1	ENROLLED
2	COMMITTEE SUBSTITUTE
3	FOR
4	Senate Bill No. 265
5	(SENATOR SNYDER, original sponsor)
6	
7	[Passed April 13, 2013; in effect ninety days from passage.]
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AN ACT to amend and reenact article 5, chapter 64 of the Code of 10 West Virginia, 1931, as amended, relating generally to the 11 promulgation of administrative rules by the Department of 12 13 Health and Human Resources; legislative mandate 14 authorization for the promulgation of certain legislative rules by various executive or administrative agencies of the 15 state; authorizing certain of the agencies to promulgate 16 certain legislative rules with various modifications presented 17 to and recommended by the Legislative Rule-Making Review 18 19 Committee; authorizing certain of the agencies to promulgate certain legislative rules with various modifications presented 20 to and recommended by the Legislative Rule-Making Review 21 Committee and as amended by the Legislature; authorizing 22 23 certain of the agencies to promulgate certain legislative rules in the form that the rules were filed in the State 24

Register; authorizing certain of the agencies to promulgate certain legislative rules in the form that the rules were filed in the State Register and as amended by the Legislature; authorizing the Department of Health and Human Resources to promulgate a legislative rule relating to reportable diseases, events and conditions; authorizing the Department of Health and Human Resources to promulgate a legislative rule relating to general sanitation; authorizing the Department of Health and Human Resources to promulgate a legislative rule relating to Grade A pasturized milk; authorizing the Department of Health and Human Resources to promulgate a legislative rule relating to fees for services; repealing the Bureau for Public Health's legislative rule relating to the regulation of opioid treatment programs, 64 CSR 90; authorizing the Department of Health and Human Resources to promulgate a legislative rule relating to pulse oximetry newborn testing; authorizing the Department of Health and Human Resources to promulgate a legislative rule relating to the regulation of opioid treatment programs, 69 CSR 7; authorizing the Department of Health and Human Resources to promulgate a legislative rule relating to chronic pain management clinic licensure; authorizing the Department of Health and Human Resources to promulgate a legislative rule relating to minimum licensing requirements for residential child care and treatment

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- facilities for children and transitioning adults in West

 Virginia; authorizing the Health Care Authority to promulgate

 a legislative rule relating to the West Virginia Health

 Information Network; and authorizing the Bureau of Senior

 Services to promulgate a legislative rule relating to the in
 home care worker registry.
- 7 Be it enacted by the Legislature of West Virginia:
- 8 That article 5, chapter 64 of the Code of West Virginia, 1931, 9 as amended, be amended and reenacted to read as follows:
- 10 ARTICLE 5. AUTHORIZATION FOR DEPARTMENT OF HEALTH AND HUMAN
 11 RESOURCES TO PROMULGATE LEGISLATIVE RULES.
- 12 **§64-5-1**. Bureau for Public Health.
- 13 (a) The legislative rule filed in the State Register on August 14 31, 2012, authorized under the authority of section four, article one, chapter sixteen of this code, modified by the Department of 15 16 Health and Human Resources to meet the objections of the Legislative Rule-Making Review Committee and refiled in the State 17 Register on January 10, 2013, relating to the Department of Health 18 and Human Resources (reportable diseases, events and conditions, 64 19 20 CSR 7), is authorized with the following amendments:
- On page twenty-four, subsection 9.1., by striking out the words "the reporting" and inserting in lieu thereof the words "the access";
- On page twenty-five, subsection 9.2., by striking out the

- 1 words "be reported" and inserting in lieu thereof the words "be
- 2 made available";
- On page twenty-five, subsection 9.2., by striking out the
- 4 words "the reporting" and inserting in lieu thereof the words "the
- 5 access";
- On page twenty-five, subsection 9.2., after the word
- 7 "activities" by inserting the following: "consistent with the
- 8 mission of the bureau. The responsibility for communication with
- 9 healthcare facilities regarding data collection, data quality and
- 10 completeness rests with the Office of Epidemiology and Prevention
- 11 Services within the Bureau for Public Health";
- 12 And,
- On page twenty-five, by striking out all of subsection 9.3.
- 14 and renumbering the remaining subsection.
- 15 (b) The legislative rule filed in the State Register on June
- 29, 2012, authorized under the authority of section four, article
- one, chapter sixteen of this code, modified by the Department of
- 18 Health and Human Resources to meet the objections of the
- 19 Legislative Rule-Making Review Committee and refiled in the State
- 20 Register on November 15, 2012, relating to the Department of Health
- 21 and Human Resources (general sanitation, 64 CSR 18), is authorized
- 22 with the following amendment:
- On page three, subdivision 2.13, by removing the period and
- inserting the following, "Bed and Breakfast Inn."

1 (c) The legislative rule filed in the State Register on August 2 27, 2012, authorized under the authority of section five, article 3 seven, chapter sixteen of this code, relating to the Department of 4 Health and Human Resources (Grade A pasturized milk, 64 CSR 34), is

authorized.

- (d) The legislative rule filed in the State Register on August 31, 2012, authorized under the authority of section one, article eleven, chapter sixteen of this code, modified by the Department of Health and Human Resources to meet the objections of the Legislative Rule-Making Review committee and refiled in the State Register on January 10, 2013, relating to the Department of Health and Human Resources (fees for services, 64 CSR 51), is authorized with the following amendment:
 - On page eleven, subdivision 9.7, after the word "emergency", by inserting a period and removing the underscored words "or as a relevant factor associated with the provision of services and may include but is not limited to, supply shortages, federal or other funding restrictions of policy changes impacting the ability to provide services".
- (e) The legislative rule filed in the State Register on October 11, 2012, authorized under the authority of section four, article one, chapter sixteen of this code, relating to the Department of Health and Human Resources (regulation of opioid treatment programs, 64 CSR 90), is repealed.

- 1 (f) The legislative rule filed in the State Register on August
- 2 27, 2012, authorized under the authority of section four, article
- 3 one, chapter sixteen of this code, modified by the Department of
- 4 Health and Human Resources to meet the objections of the
- 5 Legislative Rule-Making Review Committee and refiled in the State
- 6 Register on January 10, 2013, relating to the Department of Health
- 7 and Human Resources (pulse oximetry newborn testing, 64 CSR 100),
- 8 is authorized with the following amendment:
- 9 On page two, subdivision 5.3, by striking out the words "the
- 10 closest" and inserting in lieu thereof the word "an".

§64-5-2. Department of Health and Human Resources.

- 12 (a) The legislative rule filed in the State Register on August
- 13 31, 2012, authorized under the authority of section one, article
- eleven, chapter sixteen of this code, modified by the Department of
- 15 Health and Human Resources to meet the objections of the
- 16 Legislative Rule-Making Review Committee and refiled in the State
- 17 Register on February 5, 2013, relating to the Department of Health
- and Human Resources (regulation of opioid treatment programs, 69
- 19 CSR 7), is authorized with the following amendment:
- On page fourteen, by striking section 7.3 and inserting a new
- 21 section 7.3 to read as follows:

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- 22 "7.3. License Fees and Inspection Costs.
- 7.3.a. All applications for an initial or renewed license
- shall be accompanied by a non-refundable license fee in the amount

- 1 required by this rule. The annual renewal fee is based upon the
- 2 average daily total census of the program. In addition to the set
- 3 fee, the annual renewal fee shall be adjusted on the first day of
- 4 June of each year to correspond with increases in the consumer
- 5 price index. The base amounts for initial and renewal fees are as
- 6 follows:
- 7.3.a.1. Initial license fee \$250;
- 8 7.3.a.2. Renewal fee fewer than 500 patients \$500
- 9 plus adjustment;
- 7.3.a.3. Renewal fee 500 to 1,000 patients \$1,000
- 11 plus adjustment;
- 12 7.3.a.4. Renewal fee more than 1,000 patients \$1,500
- 13 plus adjustment.
- 7.3.b. An opioid treatment program shall pay for the cost of
- 15 the initial inspection made by the secretary prior to issuing a
- license. The cost of the initial inspection is \$400, and shall be
- billed to the applicant by the secretary within five business days
- 18 after the inspection. The cost of the initial inspection must be
- 19 paid in full by the applicant before a license may be issued.
- 20 7.3c. The Office of Health Facility Licensure and
- 21 Certification shall use the fee for increased oversight on opioid
- 22 treatment programs.";
- On page thirty-two, by inserting a new subdivision 18.3.j. to
- 24 read as follows:

- 1 "18.3.j. There shall be one (1) counselor for every fifty (50)
- 2 clients in the program.";
- On page fifty-three, by striking section 30.8 and inserting a
- 4 new section 30.8 to read as follows:
- 5 "30.8. Each opioid treatment program must provide counseling
- 6 on preventing exposure to, and the transmission of, human
- 7 immunodeficiency virus (HIV) disease and Hepatitis C disease for
- 8 each patient admitted or re-admitted to maintenance or
- 9 detoxification treatment. Services rendered to patients with HIV
- 10 disease shall comply with the requirements of section 44 of this
- 11 rule.";
- On page fifty-four, by striking subdivision 31.4.a and
- inserting a new subdivision 31.4.a to read as follows:
- "31.4.a. Preventing exposure to, and the transmission of, HIV
- 15 disease and Hepatitis C disease for each patient admitted or
- readmitted to maintenance or detoxification treatment; and";
- On page fifty-six, by striking subdivision 32.2.a and
- 18 inserting a new subdivision 32.2.a to read as follows:
- "32.2.a. The initial post-admission assessment shall consist
- of a comprehensive medical evaluation, which shall include, but not
- 21 be limited to:
- 22 32.2.a.1. A comprehensive physical evaluation;
- 32.2.a.2. A comprehensive psychiatric evaluation,
- 24 including mental status examination and psychiatric history;

- 1 32.2.a.3. A personal and family medical history;
- 2 32.2.a.4. A comprehensive history of substance abuse,
- 3 both personal and family;
- 4 32.2.a.5. A tuberculosis skin test and chest X-ray, if
- 5 skin test is positive;
- 6 32.2.a.6. A screening test for syphilis;
- 7 32.2.a.7. A Hepatitis C test;
- 8 32.2.a.8. An HIV test to the extent voluntarily elected
- 9 by the patient; and
- 32.2.a.9. Other tests as necessary or appropriate (e.g.,
- 11 CBC, EKG, chest X-ray, pap smear, hepatitis B surface antigen and
- 12 hepatitis B antibody testing).";
- On page seventy, by striking section 37.14 and inserting a new
- section 37.14 to read as follows:
- 15 "37.14 The state authority may approve exceptional
- unsupervised-medication dosages, including alternative medications,
- on a case-by-case basis upon application for an exemption by the
- 18 program physician. Any authorization for exceptions shall be
- 19 consistent with guidelines and protocols of approved authorities,
- 20 provided that the authority may not grant any exceptions during a
- 21 calendar month which exceed three (3) exceptions or ten (10)
- 22 percent of the number of patients enrolled in the program on the
- last day of the previous month, whichever is greater: Provided,

- 1 That the state authority may grant additional exceptions for
- inclement weather or clinic closure.";
- On page seventy-three, by inserting a new subdivision 38.14 to
- 4 read as follows:
- 5 "38.14 Maintenance treatment shall be discontinued within two
- 6 (2) continuous years after the treatment is begun unless, based
- 7 upon the clinical judgment of the medical director or program
- 8 physician and staff which shall be recorded in the client's record
- 9 by the medical director or program physician, the client's status
- 10 indicates that the treatment should be continued for a longer
- 11 period of time because discontinuance from treatment would lead to
- 12 a return to (i) illicit opiate abuse or dependance, or (ii)
- increased psychiatric, behavioral or medical symptomology.";
- On page seventy-five, by striking subdivision 41.2.d.3 and
- inserting a new subdivision 41.2.d.3 to read as follows:
- 16 "41.2.d.3. When using urine as a screening mechanism, all
- 17 patient drug testing shall be observed to minimize the chance of
- 18 adulterating or substituting another individual's urine.";
- 19 And,
- On page eighty-one, by striking subdivision 44.5.d.1. and
- 21 inserting a new subdivision 44.5.d.1. to read as follows:
- 22 "44.5.d.1. Maintenance treatment dosage levels of pregnant
- 23 clients shall be maintained at the lowest possible dosage level
- 24 that is a medically appropriate therapeutic dose as determined by

- 1 the medical director or clinic physician taking the pregnancy into
- 2 account."
- 3 (b) The legislative rule filed in the State Register on
- 4 January 7, 2013, authorized under the authority of section nine,
- 5 article five-h, chapter sixteen of this code, relating to the
- 6 Department of Health and Human Resources (chronic pain management
- 7 clinic licensure, 69 CSR 8), is authorized with the following
- 8 amendments:
- 9 On page one, subsection 1.4, line eleven, following the number
- 10 "2013.", by inserting the following words:
- 11 "This rule is effective upon the date specified in an
- 12 emergency rule promulgated by the Department of Health and Human
- Resources as being the date funding for implementation of Chronic
- 14 Pain Management Clinic Licensure will become available pursuant to
- a duly enacted appropriation bill authorizing the expenditure of
- 16 funds for that purpose.";
- On page four, subsection 3.1., by striking out all of
- subdivisions 3.1.a., 3.1.b., 3.1.c. and 3.1.d. and inserting in
- 19 lieu thereof the following:
- 3.1.a. The primary component of the medical practice of the
- 21 clinic, facility or office is treatment of chronic pain for non-
- 22 malignant conditions;
- 3.1.b. More than fifty percent of patients in any one month of
- 24 the prescribers are provided treatment for chronic pain for

- 1 nonmalignant conditions and are prescribed, administered or
- 2 dispensed tramadol, carisoprodol, opioid drug products or other
- 3 Schedule II or Schedule III controlled substances for such
- 4 diagnosis;
- 5 3.1.c. The calculation of more than fifty percent of patients
- 6 will be calculated by dividing the number of unique patient
- 7 encounters at the clinic, facility or office during any one month
- 8 for a diagnosis of chronic nonmalignant pain and pursuant to such
- 9 diagnosis of chronic nonmalignant pain were prescribed,
- 10 administered or dispensed tramadol, carisoprodol, opioid drugs or
- other Scheduled II or Scheduled III controlled substances by the
- 12 total number of all patient encounters at the clinic, facility or
- office during any month; and
- 3.1.d. Patients receiving tramadol, carisoprodol, opioid drug
- products or other Schedule II or Schedule III controlled substances
- for treatment of an injury or illness that lasts or is expected to
- last thirty days or less shall not be included in the calculation
- 18 of more than fifty percent of all patients." and renumbering the
- 19 remaining subdivisions;
- 20 On page five, by inserting a new paragraph, 3.2.i.2., to read
- 21 as follows:
- 22 "3.2.i.2. Medical practices, clinics or offices in which a
- 23 physician treats an average of 20 or fewer patients a day with any

- 1 diagnosis in any one month, and in which the physician holds a
- 2 Competency Certification in Controlled Substances Management.";
- 3 And,
- On page thirteen, subparagraph 6.5.b.2.B., after the words
- 5 "Osteopathic Specialist;" by inserting the words "hold Competency
- 6 Certification in Controlled Substances Management;".
- 7 (c) The legislative rule filed in the State Register on August
- 8 30, 2012, authorized under the authority of section four, article
- 9 two-b, chapter forty-nine of this code, modified by the Department
- of Health and Human Resources to meet the objections of the
- 11 Legislative Rule-Making Review Committee and refiled in the State
- Register on January 15, 2013, relating to the Department of Health
- and Human Resources (minimum licensing requirements for residential
- 14 child care and treatment facilities for children and transitioning
- adults in West Virginia, 78 CSR 3), is authorized, with the
- 16 following amendment:
- On page fifty-two, paragraph 11.2.a.3., line five, by striking
- out the word "Training" and inserting the word "Certification".
- 19 **§64-5-3**. Health Care Authority.
- The legislative rule filed in the State Register on May 14,
- 21 2012, authorized under the authority of section seven, article
- twenty-nine-g, chapter sixteen of this code, modified by the Health
- 23 Care Authority to meet the objections of the Legislative Rule-
- 24 Making Review Committee and refiled in the State Register on July

- 1 19, 2012, relating to the Health Care Authority to promulgate a
- 2 legislative rule relating to (West Virginia Health Information
- 3 Network, 65 CSR 28), is authorized.
- 4 §64-5-4. Bureau of Senior Services.
- 5 The legislative rule filed in the State Register on August 31,
- 6 2012, authorized under the authority of section fifteen, article
- 7 five-p, chapter sixteen of this code, modified by the Bureau of
- 8 Senior Services to meet the objections of the Legislative Rule-
- 9 making Review Committee and refiled in the State Register on
- January 17, 2013, relating to the Bureau of Senior Services (in-
- 11 home care worker registry, 76 CSR 2), is authorized with the
- 12 following amendment:
- On page two, subdivision 4.1(i), by striking the word
- "training" and inserting the word "certification".