstract on the

rule proposed by the **West Virginia Insurance Commission**, ***Discount Medical Plan Organizations and Discount Prescription Drug Plan Organizations***, **114CSR83**, and stated that the Commission has agreed to technical modifications.

Delegate Brown moved that the proposed rule be approved as modified. The motion was adopted.

Ms. Pauley, Associate Counsel, explained her abstract on the rule proposed by the **West Virginia Insurance Commission**, ***Professional Employer Organizations***, **114CSR85**, and stated that the Commission has agreed to technical modifications.

Tim Murphy, Associate Counsel for the West Virginia Insurance Commission, addressed the committee and responded to questions.

Delegate Brown moved that the proposed rule be approved as modified. The motion was adopted.

Mr. Lazell, Associate Counsel, explained his abstract on the rule proposed by the **Department of Environmental Protection Mining and Reclamation Division**, West Virginia Surface Mining Reclamation Rule, **38CSR2**, stated that the Department has agreed to technical modifications and responded to questions from the committee.

Delegate Miley moved that the proposed rule be approved as modified. The motion was adopted.

Senator Minard moved that the ***WV/NPDES Rules for Coal Mining Facilities***, **47CSR30**, from the Department of Environmental Protection be moved up on the agenda to right after item o, ***West Virginia Surface Mining Reclamation Rule***, **38CSR2**.

Mr. Lazell, Associate Counsel, reviewed his abstract on the rule proposed by the **Department of Environmental Protection Water Resources Division**, ***WV/NPDES Rules for Coal Mining Facilities***, **47CSR30**, stated that the Department has agreed to technical modifications and answered questions from the committee.

Delegate Poling moved that the rule be approved as modified. The motion was adopted.

Ms. Pauley, Associate Counsel, reviewed her abstract on the rule proposed by the **West Virginia Board of Pharmacy**, ***Board of Pharmacy Rules Regarding Licensure and the Practice of Pharmacy***, **15CSR1**, and stated that the Board has agreed to technical modifications.

Senator Minard moved that the proposed rule be approved as

modified.

Ms. Pauley answered questions from the committee.

The motion was adopted.

Ms. Pauley, Associate Counsel, explained her abstract on the rule proposed by the **West Virginia Board of Pharmacy, *Board of Pharmacy Rules Regarding Immunizations Administered by Pharmacists*, 15CSR12**, and stated that the Board has agreed to technical modifications.

Senator Minard moved that the proposed rule be approved as modified. The motion was adopted.

Ms. Pauley, Associate Counsel, reviewed her abstract on the rule proposed by the **West Virginia Board of Pharmacy, *Regulation of Charitable Clinic Pharmacies*, 15CSR13**, and stated that the Board has agreed to technical modifications.

David Potters, Executive Director and General Counsel of the West Virginia Board of Pharmacy, addressed the committee and responded to questions.

Delegate Brown moved that the proposed rule be approved as modified.

Delegate Brown then proposed an amendment to the rule, **15CSR13 LRMRC AM#1, Pauley 7815.**

David Potters addressed the committee again stating that he was in opposition to the amendment and responded to questions.

Delegate Sobonya addressed the committee also in opposition to the amendment.

Jeff Graham, CEO of Beckley Healthrite, addressed the committee in reference to the proposed amendment.

Ms. Pauley then answered questions from the committee.

Delegate Brown took a vote on the amendment and it was rejected by the committee.

Delegate Brown then moved that the proposed rule be approved as modified. The motion was adopted.

Senator Minard moved to direct staff to prepare a final report and bills of authorization for introduction into the Senate and House of Delegates. The motion was adopted.

Senator Minard moved to adjourn the meeting. The motion was adopted.

FEBRUARY INTERIM ATTENDANCE
Legislative Interim Meetings
February 8, 9 and 10, 2009

Tuesday, February 10, 2009

9:00 am - 11:00 am

Legislative Rule-Making Review Committee

Earl Ray Tomblin, ex officio nonvoting member		Thompson, ex officio nonvoting member	
Senate		House	
Minard, Chair	✓	Brown, Chair	✓
Fanning, Vice Chair		Miley, Vice Chair	✓
Prezioso		Poling, Daniel	✓
Unger	✓	Talbott	✓
Boley	✓	Overington	✓
Facemyer		Sobonya	✓

I certify that the attendance as noted above is correct.

A. Logan Gibson
Staff Person

Debra Graham

Please return to Brenda in Room 132-E or Fax to 347-4819 ASAP, due to payroll deadline.

TENTATIVE AGENDA

LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

Tuesday, February 10, 2009

9:00 a.m. to 11:00 a.m.

Senate Judiciary Committee Room

1. **Approval of Minutes** - Meetings of January 12, 2008

2. **Review of Legislative Rules:**

   a. **Air Quality, Office of - DEP**
   Control and Reduction of Nitrogen Oxides from Non-Electric Generating Units as a Means of Mitigate Transport of Ozone Precursors
   45CSR1

   b. **Air Quality, Office of - DEP**
   NOx Budget Trading Program as a Means of Control and Reduction of Nitrogen Oxides from Electric Generating Units
   45CSR26

   c. **Development Office, WV**
   Brownfield Economic Development Districts
   145CSR11

   d. **Fire Commission, WV State**
   Standards for the Certification and Continuing Education of Municipal, County, and other Public Building Code Officials, Building Code Inspectors and Plans Examiners
   87CSR7

   e. **Fire Marshall, WV State**
   Supervision of Fire Protection Work
   130CSR3

   f. **Governor's Committee on Crime, Delinquency and Correction**
   Law Enforcement Training Standards
   149CSR2

   g. **Highways, WV Division of**
   Use of State Road Rights of Way and Adjacent Areas
   157CSR6

   h. **Highways, WV Division of**
   Transportation of Hazardous Wastes Upon the Roads and Highways
   157CSR7

i. **Insurance Commission, WV**
Coordination of Health Benefits
114CSR28

j. **Insurance Commission, WV**
Long-Term Care Insurance
114CSR32

k. **Insurance Commission, WV**
Actuarial Opinion and Memorandum Rule
114CSR41

l. **Insurance Commission, WV**
Viatical Settlements
114CSR80

m. **Insurance Commission, WV**
Discount Medical Plan Organizations and Discount Prescription Drug Plan Organizations
114CSR83

n. **Insurance Commission, WV**
Professional Employer Organizations
114CSR85

o. **Mining and Reclamation - DEP**
West Virginia Surface Mining Reclamation Rule
38CSR32

p. **Pharmacy, WV Board of**
Board of Pharmacy Rules Regarding Licensure and the Practice of Pharmacy
15CSR1

q. **Pharmacy, WV Board of**
Board of Pharmacy Rules Regarding Immunizations Administered by Pharmacists
15CSR12

r. **Pharmacy, WV Board of**
Regulation of Charitable Clinic Pharmacies
15CSR13

s. **Water Resources - DEP**
WV/NPDES Rules for Coal Mining Facilities
47CSR30

3. **Other Business**

TENTATIVE AGENDA

LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

Tuesday, February 10, 2009

9:00 a.m. to 11:00 a.m.

Senate Judiciary Committee Room

1. **Approval of Minutes** - Meetings of January 12, 2008

2. **Review of Legislative Rules:**

   a. **Air Quality, Office of - DEP**
   Control and Reduction of Nitrogen Oxides from Non-Electric Generating Units as a Means of Mitigate Transport of Ozone Precursors
   45CSR1

      - Approve

   b. **Air Quality, Office of - DEP**
   NOx Budget Trading Program as a Means of Control and Reduction of Nitrogen Oxides from Electric Generating Units
   45CSR26

      - Approve

   c. **Development Office, WV**
   Brownfield Economic Development Districts
   145CSR11

      - Approve as Modified

   d. **Fire Commission, WV State**
   Standards for the Certification and Continuing Education of Municipal, County, and other Public Building Code Officials, Building Code Inspectors and Plans Examiners
   87CSR7

      - Approve as Modified

   e. **Fire Marshall, WV State**
   Supervision of Fire Protection Work
   130CSR3

      - Approve as Modified

f. **Governor's Committee on Crime, Delinquency and Correction**
Law Enforcement Training Standards
149CSR2

- Approve as Modified

g. **Highways, WV Division of**
Use of State Road Rights of Way and Adjacent Areas
157CSR6

- Approve as Modified

h. **Highways, WV Division of**
Transportation of Hazardous Wastes Upon the Roads and Highways
157CSR7

- Approve

i. **Insurance Commission, WV**
Coordination of Health Benefits
114CSR28

- Approve as Modified

j. **Insurance Commission, WV**
Long-Term Care Insurance
114CSR32

- Approve as Modified

k. **Insurance Commission, WV**
Actuarial Opinion and Memorandum Rule
114CSR41

- Approve as Modified

l. **Insurance Commission, WV**
Viatical Settlements
114CSR80

- Approve as Modified

m. **Insurance Commission, WV**
Discount Medical Plan Organizations and Discount Prescription Drug Plan Organizations
114CSR83

- Approve as Modified

n. **Insurance Commission, WV**
Professional Employer Organizations
114CSR85

- Approve as Modified

o. **Mining and Reclamation - DEP**
West Virginia Surface Mining Reclamation Rule
38CSR2

- Approve as Modified

p. **Pharmacy, WV Board of**
Board of Pharmacy Rules Regarding Licensure and the Practice of Pharmacy
15CSR1

- Approve as Modified

q. **Pharmacy, WV Board of**
Board of Pharmacy Rules Regarding Immunizations Administered by Pharmacists
15CSR12

- Approve as Modified

r. **Pharmacy, WV Board of**
Regulation of Charitable Clinic Pharmacies
15CSR13

- Approve as Modified

s. **Water Resources - DEP**
WV/NPDES Rules for Coal Mining Facilities
47CSR30

- Approve as Modified

3. Other Business

Direct staff to prepare final report and bills of authorization for introduction into the Senate and House of Delegates.

FEBRUARY INTERIM ATTENDANCE
Legislative Interim Meetings
February 8, 9 & 10, 2009

Tuesday, February 10, 2009
9:00 a.m. - 11:00 a.m.

Legislative Rule-Making Review Committee

Earl Ray Tomblin, ex officio nonvoting member	____	Richard Thompson, ex officio nonvoting member	____

Senate		**House**	
Minard, Chair	✓	Brown, Chair	✓
Fanning, Vice Chair	____	Poling, Vice Chair	✓
Prezioso	____	Miley	✓
Unger	✓	Talbott	✓
Boley	✓	Overington	✓
Facemyer	____	Sobonya	✓

Minard called to order

AQ 45 CSR1
Jay explained
Brown Approved

AQ 45 CSR 26
Brown Jay explained
Approved
Development office 145 CSR 11
Rita explained & responded to questions
Brown Approve as modified

Fire Commission 87 CSR 7

Brian explained and responded to questions.

Brown Approve as modified answered questions

Fire Marshall 130 CSR 3

Brian reviewed his abstract & ans'd questions

Brown Approve as modified

Governor's Committee 149 CSR 2

Rita explained and responded to questions

Brown Approve as modified

No interest in subpoena power

Highways 157 CSR 6

Rita explained and responded to questions

Commissioner of Highways displayed memorial sign and responded to questions

Brown Approve as modified

Highways 157 CSR 7

Rita explained

Brown Approve

Insurance 114 CSR 28

Rita explained

Brown Approve as modified

Insurance 114 CSR 32

Rita explained.

Tim Murphy responded to questions

Brown — Approve as modified

Insurance 114 CSR 41

Rita explained

Brown — Approve as modified

Insurance 114 CSR 80

Rita explained

Brown — Tim responded to questions.

Approve as modified

Insurance Commission 114 CSR 83

Rita explained

Brown — Approve as modified

Insurance 114 CSR 85

Rita explained

Tim responded to questions

Brown — Approx as modified

Mining & Reclamation

Ivy explained & responded to q's

Miley — Approve as modified

Water Resources 47 CSR 30

Jay explained & responded to questions

Approved as modified

Poling

Pharmacy 15 CSR 1

Rita explained

Approve as modified

Minard

distributed addl document and Brown amendment

Pharmacy 15 CSR 12

Rita explained

Approve as modified

Minard

Pharmacy 15 CSR 13

Rita explained & responded to questions

David Potters - Free Dr Board

Approve as mod.

Brown

amendment

Brown

Potters addressed the amendment & ans'd questions

Spoke against the "

Syb.

Jeff Graham - Pres Free Clinic Assoc

Amendment rejected

TENTATIVE AGENDA

LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

Tuesday, February 10, 2009

9:00 a.m. to 11:00 a.m.

Senate Judiciary Committee Room

1. **Approval of Minutes** - Meetings of January 12, 2008

2. **Review of Legislative Rules:**

Approved a. **Air Quality, Office of - DEP**
Control and Reduction of Nitrogen Oxides from Non-Electric Generating Units as a Means of Mitigate Transport of Ozone Precursors
45CSR1

- Approve

Approved b. **Air Quality, Office of - DEP**
NOx Budget Trading Program as a Means of Control and Reduction of Nitrogen Oxides from Electric Generating Units
45CSR26

- Approve

Approved as modified c. **Development Office, WV**
Brownfield Economic Development Districts
145CSR11

- Approve as Modified

Approved as modified d. **Fire Commission, WV State**
Standards for the Certification and Continuing Education of Municipal, County, and other Public Building Code Officials, Building Code Inspectors and Plans Examiners
87CSR7

- Approve as Modified

Approved as modified e. **Fire Marshall, WV State**
Supervision of Fire Protection Work
130CSR3

- Approve as Modified

Approved as modified

Governor's Committee on Crime, Delinquency and Correction
Law Enforcement Training Standards
149CSR2

- Approve as Modified

Approved as modified

Highways, WV Division of
Use of State Road Rights of Way and Adjacent Areas
157CSR6

- Approve as Modified

Approved

Highways, WV Division of
Transportation of Hazardous Wastes Upon the Roads and Highways
157CSR7

- Approve

Approved as modified

Insurance Commission, WV
Coordination of Health Benefits
114CSR28

- Approve as Modified

Approved as modified

Insurance Commission, WV
Long-Term Care Insurance
114CSR32

- Approve as Modified

Approved as modified

Insurance Commission, WV
Actuarial Opinion and Memorandum Rule
114CSR41

- Approve as Modified

Approved as modified

Insurance Commission, WV
Viatical Settlements
114CSR80

- Approve as Modified

Approved as modified

Insurance Commission, WV
Discount Medical Plan Organizations and Discount Prescription Drug Plan Organizations
114CSR83

- Approve as Modified

n. Approved as modified **Insurance Commission, WV**
Professional Employer Organizations
114CSR85

- Approve as Modified

o. Approved as modified **Mining and Reclamation - DEP**
West Virginia Surface Mining Reclamation Rule
38CSR32

- Approve as Modified

p. Approved as modified **Pharmacy, WV Board of**
Board of Pharmacy Rules Regarding Licensure and the Practice of Pharmacy
15CSR1

- Approve as Modified

q. Approved as modified **Pharmacy, WV Board of**
Board of Pharmacy Rules Regarding Immunizations Administered by Pharmacists
15CSR12

- Approve as Modified

r. Approved **Pharmacy, WV Board of**
Regulation of Charitable Clinic Pharmacies
15CSR13

- Approve as Modified

s. Approved as modified **Water Resources - DEP**
WV/NPDES Rules for Coal Mining Facilities
47CSR30

- Approve as Modified

3. **Other Business**

Direct staff to prepare final report and bills of authorization for introduction into the Senate and House of Delegates.

FEBRUARY INTERIM ATTENDANCE
Legislative Interim Meetings
February 8, 9 & 10, 2009

Tuesday, February 10, 2009
9:00 a.m. - 11:00 a.m.

Legislative Rule-Making Review Committee

Earl Ray Tomblin, ex officio nonvoting member	___	Richard Thompson, ex officio nonvoting member	___

Senate		**House**	
Minard, Chair	✓	Brown, Chair	✓
Fanning, Vice Chair	___	Poling, Vice Chair	✓
Prezioso	___	Miley	✓
Unger	✓	Talbott	✓
Boley	✓	Overington	✓
Facemyer	___	Sobonya	✓

- Senator Minard called meeting to order.
- Brown moved minutes approved — approved
- 45CSR1 — Air Quality

Jay explained rule.
Brown ~~approved~~ moved rule be approved
approved

- 45CSR26 — Air Quality

Jay explained rule.
Brown ~~approved~~ moved rule be approved
approved.

- 145CSR11 — Development Office
  Rita explained rule.
  Rita responded to ?'s
  Brown moved rule be approved as modified
  ~~Approved~~ as modified

- 87CSR7 — Fire Commission
  Brian ~~Hall~~ explained rule & responded to ?'s
  Deputy State Fire Marshall, Anthony Carrico answered ?'s from committee
  Brown moved rule as modified
  approved as modified

- 130CSR3 — State Fire Marshall
  Brian explained the rule
  Brian responded to ?'s
  Brown moved rule as modified
  ~~Approved~~ as modified

- 149CSR2 — Governor's Committee on Crime, Delinquency & Correction
  Rita explained the rule & responded to ?'s
  Brown moved rule as modified
  ~~Approved~~ as modified
  Rita addressed the committee about subpoina power

- 157CSR6 — Division of Highways
  Rita explained the rule.
  Commissioner of Highways addressed committee, showed example of memorial sign & responded to ?'s
  Rita then responded to ?'s
  Brown moved rule ~~be modified~~ approved as modified
  approved as modified

- 157CSR7 — DOH
  Rita explained the rule
  Brown moved rule to be approved
  approved

- 114CSR28 — Insurance Commission
  Rita explained the rule
  Rita responded to ?'s.
  Brown moved rule be approved as modified
  approved as modified

- 114CSR32 — Insurance Commission
  Rita explained the rule & responded to ?'s
  Tim Murphy Associate Counsel for WV Insurance Commission responded to ?'s
  Brown moved rule as modified
  approved as modified

- 114 CSR 41 — Insurance Commission
  Rita explained the rule + responded to ?'s
  Brown moved rule as modified
  approved as modified

- 114CSR 80 — Insurance Commission
  Rita explained the rule + responded to ?'s
  Tim Murphy, Associate Counsel for WV
  Insurance Commission responded to ?'s
  from committee
  Brown moved rule as modified
  approved as modified

- 114CSR 83 — Insurance Commission
  Rita explained the rule
  Brown moved rule as modified
  approved rule as modified

- 114CSR 85 — Insurance Commission
  Rita explained the rule
  Tim Murphy, Associate Counsel for WV
  Insurance Commission addressed the
  committee on topic + answered ?'s
  Brown moved rule as modified
  approved as modified

- 38CSR2 — Mining + Reclamation
  Jay explained the rule + responded to ?'s
  Miley moved rule approved as modified
  approved as modified
  Senator minard
- Moved water resources — DEP
  rule up on agenda to after o. mining + reclamation

- 47CSR30 — water Resources — DEP
  Jay explained the rule + responded to ?'s
  Polling moved rule as modified
  approved as modified

- 15CSR1 / [redacted] — Pharmacy Board
  Rita explained rule
  rule moved by minard as modified
  Rita responded to ?'s
  approved as modified

- 15CSR12 — Pharmacy Board
  Rita explained rule.
  minard moved rule as modified
  rule approved as modified

• 15CSR13 — Pharmacy Board
- Rita explained the rule.
- David Potters addressed the committee — Exe. Director & General Counsel of the WV Pharmacy Board & responded to questions
- Brown moved rule as modified
- Brown brought forth amendment to rule 15CSR13 LRMRC AM #1 Pauley 7815
- David Potters addressed the committee; opposed the amendment (9 out of 10 clinics also oppose amendment) and responded to ?'s
- Delegate [redacted] Sobonya spoke to oppose amendment
- Delegate Brown addressed committee on amendment
- Jeff Grahan, CEO of Beckley Healthrite addressed committee on amendment
- Rita then answered ?'s from committee
- Amendment rejected
- Brown moved rule be approved as modified
- Approved rule as modified

- Minard moved to direct staff to prepare final report
- Brown moved mtg. adjourned
- Senator Minard adjourned mtg.

REGISTRATION OF PUBLIC
AT COMMITTEE MEETINGS

WEST VIRGINIA LEGISLATURE

Committee: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE **Date:** 2/10/09

Please print or write plainly.

NAME	ADDRESS	REPRESENTING	RULE NUMBER	Please mark with an (X) if you desire to make a statement.
David E. Potters	WV Bd of Pharmacy 232 Capitol St. Charleston, WV 25301	Bd. of Pharmacy		X

*Please return to Felisha Sutherland - Room MB-49

15CSR13 LRMRC AM #1

Pauley 7815

Delegate Brown moves to amend the rule on page four , section four, by adding a new sub-section 4.6 to read as follows:

4.6. Any other rule not withstanding, the label affixed to a container in which a drug is dispensed by a charitable clinic pharmacy may omit the name of the prescribing practitioner, but shall include the phone number of the charitable clinic.

Adopted

✓Rejected

Handout from Rita

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 1
BOARD OF PHARMACY RULES REGARDING LICENSURE AND THE PRACTICE OF PHARMACY

§15-1-1. General.

1.1. Scope. -- This rule provides definitions of many terms and establishes general provisions for Board operation; establishes internship requirements; provides the requirements for application as a pharmacist, including examination requirements, renewals, and reinstatement of lapsed licenses; establishes the qualifications for obtaining a license by reciprocity, including requirements for a foreign pharmacy graduates; establishes proceedings for disciplinary action; establishes how drugs may be transferred and the restrictions on refilling and transferring of prescription orders, including establishing communications requirements for the manual and electronic prescribing and dispensing of prescription drugs, specifically providing for E-prescribing and Electronic Data Intermediaries in accordance with SB 1001 passed during the 2007 1st Special Legislative Session; establishes how drugs and devices may be returned; states the requirements for drug product selection and substitution; establishes the requirements for pharmacy permits, including the minimum requirements, security, and professional work environment; states the required equipment, facilities, and record systems required by a pharmacy; establishes the requirements for a permit to conduct sterile pharmaceutical compounding; establishes licensure and control of nuclear pharmacies; establishes the sanitary requirements in a pharmacy; establishes rules of professional conduct for pharmacists; establishes the duties and responsibilities of a pharmacist-in-charge; establishes the manner of issuance of a prescription; states different labeling requirements; establishes the requirements and responsibilities of a consultant pharmacist; establishes different types of specialized dispensing systems, including the use of emergency kits; states the requirement for places that need to obtain a controlled substance permit, including the fees for such permit.

1.2 Authority – W.Va. Code 30-5-12C(d) and 30-5-19

1.3 Filing date ~~June 25, 2002~~_____.

1.4 Effective date ~~June 30, 2002~~_____.

§15-1-2. Definitions.

2.1. The following words and phrases as used in this Rule have the following meanings, unless the context otherwise requires:

2.1.1. "Act" or "Uniform Controlled Substance Act" means ~~and refers~~ W. Va. Code ~~§60a-1-1~~ 60A-1-1, et seq.

2.1.2. "Administer" means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion or any other means.

2.1.3 "Automated pharmacy system" means mechanical systems which perform operations or activities, other than compounding or administration, relative to the storage, packaging,

dispensing, or distribution of medications, and which collect, control, and maintain all transaction information.

2.1.4. "Board of Pharmacy" or "Board" means the West Virginia state board of pharmacy.

2.1.5. "Compounding" means:

a. The preparation, mixing, assembling, packaging, or labeling of a drug or device:

1. As the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/ pharmacist relationship in the course of professional practice for sale or dispensing, or

2. For the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing, or

3. The preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

2.1.6. "Confidential information" means patient-identifiable information maintained by the pharmacist in the patient record or which is communicated to the patient as part of patient counseling, or which is communicated by the patient to the pharmacist.

This information is privileged and may be released only to the patient or to other members of the health care team and other pharmacists where, in the pharmacist's professional judgement, such release is necessary to the patient's health and well-being; to health plans, as that term is defined in 45 CFR § 160.103, for payment; to such other persons or governmental agencies authorized by law to receive such privileged information; as necessary for the limited purpose of peer review and utilization review; and as authorized by the patient or required by court order. Appropriate disclosure, as permitted by this section, may occur by the pharmacist either directly or through an electronic data intermediary.

2.1.7. "Controlled Substance" means a drug, substance, or immediate precursor in Schedule I through Schedule V of either the Federal Controlled Substances Act or the West Virginia Uniform Controlled Substances Act.

2.1.8. The term "Cosmetic" which shall be held to include "Dentifrice" and "Toilet articles" means:

a. Articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into, or otherwise applied to the human body, or any part of the human body for cleansing, beautifying, promoting attractiveness or temporarily altering the appearance; and

b. Articles intended for use as a component of those articles, except that the term shall not include soap.

2.1.9. "Deliver" or "delivery" means the actual, constructive or attempted transfer of a drug or device from one person to another, whether or not for a consideration.

2.1.10. "Device" means an instrument, apparatus, implement or machine, contrivance, implant or other similar or related article, including any component part or accessory, which is required under federal law to bear the label, "Caution: Federal or state law requires dispensing by or on the order of a physician" or the language or symbol as determined by the U. S. Food and Drug Administration.

2.1.11. "Direct supervision" means that a licensed pharmacist is physically present in the pharmacy and is available to verify the accuracy of a prescription before it is dispensed.

2.1.12. "Dispense" or "dispensing" is that aspect of the practice of pharmacy concerned with the preparation, verification of contents, and delivery of a drug or device in an appropriately labeled and suitable container to a patient or a patient's representative or surrogate pursuant to a lawful order of a practitioner for subsequent administration to, or use by, a patient. Dispensing has not occurred until the drug is actually delivered to the patient or patient's representative.

2.1.13. "Distribute" means the delivery of a drug or device other than by administering or dispensing.

2.1.14. Distributor" means a person licensed as a wholesaler.

2.1.15. "Drug" means:

a. Articles recognized as drugs by the U. S. Food and Drug Administration (FDA) and/or published in such references as the USP-NF, Facts and Comparisons, Physicians Desk Reference or supplements thereto, for use in the diagnosis, cure, mitigation, treatment or prevention of disease in human or other animals;

b. Articles, other than food, intended to affect the structure or any function of the body of human or other animals; and

c. Articles intended for use as a component of any articles specified in subsection (b) or (c) of this section.

2.1.16. "Drug regimen review" includes, but is not limited to, the following activities:

a. Evaluation of prescription orders and patient records readily available to the pharmacist for:

1. Known significant allergies;
2. Rational drug therapy and contraindications;
3. Reasonable dose and route of administration; and
4. Reasonable directions for use.

b. Evaluation of readily available prescription drug orders and patient records for duplication of therapy;

c. Evaluation of the prescription drug for interactions and/or adverse effects which may include, but are not limited to, any of the following:

1. Drug-drug;
2. Drug-food;
3. Drug-disease; and
4. Adverse drug reactions.

d. Evaluation of the prescription drug orders and patient records for proper utilization, including over utilization, under utilization and optimum therapeutic outcomes.

2.1.17. "Electronic data intermediary" means an entity that provides the infrastructure to connect a computer system, hand-held electronic device or other electronic device used by a prescribing practitioner with a computer system or other electronic device used by a pharmacist to facilitate the secure transmission of:

a. An electronic prescription order;

b. A refill authorization request;

c. A communication; or

d. Other patient care information.

2.1.18. "E-prescribing" means the transmission, using electronic media, of prescription or prescription-related information between a practitioner, pharmacist, pharmacy benefit manager or health plan as defined in 45 CFR §160.103, either directly or through an electronic data intermediary. E-prescribing includes, but is not limited to, two-way transmissions between the point of care and the pharmacist. E-prescribing may also be referenced by the terms "electronic prescription" or "electronic order".

~~2.1.17~~ 2.1.19. "Inpatient pharmacy" means the area within a licensed institution; i.e., a hospital, or other place where patients stay at least one night, where drugs are stored and dispensed to other areas of the institution for administration to the patients by other licensed health care providers.

~~2.1.18~~ 2.1.20. "Inspector" means an agent of the Board, who is a licensed pharmacist, appointed by the Board to conduct periodic inspections of permittees and perform other duties as designated by the Board.

~~2.1.19~~ 2.1.21. "Institutional facility" means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services, including but not limited to a hospital, convalescent home, nursing home, extended care facility, mental health facility, rehabilitation center, psychiatric center, developmental disability center, drug abuse treatment center, family planning clinic, penal institution, hospice, public health facility, or athletic facility.

~~2.1.20~~ 2.1.22. "Institutional pharmacy" means that physical portion of an institutional facility that is engaged in the compounding, dispensing, and distribution of drugs, devices, and other materials used in the diagnosis and treatment of injury, illness, and disease and which holds a pharmacy license from the Board.

~~2.1.21~~ 2.1.23. "Intern" means an individual who is:

a. Currently licensed by the Board to engage in the practice of pharmacy while under the supervision of a licensed pharmacist and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist;

b. A graduate of an approved college of pharmacy or a graduate who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee certificate, who is currently licensed by the Board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist;

c. A qualified applicant who is licensed by the Board and is awaiting examination for licensure; or

d. An individual participating in a residency or fellowship program.

~~2.1.22~~ 2.1.24. "Labeling" means the process of preparing and affixing a label and the affixing of auxiliary labels to a drug container exclusive, however, of a labeling by a manufacturer, packer or distributor of a nonprescription drug or commercially packaged legend drug or device. The label shall include all information required by federal law or regulation or state law or rule.

~~2.1.23~~ 2.1.25. "Mail order pharmacy" means a pharmacy, regardless of its location, which dispenses greater than ten percent (10%) prescription drugs in the United States Mail or otherwise.

~~2.1.24~~ 2.1.26. "Manufacturer" means a person engaged in the manufacturing of drugs or devices.

~~2.1.25~~ 2.1.27. "Manufacturing" means production, preparation, propagation or processing of any drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis and includes any packaging or repackaging of the substance(s) or labeling or relabeling of its contents and the promotion and marketing of the drugs or devices. Manufacturing also includes the preparation or repackaging, and promotion of commercially available products from bulk compounds for resale by pharmacies,
practitioners or other persons.

~~2.1.26~~ 2.1.28. "Nonprescription drug" means a drug which may be sold without a prescription and which is labeled for use by the consumer in accordance with the requirements of the laws and rules of this state and the federal government.

~~2.1.27~~ 2.1.29. "Nuclear pharmacist" means a pharmacist who has been certified in the specialty of nuclear pharmacy.

~~2.1.28~~ 2.1.30. "Nuclear pharmacy" means a place where radioactive drugs are prepared and dispensed and which operates under specialized rules.

~~2.1.29~~ 2.1.31. "Original License" means a license issued by the Board to an applicant when:

a. the applicant is a new business;

b. the applicant is an established business that is transferred to a successor;

c. the applicant is an established business in which fifty percent (50%) ownership or more is transferred to a new owner;

d. the applicant is an established business in which control of pharmaceutical services is transferred; not including a change in pharmacist-in-charge; or

e. the applicant is an established business which moves to a new location.

~~2.1.30~~ 2.1.32. "Outpatient pharmacy" means any pharmacy, apothecary, or place within this state where drugs are dispensed and sold at retail or displayed for sale at retail and where the practice of pharmacy is conducted and pharmaceutical care is provided; and anyplace outside of this state where drugs are dispensed and the practice of pharmacy and pharmaceutical care is provided to residents of this state. ~~The terms pharmacy, drug store, or apothecary do not include a free clinic or physician's office that dispenses drugs for free.~~

~~2.1.31~~ 2.1.33. "Over-the counter drug" or "OTC drug" means any drug that is not a prescription drug or legend drug.

~~2.1.32~~ 2.1.34. "Patient counseling" means the oral communication by the pharmacist of information, which may include supplemental media according to the pharmacist's professional judgement, to the patient or care giver, to ensure the proper use of drugs and devices.

~~2.1.33~~ 2.1.35. "Permit" means any license, registration, or other privilege granted or issued by the board to any person for the purpose of providing a business or service to individuals or the public and the holder of the permit is the "permittee". No permit will be issued unless a business is operated or a service is provided. Not more than one permit may be issued in any one name in more than one location.

~~2.1.34~~ 2.1.36. "Person" means an individual, corporation, partnership, association or any other legal entity, including government.

~~2.1.35~~ 2.1.37. "Person Addicted" means one who has acquired the habit of using alcoholic beverages or controlled substances or other agents to such an extent as to deprive him or her of reasonable self-control.

~~2.1.36~~ 2.1.38. "Pharmaceutical care" is the provision of drug therapy and other pharmaceutical patient care services intended to achieve outcomes related to:

a. The cure or prevention of a disease;

b. the elimination or reduction of a patient's symptoms; or

c. the arresting or slowing of a disease process.

~~2.1.37~~ 2.1.39. "Pharmacist" or "registered pharmacist" means an individual currently licensed by this state to engage in the practice of pharmacy and pharmaceutical care.

~~2.1.38~~ 2.1.40. "Pharmacist-in-charge" means a pharmacist currently licensed in this state who:

a. Accepts responsibility for the operation of a pharmacy in conformance with all state and federal laws and rules pertinent to the practice of pharmacy and the distribution of drugs;

b. has the responsibility for the practice of pharmacy, as defined in this rule, at the pharmacy for which he or she is pharmacist-in-charge. The pharmacy permit holder has responsibility for all other functions, administrative and operational, of the pharmacy. The pharmacist-in-charge may advise the pharmacy permit holder on administrative and operational matters but following such advice shall not be legally ~~required~~ responsible; ~~and~~

c. works at least 30 hours a week, with the pharmacist-in-charge working at least three days per week, in that pharmacy, including the use of any accrued annual or sick leave. ~~;~~ Provided That, in any pharmacy which is open on average less than 40 hours per week in a calendar year, he or she must work in the pharmacy a majority of the hours that the pharmacy is

open (e.g., if open 20 hours per week, the pharmacist-in-charge must work 11 hours per week within the pharmacy); and

d. With regard to a pharmacist-in-charge in a Charitable Clinic Pharmacy, this position may be filled by a committee of up to three (3) pharmacists who accept as a group the responsibilities of the required pharmacist-in-charge. Further notwithstanding the requirements of subsection c. above, with regard to a Charitable Clinic Pharmacy, if the pharmacy is open an average of more than 40 hours per week, the pharmacist-in-charge or pharmacist-in-charge committee must work at least 8 hours per calendar month; if the pharmacy is open on average at least 30 and up to 40 hours per week, the pharmacist-in-charge or pharmacist-in-charge committee must work in the charitable clinic pharmacy at least 6 hours per calendar month; if the pharmacy is open on average at least 15 and up to 30 hours per week, the pharmacist-in-charge or pharmacist-in-charge committee must work in the charitable clinic pharmacy at least 4 hours per calendar month; if the charitable clinic pharmacy is open on average at least 5 and up to 15 hours per week, the pharmacist-in-charge or pharmacist-in-charge committee must work in the charitable clinic pharmacy at least 2 hours per calendar month; and, if the charitable clinic pharmacy is open less than 5 hours per week, the pharmacist-in-charge or pharmacist-in-charge committee must work in the charitable clinic pharmacy the lesser of 2 hours per month or 50% of the hours the charitable clinic pharmacy is open.

Charitable Clinic Pharmacy hours per week	**Hours required by PIC per month**
More than 40	8
30 to 40	6
15 to 30	4
5 to 15	2
Less than 5	The lesser of 2 or 50% of hours open

~~2.1.39~~ 2.1.41. "Pharmacy technician" means registered supportive personnel who work under the direct supervision of a pharmacist, and who have passed an approved training program.; Provided That, in a Charitable Clinic Pharmacy, when no pharmacist is on-site, a pharmacy technician may work under the direct supervision of a prescribing practitioner who is licensed as a prescribing practitioner who is licensed as such in the State of West Virginia.

~~2.1.40~~ 2.1.42. "Pharmacy technician trainee" means an individual currently engaged in a pharmacy technician training program which has been approved by the Board and who is under the direct supervision of a pharmacist.

~~2.1.41~~ 2.1.43. "The practice of pharmacy" is the personal health 3service concerned with the preparing, compounding and dispensing of drugs and medical devices used in the diagnosis, treatment or prevention of disease, dispensed on the prescription of a practitioner, or otherwise legally dispensed or sold and shall include the proper and safe storage of drugs, the maintenance of proper records and the dissemination of information to other health care professionals and proper counseling to the patient concerning the therapeutic value and proper use of drugs and devices.

2.1.42 2.1.44. ~~"Practitioner" means an individual currently licensed, registered or otherwise authorized by the jurisdiction in which he or she practices to prescribe and administer drugs in the course of professional practices, as allowed by law.~~ "Practitioner" or "prescribing practitioner" means an individual currently licensed, registered or otherwise authorized by any state, territory or district of the United States to prescribe and administer drugs in the course of

professional practices including allopathic and osteopathic physicians, dentists, physician assistants, optometrists, veterinarians, podiatrists and nurse practitioners as allowed by law.

~~2.1.43~~ 2.1.45. "Preceptor" means an individual who is currently licensed as a pharmacist by the board, meets the qualifications as a preceptor under the rules of the board, and participates in the instructional training of pharmacy interns.

~~2.1.44~~ 2.1.46. "Prescription drug" or "legend drug" means a drug which, under federal law, is required, prior to being dispensed or delivered, to be labeled with any of the following statements or the language or symbol as determined by the U. S. Food and Drug Administration.

a. "Caution: Federal law prohibits dispensing without prescription".

b. "Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian"; or a drug which is required by any applicable federal or state law or rule to be dispensed pursuant to a prescription drug order or is restricted to use by practitioners only.

~~2.1.45~~ 2.1.47. "Prescription" or "Prescription order" means a lawful order from a properly licensed practitioner to a pharmacist for a drug or device for a specific patient and transmitted by:

a. Written order;

b. An oral order to a pharmacist who shall immediately:

1. Reduce it to writing which becomes the original order;
2. Hand initial it to identify the receiver; and
3. Show the date, time and name of person transmitting the order;

c. An electronic transmission which has the capability to produce a printed copy, and shows the date, time and name of person transmitting the order; or

d. other methods of transmission approved by the Board.

~~2.1.46~~ 2.1.48. "President" means the President of the West Virginia Board of Pharmacy.

~~2.1.47~~ 2.1.49. "Sample" means a package of a legend drug provided by a manufacturer on the request of a practitioner or charitable clinic to be given to a patient without charge in accordance with federal law.

~~2.1.48~~ 2.1.50. An approved or recognized "School of Pharmacy" means a school of pharmacy accredited by the American Council on Pharmaceutical Education.

~~2.1.49~~ 2.1.51. "Secretary" means the Secretary of the West Virginia Board of Pharmacy.

~~2.1.50~~ 2.1.52. "Vice-President" means the Vice-President of the West Virginia Board of Pharmacy.

~~2.1.51~~ 2.1.53. A "Wholesaler" is a person or entity licensed by the Board to distribute, by sales or otherwise, prescription legend drugs to persons other than a consumer or patient.

§15-1-20 Duties and Responsibilities of the Pharmacist-in-Charge.

20.1. A pharmacy may not operate without a pharmacist-in-charge (hereinafter "PIC"), who shall be designated on the application for a pharmacy license, and in each license renewal. A pharmacist may not serve as PIC unless he or she is physically present in the pharmacy a sufficient amount of time to provide supervision and control. A pharmacist may not serve as PIC for more than one pharmacy at any one time; Provided that, he or she may volunteer as the pharmacist-in-charge at a charitable clinic pharmacy while serving as a PIC in another pharmacy.

20.2. The pharmacist-in-charge has the following responsibilities:

20.2.1. The pharmacist-in-charge shall be responsible for the practice of pharmacy, as defined in this rule, at the pharmacy for which he or she is the pharmacist-in-charge. The pharmacy permit holder shall be responsible for all other functions, administrative and operational, of the pharmacy. The pharmacist-in-charge may advise the pharmacy permit holder on administrative and operational matters but following such advice shall not be legally ~~required~~ responsible.

20.2.2. The pharmacist-in-charge shall notify the pharmacy permit holder of potential violations of any statute, rule or court order existing within the pharmacy. If appropriate action has not been taken within a reasonable amount of time the pharmacist-in-charge shall reduce to writing the above and submit to the pharmacy permit holder with a copy to the Board. No pharmacist-in-charge shall be sanctioned by the Board for any violation of any statute, rule or court order if they have previously given this written notice to the pharmacy permit holder. The pharmacy permit holder shall be responsible for such violations.

20.2.3. Implementing quality assurance programs for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems. Quality assurance programs shall be designed to prevent and detect drug diversion;

20.2.4. The PIC shall implement, and maintain a Pharmacy Technician Training Manual for the specific practice setting of which he or she is in charge. He or she shall supervise a training program conducted pursuant to the training manual for all individuals employed by the pharmacy who will assist in the practice of pharmacy. The PIC shall maintain a record of all technicians successfully completing the pharmacy's technician training program and shall attest to the Board, in a timely manner, those persons who, from time to time, have met the training requirements necessary for registration with the Board;

20.2.5. Implementing policies and procedures for the procurement, storage, security, and disposition of drugs and devices;

20.2.6. Assuring that all pharmacists and interns employed at the pharmacy are currently licensed and that all pharmacy technicians employed at the pharmacy are currently registered with the board;

20.2.7. Notifying the board immediately of any of the following changes:

a. Change of employment or responsibility as the PIC;

b. Change of ownership of the pharmacy;

c. Change of address of the pharmacy; or

d. Permanent closing of the pharmacy;

20.2.8. Making or filing any reports required by state or federal laws, rules, and regulations;

20.2.9. Responding to the board regarding any warning notice issued by the Board. The Board shall provide notification of the issuance of the warning notice to the pharmacy permit holder;

20.2.10. Implementing policies and procedures for maintaining the integrity and confidentiality of prescription information and patient health care information, or verifying their existence and ensuring that all employees of the pharmacy read, sign, and comply with the established policies and procedures; and

20.2.11. Providing the board with prior written notice of the installation or removal of an Automated Pharmacy System. The notice shall include, but is not limited to:

a. The name and address of the pharmacy;

b. The location of the automated equipment; and

c. The identification of the responsible pharmacist.

20.3. The PIC shall be assisted by a sufficient number of pharmacists and pharmacy technicians as may be required to competently and safely provide pharmacy services.

20.3.1. The PIC shall maintain and file with the Board, on a form provided by the Board, a current list of all pharmacy technicians assisting in the provision of pharmacy services.

20.3.2. The PIC shall implement written policies and procedures to specify the duties to be performed by pharmacy technicians. The duties and responsibilities of these personnel shall be consistent with their training and experience. These policies and procedures shall specify that pharmacy technicians are to be personally and directly supervised by a pharmacist stationed within the same work area who has the ability to control and who is responsible for the activities of pharmacy technicians, and that pharmacy technicians are not assigned duties that may be performed only by a pharmacist.

§15-1-21. Manner of Issuance of a Prescription.

21.1. A prescription, to be valid, shall be issued for a legitimate medical purpose by a practitioner acting within the course of legitimate professional practice.

21.1.1. A pharmacist shall receive the communication of a prescription. A pharmacist may accept a prescription, including that for a controlled substance listed in Schedules II through V, that is communicated in written form or by E-prescribing. A pharmacist may accept a prescription, including that for a controlled substance listed in Schedules III through V, and, in certain situations, that for a controlled substance listed in Schedule II, that is communicated orally (including telephone voice communication) or by way of electronic transmission other than E-prescribing.

21.1.2. If communicated orally or by way of electronic transmission other than E-prescribing, the pharmacist shall immediately reduce the prescription to a form that may be

maintained for the time period required by any applicable federal and State of West Virginia laws and rules.

21.1.3. A prescription for a Schedule II controlled substance may be communicated orally or by way of electronic transmission other than E-prescribing only in the following situations and with the following restrictions. Otherwise, a prescription for a Schedule II controlled substance shall be communicated in written form or by E-prescribing.

a. A prescription for a Schedule II controlled substance may be communicated by the practitioner or the practitioner's agent by way of electronic transmission, provided ~~the original written, signed prescription~~ the original written prescription, signed by the practitioner, is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except the hard copy of the electronic transmission may serve as the original, written prescription in the following instances:

1. the prescription for a Schedule II narcotic substance is to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion;

2. the prescription for a Schedule II controlled substance is for a resident of a Long Term Care Facility; or

3. the prescription for a Schedule II controlled substance is for a patient under the care of a hospice certified by Medicare or licensed by the state. The practitioner or Practitioner's agent shall note on the prescription that the patient is a hospice patient.

21.1.4. In the case of an emergency situation, a prescription for a Schedule II controlled substance may be communicated by the practitioner orally or by way of electronic transmission, provided that if the prescribing practitioner is not known to the pharmacist, he or she shall make a reasonable effort to determine that the ~~oral~~ authorization came from a registered practitioner, which may include a callback to the practitioner using the practitioner's phone number as listed in the telephone directory and other good faith efforts to insure his identity; and:

a. the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing practitioner);

b. the orally communicated prescription is immediately reduced to writing by the pharmacist, or, if necessary, the prescription communicated by way of electronic transmission is immediately reduced to a hard copy;

c. within seven (7) days after authorizing an emergency oral prescription, the practitioner has a written prescription for the emergency quantity prescribed delivered to the dispensing pharmacist. The prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the orally or electronically transmitted prescription. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail, it must be postmarked within the seven (7) day period.

Upon receipt, the dispensing pharmacist shall attach this written prescription to the emergency oral prescription which had earlier been reduced to writing or to the hard copy of the electronically transmitted prescription. The pharmacist shall notify the nearest office of the U.S. Drug Enforcement Administration if the prescribing practitioner fails to deliver a written prescription.

21.1.5. A prescribing practitioner may authorize his or her agent to communicate a prescription orally or by way of electronic transmission either directly or through an electronic data intermediary to a pharmacist in a licensed pharmacy, provided:

a. the identity of the transmitting agent is included in the order;

b. the prescription is transmitted ~~directly~~ either directly or through an electronic data intermediary to a pharmacist in a licensed pharmacy of the patient's choice with no unauthorized ~~intervening~~ person having access to the prescription;

c. the prescription identifies the transmitter's phone number for verbal confirmation, the time and date of transmission, and the identity of the pharmacy intended to receive the transmission, as well as any other information required by federal or state law;

d. the pharmacist exercises professional judgment regarding the accuracy, validity, and authenticity of the prescription communicated by way of electronic transmission; and

e. all electronic equipment for receipt of prescriptions communicated by way of electronic transmission is maintained so as to ensure against unauthorized access.

21.1.6 Electronic Data Intermediaries

a. Electronic data intermediaries may transmit electronic prescriptions, prescription refill authorization requests, communications, and other patient care information using a secure infrastructure between an authorized prescribing practitioner and a pharmacy of the patient's choice.

b. Electronic data intermediaries shall meet the following requirements for electronically transmitted prescription orders, refill authorization requests, communications and other transmitted patient care information:

(1) Maintain the confidentiality and security of transmitted information as required by applicable federal and state laws.

(2) Transmit prescriptions to the pharmacy of the patient's choice.

(3) Maintain the integrity, ~~confidentiality~~privacy, and security of archived copies of the electronic information related to the transmissions as required by applicable state and federal laws, including maintaining them as confidential information.

Handout from Rita

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 13
BOARD OF PHARMACY RULES
Charitable Clinic Pharmacies

§15-13-1. General.

1.1. Scope. -- To establish rules for charitable clinic pharmacies to operate in West Virginia to prepare and dispense prescriptions to patients of the clinics in this State.

1.2. Authority. -- These regulations are promulgated in accordance with the authority granted by Senate Bill 722 passed during the 2008 Regular Legislative Session and enacted into law, which amended certain sections of the West Virginia Code, at §30-5-1, et seq., providing for oversight and regulation of Charitable Clinic Pharmacies..

1.3. Filing Date. -- July 30, 2008.

1.4. Effective Date. -- _____.

1.5 PREAMBLE: The West Virginia Board of Pharmacy exists to protect the public health, safety, and welfare through, among other things, the regulation of pharmacies, pharmacists, technicians, drug distributors, and places that stock controlled substances. The Board also enforces requirements established by the FDA, USP, DEA, EPA, and the CPSC for the storage, delivery, dispensing, and destruction of drugs and construction of sterile preparation areas and nuclear pharmacy facilities within this State.

Under the auspices of the West Virginia Department of Health and Human Resources, the West Virginia Legislature created a system of Basic Public Health Services as defined and set forth in W.Va. Code § 16-1-1 et seq. Pursuant to its commitment to the citizens of its state, the West Virginia Legislature, acting through of WV Department of Health and Human Resources, created the Primary Care Support Program pursuant to W.Va. Code § 16-2-H-1 et seq. The Primary Care Support Program has been and continues to be instrumental in providing basic medical and dental services to West Virginia residents that do not have sufficient access. As such, there are numerous facilities in West Virginia which operate tax exempt free clinics and free clinic pharmacies to provide free medical care and drug therapies to their clients. The Board of Pharmacy requirements for the practice of pharmacy, including, but not limited to, sanitary practices, proper storage and handling of drugs, counseling, and providing correct treatment as prescribed are essential to ensure proper therapeutic outcomes which involve pharmaceutical care. These requirements can only be accomplished by the presence of a properly licensed and trained pharmacist to oversee the delivery of the pharmaceutical care provided. After receiving the direct input and advice of the West Virginia Department of Health and Human Resources and the West Virginia Board of Pharmacy, the West Virginia Legislature determined that the role of

the nonprofit, community-based free health and dental clinics of providing no cost drug therapies to its patients, needed to be formally recognized and made part of the regulatory framework of the State of West Virginia. Accordingly, the West Virginia Legislature created a new designation within the regulatory framework already existing for pharmacies, the "Charitable Clinic Pharmacies", to continue the delivery of drug therapies to those citizens who meet the requirements of the Primary Care Support Program and to receive free medical and dental services under guidelines established and enforced by the West Virginia Department of Health and Human Resources. Such Charitable Clinic Pharmacies were created pursuant the enactment of Senate Bill No. 722, which passed the West Virginia Legislature on March 8, 2008.

It is in the interest of both the charitable clinic pharmacies and their clients to provide those clients the same minimum protection afforded all other citizens of West Virginia as required by the statutes and regulations applicable to the practice of pharmacy in this State. The Board of Pharmacy recognizes that the charitable clinics and their pharmacies operate on limited grant funding along with donations from many professionals and suppliers of materials, time, and monetary support. Therefore, necessarily, they operate on tightly controlled and limited budgets.

As such, given the unique nature of the free clinics and the valuable service they provide to the community, these regulations applicable to charitable clinic pharmacies are designed to protect the health, safety, and welfare of the public while relieving the clinics from, due to the limited nature of their practice of pharmacy, certain unnecessary regulatory burdens. Providing these limited exemptions, the Board of Pharmacy believes, will not infringe on safe-guarding the pharmaceutical care provided to the clients of the free clinics, and will allow the clinics the necessary leeway to provide safe and effective care on their limited resources.

§15-13-2. Definitions.

2.1. The following terms and phrases as used in this Rule shall have the following meanings, unless the context otherwise requires:

2.1.1. "Charitable clinic pharmacy" means a clinic or facility organized as a not-for-profit corporation that offers pharmaceutical care and dispenses prescriptions free of charge to appropriately screened and qualified patients. A charitable clinic pharmacy shall meet the minimum standards for a pharmacy as set forth in this article and by legislative rule promulgated by the Board of Pharmacy, but may not be charged any applicable licensing fees. A charitable clinic pharmacy may have pharmacists-in-charge, as that term is defined in this section, who volunteers his or her services. A charitable clinic may also receive donated drugs. It is not the intent of this regulation to affect any organizations which are merely operating a prescribing practitioner's or clinic free sample drug room.

2.1.2. "Charitable organization" means an organization which operates a clinic or facility organized as a not-for-profit corporation which is qualified as a charitable organization pursuant to Section 501(c)(3) of the Internal Revenue Code, or its successor.

2.1.3. "Legend drug sample" for purposes of this Series means an unopened package of a manufacturers legend drug product that has been distributed to either a practitioner or the charitable clinic pharmacy in accordance with the provisions of the Prescription Drug Marketing Act of 1987, 21 U.S.C. §301 et seq, or its successor.

2.1.4. "Qualified patient" means a patient of the charitable clinic pharmacy that has been screened and approved by the charitable organization as meeting the organization's mission of

providing pharmaceutical care to those who are without sufficient funds to obtain needed legend drugs, which requirements and screening process employed by the charitable organization must be in accordance with the "Guidelines" and other program requirements developed by the West Virginia Department of Health and Human Resources, Office of Community Health Systems, Division of Primary Care, for eligibility to receive funding as a "Free Clinic" for "Uncompensated Care and Equipment and Capital Costs Funding".

Section §15-13-3. Charitable Clinic Pharmacy Permit Required.

3.1. A charitable clinic pharmacy is considered to be a pharmacy and must follow all federal and state laws, rules, and regulations that pertain to pharmacies and the practice of pharmacy, except as otherwise provided specifically herein. As such, a charitable clinic pharmacy permit shall be required for a charitable organization to operate a pharmacy in this State to dispense prescription drugs to qualified patients ~~in this State~~. No fee shall be required to apply for or obtain the permit.

3.2. Permits obtained pursuant to this section shall expire on June 30 of each calendar year. Renewal will be conducted in accordance with the laws and rules for renewing pharmacy permits as outlined in this Title.

3.3. Charitable Clinic Pharmacies may petition the Board for exemptions from portions of the regulations set forth in Title 15 which are not addressed here on a case by case basis, including, but not limited to, for such things as the requirement for weights and measures if no compounding is to be done, the requirement for separate security features and alarms if they are available on the clinic building as a whole, and other such requirements.

§15-13-4. Controlled Substances Restricted: Prescriptions to qualified patients.

4.1. A charitable clinic pharmacy shall not purchase, possess, trade, distribute, or dispense controlled substances.

4.2. Patient Dispensing. Prescriptions filled in a charitable clinic pharmacy may only be dispensed to qualified patients of that pharmacy on lawful orders or prescriptions of practitioners authorized by law to prescribe or administer said drugs.

4.2.1. All prescriptions filled by the charitable clinic pharmacy must be checked by a pharmacist or a ~~medical doctor or osteopathic physician~~ prescribing practitioner licensed as such in the State of West Virginia ~~prescribing practitioner~~ prior to being dispensed: Provided That any prescribing practitioner licensed in this State may access the charitable clinic pharmacy to fill, check, or dispense prescriptions to his or her own patients when no pharmacist is present, provided that he or she insures proper labeling and documentation of the dispensing.

4.2.2. Any other rule notwithstanding, ~~a prescribing practitioner who is licensed as a dispensing physician or other such designation by his or her licensing board may access the charitable clinic pharmacy to fill, check, or dispense prescriptions when no pharmacist is present. Provided That he or she insures proper labeling and documentation of the dispensing. In~~ in the absence of a pharmacist, ~~such~~ a prescribing practitioner who is licensed in the State of West Virginia ~~as a medical doctor or osteopathic physician~~ may also supervise the work of pharmacy technicians within the pharmacy, such that they may continue to work during that period of time.

4.2.3. Any other rule notwithstanding, if there is no pharmacist or prescribing practitioner who is licensed in the State of West Virginia ~~as a dispensing physician or other such designation by his or her licensing board medical doctor or osteopathic physician~~ present to supervise the pharmacy technicians, the pharmacy technicians may continue to process and fill

prescriptions, and perform all other duties which may be performed by a pharmacy technician, for up to two hours during the charitable clinic pharmacy's regular hours of operation. ~~pharmacy technicians may continue to process and fill prescriptions during that period of time~~ provided that no actual dispensing may occur until the prescriptions filled are checked in accordance with subsection 4.2.1 above.

4.3. The charitable clinic pharmacy shall not charge any fee for the dispensing of prescription drug samples or prescription legend drugs to qualified patients of the charitable clinic pharmacy. However, this rule shall not prevent a charitable clinic or charitable clinic pharmacy from requesting voluntary donations from its patients who receive prescriptions, provided that a sign is visibly posted in a conspicuous location stating that a donation is not required to receive prescription drugs.

~~4.4. Strict screening guidelines based on needs assessment shall be developed by the charitable clinic pharmacy to determine who is eligible as a qualified patient. This may be accomplished in conjunction with the clinic itself, and documented through a patient medical record shared between the charitable clinic pharmacy and the clinic itself.~~

~~4.5. All screening guidelines, needs assessments, and revisions shall be submitted to the Board upon request.~~

4.4 Any other rule notwithstanding, a charitable clinic pharmacy may allow completed prescription orders to be dispensed to its patients by permitting a pharmacy technician or other licensed health care provider working on behalf of the charitable clinic to transport the completed prescription to another remote clinic operated by the charitable clinic. Provided That:

a. the completed prescriptions are kept in a locked tote or other such storage container and remain in the possession of the licensed health care provider until such time as they are actually dispensed directly to the patient or someone picking up on behalf of the patient;

b. the completed prescriptions are accompanied by a manifest indicating the contents of the tote at the time they leave the pharmacy;

c. the patient or person picking up the prescription on behalf of the patient signs for receipt of the prescription; and

d. any prescriptions which are not dispensed at the remote clinic site are returned in the locked tote to the charitable clinic pharmacy, along with the manifest, by a licensed health care provider working on behalf of the charitable clinic, and are reconciled by the pharmacy.

~~4.6~~4.5. Charitable clinic pharmacies are exempt from the restrictions in Section 15-1.19.10 insofar as the charitable clinic pharmacy may provide prescription blanks imprinted with its name for prescribers working in the clinic to write prescriptions to be filled at the charitable clinic pharmacy.

§15-13-5. Prescription Drug Samples.

5.1. Except insofar as it may conflict with federal law, charitable clinic pharmacies are exempt from any State law or rule which restricts who may receive sample drugs from a manufacturer. Specifically, unless it conflicts with federal law, a charitable clinic pharmacy may accept donated prescription drugs in their unbroken original packaging from pharmacies, licensed prescribers, wholesalers, or manufacturers provided appropriate records of transfer, donation, and receipt are maintained; Provided That the samples have been stored under the proper conditions required by the manufacturer and applicable law to prevent deterioration or

contamination. However, a charitable clinic pharmacy shall only receive, possess, and dispense prescription drug samples if the following conditions are satisfied:
(a) The samples are dispensed at no charge to qualified patients of that charitable clinic pharmacy;
(b) The samples are possessed in compliance with the Federal Prescription Drug Marketing Act of 1987, 21 U.S.C. §301 et seq. or its successor;
(c) The samples are in the original container in which they were placed by the manufacturer and the container is clearly marked sample;
(d) Prior to being furnished or dispensed, the samples have been stored under the proper conditions to prevent deterioration or contamination;
(e) The samples are clearly marked with an expiration date and lot number;
(f) The samples are not expired; and
(g) The samples are not a controlled substance.
5.2. If donated samples are received which do not comply with Section 15-13-5.1, then they must be refused, returned, or properly disposed of by the charitable clinic pharmacy.
5.25.3. A charitable clinic pharmacy shall not sell, purchase, or trade prescription drug samples.
5.35.4. Dispensing A Sample Drug By A Charitable Clinic Pharmacy shall comply with the following:
5.3.1. A pharmacist in a charitable clinic pharmacy must have a valid prescription prior to dispensing a sample drug to a patient.
5.3.2. The charitable clinic pharmacy must determine the eligibility requirements for a patient to receive a sample drug.
~~5.3.3. The sample drug is dispensed to the patient free of charge.~~
~~5.3.4~~5.3.3. The sample drug is dispensed:
(a) In the original container in which it was placed by its manufacturer where the container is clearly marked as sample; or
(b) By removing the sample drug from the original container only if the prescription label on the appropriate container, pursuant to rule 4729-9-02 of the Administrative Code, clearly states that the drug dispensed is a sample drug.
5.3.4. Nothing is this rule shall restrict a prescribing practitioner from providing samples in their original container from being given to the practitioner's patients in accordance with federal law.

§15-13-6. Pharmacist-In-Charge Responsibilities.
6.1. The pharmacist-in-charge at the charitable clinic pharmacy shall be responsible for implementing policies and procedures and a quality assurance program for operation of the charitable clinic pharmacy.
6.2. The pharmacist-in-charge at the charitable clinic pharmacy shall ensure through implementation of policies and procedures that the following occurs at the charitable clinic pharmacy:
(a) donated drugs dispensed from pharmacy are properly labeled;
(b) donated drugs that are expired, adulterated, misbranded, recalled, deteriorated, not kept under proper conditions, or did not have the identifying drug information on them as required are not dispensed to patients;
(c) donated drugs are inspected prior to dispensing to determine that the donated drugs meet all federal and state requirements for product integrity;

(d) donated drugs that are expired, adulterated, misbranded, recalled, deteriorated, not kept under proper conditions ~~are destroyed~~, or did not have the identifying drug information on them as required are destroyed; and

(e) manifests for donated drugs that are dispensed ~~or destroyed~~pursuant to prescriptions from the charitable clinic pharmacy are created ~~and/or~~ maintained at the charitable clinic pharmacy as required for all prescription records ~~for two (2) years from the date of destruction~~.

(f) dispensing errors are documented and reported monthly to the Board.

§15-13-7. Limitations of Charitable Clinic Pharmacies

5.2 All drug therapies and prescriptions shall be prescribed on an individual basis.

5.3 A Charitable Clinic Pharmacy shall not accept lost identity or unknown drugs.

5.4 No misbranded drugs shall be accepted by the Charitable Clinic Pharmacy.

5.5 A Charitable Pharmacy may accept donated and unadulterated prescription drugs in their unbroken original manufacturer packaging from pharmacies, licensed prescribers, wholesalers or manufacturers, the State of West Virginia, the Board of Pharmacy or by other means, provided appropriate records of receipt are maintained.

§15-13-8. Continuing Education Credits for Volunteering in Charitable Clinic Pharmacy

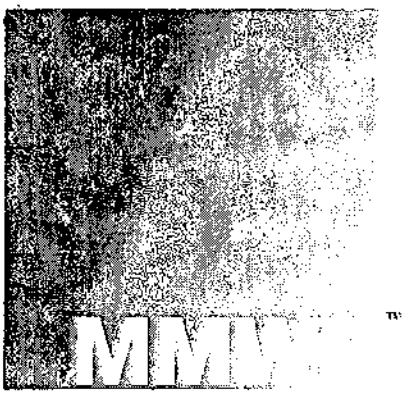
~~7~~8.1. A pharmacists who volunteers as a pharmacist-in-charge or a staff pharmacist in a charitable clinic pharmacy may earn up to a maximum of six live continuing education credits for such activities. For every eight hours worked in a charitable clinic pharmacy as the PIC, the PIC may earn one hour of live continuing education credit. For every ten hours worked in a charitable clinic pharmacy as a staff pharmacist, the pharmacist may earn one hour of live continuing education credit.

15-13-9 Inspection and Investigation of Charitable Clinic Pharmacies

9.1 The Board of Pharmacy shall create and implement the use of an Inspection Form which is consistent with the requirements under which a Charitable Clinic Pharmacy shall operate as contemplated by W.Va. Code § 30-5-1b and established by S.B. 722.

9.2 Upon receipt of the completed inspection form, the Board of Pharmacy and any appointed Quality Control Committee or other such body of the Charitable Clinic Pharmacy my meet and confer to address and resolve issues which may impact the health and safety of the pharmacy's patients. To the extent necessary, corrective plans may result from such meeting(s) with timeframes established by the Board of Pharmacy for the resolution of Quality control measures.

Handout



QuickGuide

Recommended Adult Immunization Schedule — United States, 2009

Weekly January 9, 2009 / Vol. 57 / No. 53

The Advisory Committee on Immunization Practices (ACIP) annually reviews the recommended Adult Immunization Schedule to ensure that the schedule reflects current recommendations for the licensed vaccines. In October 2008, ACIP approved the Adult Immunization Schedule for 2009. No new vaccines were added to the schedule; however, several indications were added to the pneumococcal polysaccharide vaccine footnote, clarifications were made to the footnotes for human papillomavirus, varicella, and meningococcal vaccines, and schedule information was added to the hepatitis A and hepatitis B vaccine footnotes.

Additional information is available as follows: schedule (in English and Spanish) at http://www.cdc.gov/vaccines/recs/schedules/adult-schedule.htm; adult vaccination at http://www.cdc.gov/vaccines/default.htm; ACIP statements for specific vaccines at http://www.cdc.gov/vaccine/pubs/acip-list.htm; and reporting adverse events at http://www.vaers.hhs.gov or by telephone, 800-822-7967.

Changes for 2009

Format Changes (Figures 1 and 2)

To make the figures easier to understand, several formatting changes were implemented to both the age group–based schedule and the medical and other indications schedule. The changes include 1) increasing the number of age groups; 2) deleting the hatched yellow bar for tetanus, diphtheria, pertussis (Td/Tdap) vaccine while adding explanatory text to the Td/Tdap bar; 3) simplifying the figures by removing schedule text from the vaccine bars; 4) revising the order of the vaccines to more appropriately group the vaccines, and 5) adding a legend box to clarify the meaning of blank spaces in the table.

The Recommended Adult Immunization Schedule has been approved by the Advisory Committee on Immunization Practices, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, and the American College of Physicians.

Suggested citation: Centers for Disease Control and Prevention. Recommended adult immunization schedule—United States, 2009. MMWR 2008;57(53).

Footnote (Figures 1 and 2)

- The human papillomavirus (HPV) footnote (#2) has language added to indicate that health-care personnel are not at increased risk because of occupational exposure, but they should be vaccinated consistent with age-based recommendations. Also, text has been added to indicate that vaccination with HPV may begin at age 9 years.
- The varicella footnote (#3) has language added to clarify that adults who previously received only 1 dose of vaccine should receive a second dose.
- Asthma and cigarette smoking have been added as indications for pneumococcal polysaccharide vaccination (#7). Also, text has been added to clarify vaccine use in Alaska Natives and American Indians.
- The Hepatitis A footnote (#9) has additional schedule information for the 4-dose combined hepatitis A/hepatitis B vaccine.
- The Hepatitis B footnote (#10) has additional schedule information for the 4-dose combined hepatitis A/hepatitis B vaccine, and a clarification of schedule information for special formulation indications has been added.
- The meningococcal vaccine footnote (#11) clarifies that the revaccination interval is 5 years.

FIGURE 1. Recommended adult immunization schedule by vaccine and age group — United Sates, 2009

VACCINE ▼ AGE GROUP ▶	19–26 years	27–49 years	50–59 years	60–64 years	≥65 years
Tetanus, diphtheria, pertussis (Td/Tdap)[1,*]	Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yr				Td booster every 10 yrs
Human papillomavirus (HPV)[2,*]	3 doses (females)				
Varicella[3,*]	2 doses				
Zoster[4]				1 dose	
Measles, mumps, rubella (MMR)[5,*]	1 or 2 doses		1 dose		
Influenza[6,*]	1 dose annually				
Pneumococcal (polysaccharide)[7,8]	1 or 2 doses				1 dose
Hepatitis A[9,*]	2 doses				
Hepatitis B[10,*]	3 doses				
Meningococcal[11,*]	1 or more doses				

*Covered by the Vaccine Injury Compensation Program.

For all persons in this category who meet the age requirements and who lack evidence of immunity (e.g., lack documentation of vaccination or have no evidence of prior infection)

Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications)

No recommendation

NOTE: The above recommendations must be read along with the footnotes on pages Q2–Q4 of this schedule.

1. Tetanus, diphtheria, and acellular pertussis (Td/Tdap) vaccination

Tdap should replace a single dose of Td for adults aged 19 through 64 years who have not received a dose of Tdap previously

Adults with uncertain or incomplete history of primary vaccination series with tetanus and diphtheria toxoid–containing vaccines should begin or complete a primary vaccination series. A primary series for adults is 3 doses of tetanus and diphtheria toxoid–containing vaccines; administer the first 2 doses at least 4 weeks apart and the third dose 6–12 months after the second. However, Tdap can substitute for any one of the doses of Td in the 3-dose primary series. The booster dose of tetanus and diphtheria toxoid–containing vaccine should be administered to adults who have completed a primary series and if the last vaccination was received 10 or more years previously. Tdap or Td vaccine may be used, as indicated.

If a woman is pregnant and received the last Td vaccination 10 or more years previously, administer Td during the second or third trimester. If the woman received the last Td vaccination less than 10 years previously, administer Tdap during the immediate postpartum period. A dose of Tdap is recommended for postpartum women, close contacts of infants aged less than 12 months, and all health-care personnel with direct patient contact if they have not previously received Tdap. An interval as short as 2 years from the last Td is suggested; shorter intervals can be used. Td may be deferred during pregnancy and Tdap substituted in the immediate postpartum period, or Tdap may be administered instead of Td to a pregnant woman after an informed discussion with the woman.

Consult the ACIP statement for recommendations for administering Td as prophylaxis in wound management.

2. Human papillomavirus (HPV) vaccination

HPV vaccination is recommended for all females aged 11 through 26 years (and may begin at age 9 years) who have not completed the vaccine series. History of genital warts, abnormal Papanicolaou test, or positive HPV DNA test is not evidence of prior infection with all vaccine HPV types; HPV vaccination is recommended for persons with such histories.

Ideally, vaccine should be administered before potential exposure to HPV through sexual activity; however, females who are sexually active should still be vaccinated consistent with age-based recommendations. Sexually active females who have not been infected with any of the four HPV vaccine types receive the full benefit of the vaccination. Vaccination is less beneficial for females who have already been infected with one or more of the HPV vaccine types.

A complete series consists of 3 doses. The second dose should be administered 2 months after the first dose; the third dose should be administered 6 months after the first dose.

HPV vaccination is not specifically recommended for females with the medical indications described in Figure 2, "Vaccines that might be indicated for adults based on medical and other indications." Because HPV vaccine is not a live-virus vaccine, it may be administered to persons with the medical indications described in Figure 2. However, the immune response and vaccine efficacy might be less for persons with the medical indications described in Figure 2 than in persons who do not have the medical indications described or who are immunocompetent. Health-care personnel are not at increased risk because of occupational exposure, and should be vaccinated consistent with age-based recommendations.

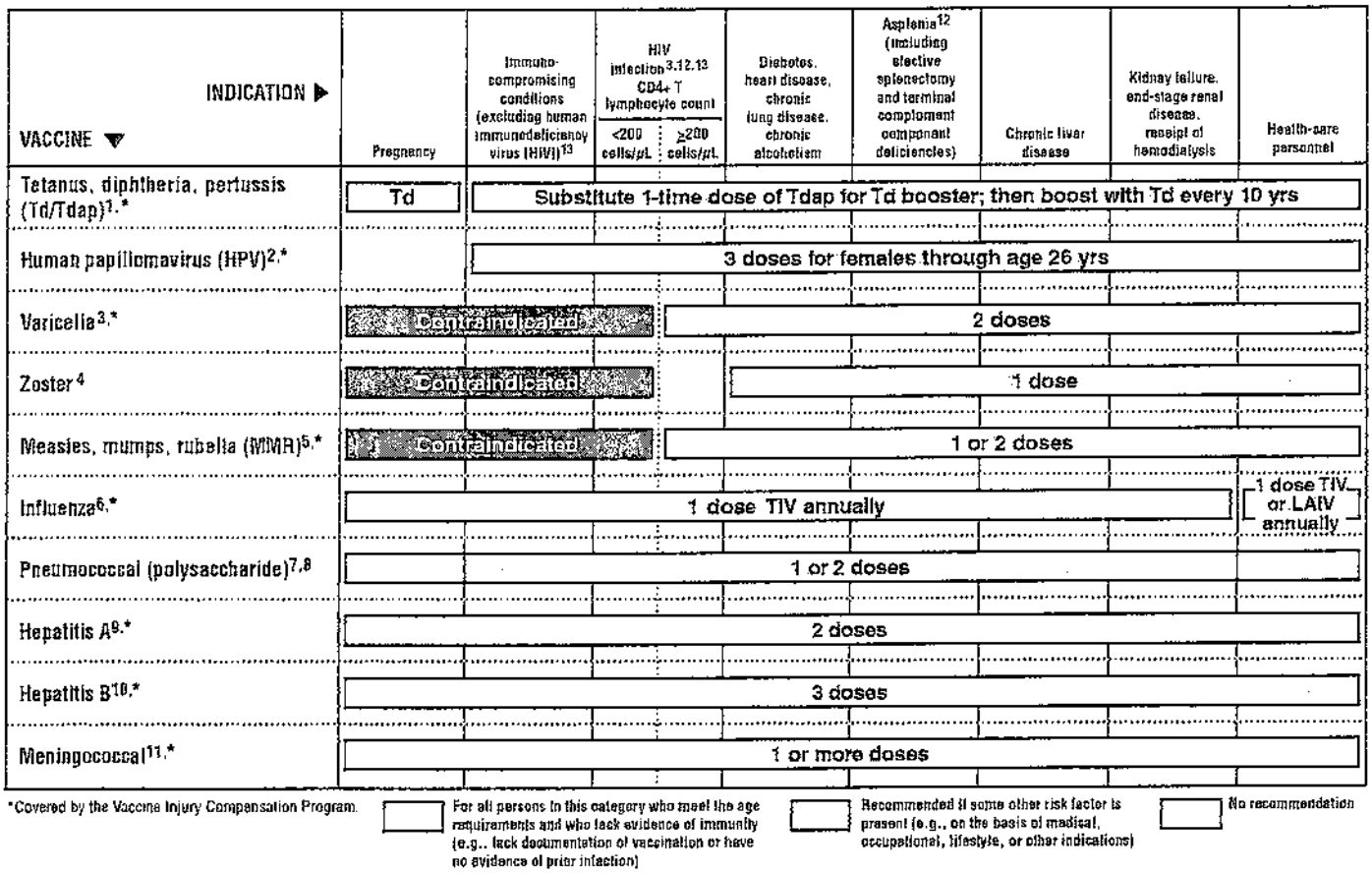
3. Varicella vaccination

All adults without evidence of immunity to varicella should receive 2 doses of single-antigen varicella vaccine if not previously vaccinated or the second dose if they have received only one dose, unless they have a medical contraindication. Special consideration should be given to those who 1) have close contact with persons at high risk for severe disease (e.g., health-care personnel and family contacts of persons with immunocompromising conditions) or 2) are at high risk for exposure or transmission (e.g., teachers; child care employees; residents and staff members of institutional settings, including correctional institutions; college students; military personnel; adolescents and adults living in households with children; nonpregnant women of childbearing age; and international travelers).

Evidence of immunity to varicella in adults includes any of the following: 1) documentation of 2 doses of varicella vaccine at least 4 weeks apart; 2) U.S.-born before 1980 (although for health-care personnel and pregnant women, birth before 1980 should not be considered evidence of immunity); 3) history of varicella based on diagnosis or verification of varicella by a health-care provider (for a patient reporting a history of or presenting with an atypical case, a mild case, or both, health-care providers should seek either an epidemiologic link to a typical varicella case or to a laboratory-confirmed case or evidence of laboratory confirmation, if it was performed at the time of acute disease); 4) history of herpes zoster based on health-care provider diagnosis or verification of herpes zoster by a health-care provider; or 5) laboratory evidence of immunity or laboratory confirmation of disease.

Pregnant women should be assessed for evidence of varicella immunity. Women who do not have evidence of immunity should receive the first dose

FIGURE 2. Vaccines that might be indicated for adults based on medical and other indications — United States, 2009



NOTE: The above recommendations must be read along with the footnotes on pages Q2–Q4 of this schedule.

of varicella vaccine upon completion or termination of pregnancy and before discharge from the health-care facility. The second dose should be administered 4–8 weeks after the first dose.

4. Herpes zoster vaccination

A single dose of zoster vaccine is recommended for adults aged 60 years and older regardless of whether they report a prior episode of herpes zoster. Persons with chronic medical conditions may be vaccinated unless their condition constitutes a contraindication.

5. Measles, mumps, rubella (MMR) vaccination

Measles component: Adults born before 1957 generally are considered immune to measles. Adults born during or after 1957 should receive 1 or more doses of MMR unless they have a medical contraindication, documentation of 1 or more doses, history of measles based on health-care provider diagnosis, or laboratory evidence of immunity.

A second dose of MMR is recommended for adults who 1) have been recently exposed to measles or are in an outbreak setting; 2) have been vaccinated previously with killed measles vaccine; 3) have been vaccinated with an unknown type of measles vaccine during 1963–1967; 4) are students in postsecondary educational institutions; 5) work in a health-care facility; or 6) plan to travel internationally.

Mumps component: Adults born before 1957 generally are considered immune to mumps. Adults born during or after 1957 should receive 1 dose of MMR unless they have a medical contraindication, history of mumps based on health-care provider diagnosis, or laboratory evidence of immunity.

A second dose of MMR is recommended for adults who 1) live in a community experiencing a mumps outbreak and are in an affected age group; 2) are students in postsecondary educational institutions; 3) work in a health-care facility; or 4) plan to travel internationally. For unvaccinated health-care personnel born before 1957 who do not have other evidence of mumps immunity, administering 1 dose on a routine basis should be considered and administering a second dose during an outbreak should be strongly considered.

Rubella component: 1 dose of MMR vaccine is recommended for women whose rubella vaccination history is unreliable or who lack laboratory evidence of immunity. For women of childbearing age, regardless of birth year, rubella immunity should be determined and women should be counseled regarding congenital rubella syndrome. Women who do not have evidence of immunity should receive MMR vaccine upon completion or termination of pregnancy and before discharge from the health-care facility.

6. Influenza vaccination

Medical indications: Chronic disorders of the cardiovascular or pulmonary systems, including asthma; chronic metabolic diseases, including diabetes mellitus, renal or hepatic dysfunction, hemoglobinopathies, or immunocompromising conditions (including immunocompromising conditions caused by medications or human immunodeficiency virus [HIV]); any condition that compromises respiratory function or the handling of respiratory secretions or that can increase the risk of aspiration (e.g., cognitive dysfunction, spinal cord injury, or seizure disorder or other neuromuscular disorder); and pregnancy during the influenza season. No data exist on the risk for severe or complicated influenza disease among persons with asplenia; however, influenza is a risk factor for secondary bacterial infections that can cause severe disease among persons with asplenia.

Occupational indications: All health-care personnel, including those employed by long-term care and assisted-living facilities, and caregivers of children less than 5 years old.

Other indications: Residents of nursing homes and other long-term care and assisted-living facilities; persons likely to transmit influenza to persons at high risk (e.g., in-home household contacts and caregivers of children aged less than 5 years old, persons 65 years old and older and persons of all ages with high-risk condition[s]); and anyone who would like to decrease their risk of getting influenza. Healthy, nonpregnant adults aged less than 50 years without high-risk medical conditions who are not contacts of severely immunocompromised persons in special care units can receive either intranasally administered live, attenuated influenza vaccine (FluMist®) or inactivated vaccine. Other persons should receive the inactivated vaccine.

7. Pneumococcal polysaccharide (PPSV) vaccination

Medical indications: Chronic lung disease (including asthma); chronic cardiovascular diseases; diabetes mellitus; chronic liver diseases, cirrhosis; chronic alcoholism, chronic renal failure or nephrotic syndrome; functional or anatomic asplenia (e.g., sickle cell disease or splenectomy [if elective splenectomy

is planned, vaccinate at least 2 weeks before surgery]); immunocompromising conditions; and cochlear implants and cerebrospinal fluid leaks. Vaccinate as close to HIV diagnosis as possible.

Other indications: Residents of nursing homes or other long-term care facilities and persons who smoke cigarettes. Routine use of PPSV is not recommended for Alaska Native or American Indian persons younger than 65 years unless they have underlying medical conditions that are PPSV indications. However, public health authorities may consider recommending PPSV for Alaska Natives and American Indians aged 50 through 64 years who are living in areas in which the risk of invasive pneumococcal disease is increased.

8. Revaccination with PPSV

One-time revaccination after 5 years is recommended for persons with chronic renal failure or nephrotic syndrome; functional or anatomic asplenia (e.g., sickle cell disease or splenectomy); and for persons with immunocompromising conditions. For persons aged 65 years and older, one-time revaccination if they were vaccinated 5 or more years previously and were aged less than 65 years at the time of primary vaccination.

9. Hepatitis A vaccination

Medical indications: Persons with chronic liver disease and persons who receive clotting factor concentrates.

Behavioral indications: Men who have sex with men and persons who use illegal drugs.

Occupational indications: Persons working with hepatitis A virus (HAV)–infected primates or with HAV in a research laboratory setting.

Other indications: Persons traveling to or working in countries that have high or intermediate endemicity of hepatitis A (a list of countries is available at http://wwwn.cdc.gov/travel/contentdiseases.aspx) and any person seeking protection from HAV infection.

Single-antigen vaccine formulations should be administered in a 2-dose schedule at either 0 and 6–12 months (Havrix®), or 0 and 6–18 months (Vaqta®). If the combined hepatitis A and hepatitis B vaccine (Twinrix®) is used, administer 3 doses at 0, 1, and 6 months; alternatively, a 4-dose schedule, administered on days 0, 7, and 21 to 30 followed by a booster dose at month 12 may be used.

10. Hepatitis B vaccination

Medical indications: Persons with end-stage renal disease, including patients receiving hemodialysis; persons with HIV infection; and persons with chronic liver disease.

Occupational indications: Health-care personnel and public-safety workers who are exposed to blood or other potentially infectious body fluids.

Behavioral indications: Sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., persons with more than 1 sex partner during the previous 6 months); persons seeking evaluation or treatment for a sexually transmitted disease (STD);current or recent injection-drug users; and men who have sex with men.

Other indications: Household contacts and sex partners of persons with chronic hepatitis B virus (HBV) infection; clients and staff members of institutions for persons with developmental disabilities; international travelers to countries with high or intermediate prevalence of chronic HBV infection (a list of countries is available at http://wwwn.cdc.gov/travel/contentdiseases.aspx); and any adult seeking protection from HBV infection.

Hepatitis B vaccination is recommended for all adults in the following settings: STD treatment facilities; HIV testing and treatment facilities; facilities providing drug-abuse treatment and prevention services; health-care settings targeting services to injection-drug users or men who have sex with men; correctional facilities; end-stage renal disease programs and facilities for chronic hemodialysis patients; and institutions and nonresidential daycare facilities for persons with developmental disabilities.

If the combined hepatitis A and hepatitis B vaccine (Twinrix®) is used, administer 3 doses at 0, 1, and 6 months; alternatively, a 4-dose schedule, administered on days 0, 7, and 21 to 30 followed by a booster dose at month 12 may be used.

Special formulation indications: For adult patients receiving hemodialysis or with other immunocompromising conditions, 1 dose of 40 µg/mL (Recombivax HB®) administered on a 3-dose schedule or 2 doses of 20 µg/mL (Engerix-B®) administered simultaneously on a 4-dose schedule at 0,1, 2 and 6 months.

11. Meningococcal vaccination

Medical indications: Adults with anatomic or functional asplenia, or terminal complement component deficiencies.

Other indications: First-year college students living in dormitories; microbiologists routinely exposed to isolates of Neisseria meningitidis; military recruits; and persons who travel to or live in countries in which meningococcal disease is hyperendemic or epidemic (e.g., the "meningitis belt" of sub-Saharan Africa during the dry season [December–June]), particularly if their contact with local populations will be prolonged. Vaccination is required by the government of Saudi Arabia for all travelers to Mecca during the annual Hajj.

Meningococcal conjugate vaccine (MCV) is preferred for adults with any of the preceding indications who are aged 55 years or younger, although meningococcal polysaccharide vaccine (MPSV) is an acceptable alternative. Revaccination with MCV after 5 years might be indicated for adults previously vaccinated with MPSV who remain at increased risk for infection (e.g., persons residing in areas in which disease is epidemic).

12. Selected conditions for which Haemophilus influenzae type b (Hib) vaccine may be used

Hib vaccine generally is not recommended for persons aged 5 years and older. No efficacy data are available on which to base a recommendation concerning use of Hib vaccine for older children and adults. However, studies suggest good immunogenicity in patients who have sickle cell disease, leukemia, or HIV infection or who have had a splenectomy; administering 1 dose of vaccine to these patients is not contraindicated.

13. Immunocompromising conditions

Inactivated vaccines generally are acceptable (e.g., pneumococcal, meningococcal, and influenza [trivalent inactivated influenza vaccine]) and live vaccines generally are avoided in persons with immune deficiencies or immunocompromising conditions. Information on specific conditions is available at http://www.cdc.gov/vaccines/pubs/acip-list.htm.

These schedules indicate the recommended age groups and medical indications for which administration of currently licensed vaccines is commonly indicated for adults ages 19 years and older, as of January 1, 2009. Licensed combination vaccines may be used whenever any components of the combination are indicated and when the vaccine's other components are not contraindicated. For detailed recommendations on all vaccines, including those used primarily for travelers or that are issued during the year, consult the manufacturers' package inserts and the complete statements from the Advisory Committee on Immunization Practices (http://www.cdc.gov/vaccines/pubs/acip-list.htm).

Report all clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System (VAERS). Reporting forms and instructions on filing a VAERS report are available at http://www.vaers.hhs.gov or by telephone, 800-822-7967.

Information on how to file a Vaccine Injury Compensation Program claim is available at http://www.hrsa.gov/vaccinecompensation or by telephone, 800-338-2382. To file a claim for vaccine injury, contact the U.S. Court of Federal Claims, 717 Madison Place, N.W., Washington, D.C. 20005; telephone, 202-357-6400.

Additional information about the vaccines in this schedule, extent of available data, and contraindications for vaccination is also available at http://www.cdc.gov/vaccines or from the CDC-INFO Contact Center at 800-CDC-INFO (800-232-4636) in English and Spanish, 24 hours a day, 7 days a week.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.