

WEST VIRGINIA LEGISLATURE

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Committee Substitute

for

House Bill 4248

(BY DELEGATES ROHRBACH, SOBONYA, BATES,
ELLINGTON, HOUSEHOLDER, MILLER, PERDUE,
STANSBURY, WAXMAN, B. WHITE AND FRICH)

[Originating in the Committee on the Judiciary,
February 27, 2016.]

1 A BILL to amend and reenact §16-1-4 of the Code of West Virginia, 1931, as amended; and to
2 amend said code by adding thereto a new article, designated §16-5Y-1, all relating to
3 methadone regulation; requiring the secretary of Health and Human Resources to propose
4 legislative rules for the regulation of opioid treatment programs; requiring the Health Care
5 Authority to develop new certificate of need standards; prohibiting the Health Care
6 Authority from approving applications of certificate of need for opioid treatment programs;
7 imposing a moratorium on licensure of certain new opioid treatment programs; providing
8 the secretary monitor opioid treatment programs; requiring program staff to receive
9 minimum training; setting forth standards for initial assessment to admission to a program;
10 setting forth criteria to be admitted to a treatment program; requiring a program to develop
11 individualized treatment plans; providing for random drug testing for program patients;
12 enunciating consequences for positive drug tests, including mandatory counseling;
13 requiring mandatory statistical reporting to the Department of Health and Human
14 Resources and the Legislative Oversight Commission on Health and Human Resources;
15 prescribing times programs must be open; setting forth certain staff requirements for
16 programs; requiring programs to establish peer review committees that include a physician
17 member; and requiring the secretary to prescribe the procedure for peer review.

Be it enacted by the Legislature of West Virginia:

1 That §16-1-4 of the Code of West Virginia, 1931, be amended and reenacted; and that
2 said code be amended by adding thereto a new article, designated §16-5Y-1, all to read as
3 follows:

ARTICLE 1. STATE PUBLIC HEALTH SYSTEM.

§16-1-4. Proposal of rules by the secretary.

1 (a) The secretary may propose rules in accordance with the provisions of article three,
2 chapter twenty-nine-a of this code that are necessary and proper to effectuate the purposes of
3 this chapter. The secretary may appoint or designate advisory councils of professionals in the

4 areas of hospitals, nursing homes, barbers and beauticians, postmortem examinations, mental
5 health and intellectual disability centers and any other areas necessary to advise the secretary
6 on rules.

7 (b) The rules may include, but are not limited to, the regulation of:

8 (1) Land usage endangering the public health: *Provided*, That no rules may be
9 promulgated or enforced restricting the subdivision or development of any parcel of land within
10 which the individual tracts, lots or parcels exceed two acres each in total surface area and which
11 individual tracts, lots or parcels have an average frontage of not less than one hundred fifty feet
12 even though the total surface area of the tract, lot or parcel equals or exceeds two acres in total
13 surface area, and which tracts are sold, leased or utilized only as single-family dwelling units.
14 Notwithstanding the provisions of this subsection, nothing in this section may be construed to
15 abate the authority of the department to:

16 (A) Restrict the subdivision or development of a tract for any more intense or higher density
17 occupancy than a single-family dwelling unit;

18 (B) Propose or enforce rules applicable to single-family dwelling units for single-family
19 dwelling unit sanitary sewerage disposal systems; or

20 (C) Restrict any subdivision or development which might endanger the public health, the
21 sanitary condition of streams or sources of water supply;

22 (2) The sanitary condition of all institutions and schools, whether public or private, public
23 conveyances, dairies, slaughterhouses, workshops, factories, labor camps, all other places open
24 to the general public and inviting public patronage or public assembly, or tendering to the public
25 any item for human consumption and places where trades or industries are conducted;

26 (3) Occupational and industrial health hazards, the sanitary conditions of streams, sources
27 of water supply, sewerage facilities and plumbing systems and the qualifications of personnel
28 connected with any of those facilities, without regard to whether the supplies or systems are
29 publicly or privately owned; and the design of all water systems, plumbing systems, sewerage

30 systems, sewage treatment plants, excreta disposal methods and swimming pools in this state,
31 whether publicly or privately owned;

32 (4) Safe drinking water, including:

33 (A) The maximum contaminant levels to which all public water systems must conform in
34 order to prevent adverse effects on the health of individuals and, if appropriate, treatment
35 techniques that reduce the contaminant or contaminants to a level which will not adversely affect
36 the health of the consumer. The rule shall contain provisions to protect and prevent contamination
37 of wellheads and well fields used by public water supplies so that contaminants do not reach a
38 level that would adversely affect the health of the consumer;

39 (B) The minimum requirements for: Sampling and testing; system operation; public
40 notification by a public water system on being granted a variance or exemption or upon failure to
41 comply with specific requirements of this section and rules promulgated under this section; record
42 keeping; laboratory certification; as well as procedures and conditions for granting variances and
43 exemptions to public water systems from state public water systems rules; and

44 (C) The requirements covering the production and distribution of bottled drinking water
45 and may establish requirements governing the taste, odor, appearance and other consumer
46 acceptability parameters of drinking water;

47 (5) Food and drug standards, including cleanliness, proscription of additives, proscription
48 of sale and other requirements in accordance with article seven of this chapter as are necessary
49 to protect the health of the citizens of this state;

50 (6) The training and examination requirements for emergency medical service attendants
51 and emergency medical care technician-paramedics; the designation of the health care facilities,
52 health care services and the industries and occupations in the state that must have emergency
53 medical service attendants and emergency medical care technician-paramedics employed and
54 the availability, communications and equipment requirements with respect to emergency medical
55 service attendants and to emergency medical care technician-paramedics. Any regulation of

56 emergency medical service attendants and emergency medical care technician-paramedics may
57 not exceed the provisions of article four-c of this chapter;

58 (7) The health and sanitary conditions of establishments commonly referred to as bed and
59 breakfast inns. For purposes of this article, "bed and breakfast inn" means an establishment
60 providing sleeping accommodations and, at a minimum, a breakfast for a fee. The secretary may
61 not require an owner of a bed and breakfast providing sleeping accommodations of six or fewer
62 rooms to install a restaurant-style or commercial food service facility. The secretary may not
63 require an owner of a bed and breakfast providing sleeping accommodations of more than six
64 rooms to install a restaurant-type or commercial food service facility if the entire bed and breakfast
65 inn or those rooms numbering above six are used on an aggregate of two weeks or less per year;

66 (8) Fees for services provided by the Bureau for Public Health including, but not limited to,
67 laboratory service fees, environmental health service fees, health facility fees and permit fees;

68 (9) The collection of data on health status, the health system and the costs of health care;

69 ~~(10) Opioid treatment programs duly licensed and operating under the requirements of
70 chapter twenty-seven of this code.~~

71 ~~(A) The Health Care Authority shall develop new certificate of need standards, pursuant
72 to the provisions of article two-d of this chapter, that are specific for opioid treatment program
73 facilities.~~

74 ~~(B) No applications for a certificate of need for opioid treatment programs may be
75 approved by the Health Care Authority as of the effective date of the 2007 amendments to this
76 subsection.~~

77 ~~(C) There is a moratorium on the licensure of new opioid treatment programs that do not
78 have a certificate of need as of the effective date of the 2007 amendments to this subsection,
79 which shall continue until the Legislature determines that there is a necessity for additional opioid
80 treatment facilities in West Virginia.~~

81 ~~(D) The secretary shall file revised emergency rules with the Secretary of State to regulate
82 opioid treatment programs in compliance with the provisions of this section. Any opioid treatment~~

83 ~~program facility that has received a certificate of need pursuant to article two-d, of this chapter by~~
84 ~~the Health Care Authority shall be permitted to proceed to license and operate the facility.~~

85 ~~(E) All existing opioid treatment programs shall be subject to monitoring by the secretary.~~

86 ~~All staff working or volunteering at opioid treatment programs shall complete the minimum~~
87 ~~education, reporting and safety training criteria established by the secretary. All existing opioid~~
88 ~~treatment programs shall be in compliance within one hundred eighty days of the effective date~~
89 ~~of the revised emergency rules as required herein. The revised emergency rules shall provide at~~
90 ~~a minimum:~~

91 ~~(i) That the initial assessment prior to admission for entry into the opioid treatment program~~
92 ~~shall include an initial drug test to determine whether an individual is either opioid addicted or~~
93 ~~presently receiving methadone for an opioid addiction from another opioid treatment program.~~

94 ~~(ii) The patient may be admitted to the opioid treatment program if there is a positive test~~
95 ~~for either opioids or methadone or there are objective symptoms of withdrawal, or both, and all~~
96 ~~other criteria set forth in the rule for admission into an opioid treatment program are met.~~
97 ~~Admission to the program may be allowed to the following groups with a high risk of relapse~~
98 ~~without the necessity of a positive test or the presence of objective symptoms: Pregnant women~~
99 ~~with a history of opioid abuse, prisoners or parolees recently released from correctional facilities,~~
100 ~~former clinic patients who have successfully completed treatment but who believe themselves to~~
101 ~~be at risk of imminent relapse and HIV patients with a history of intravenous drug use.~~

102 ~~(iii) That within seven days of the admission of a patient, the opioid treatment program~~
103 ~~shall complete an initial assessment and an initial plan of care.~~

104 ~~(iv) That within thirty days after admission of a patient, the opioid treatment program shall~~
105 ~~develop an individualized treatment plan of care and attach the plan to the patient's chart no later~~
106 ~~than five days after the plan is developed. The opioid treatment program shall follow guidelines~~
107 ~~established by a nationally recognized authority approved by the secretary and include a recovery~~
108 ~~model in the individualized treatment plan of care. The treatment plan is to reflect that~~

109 ~~detoxification is an option for treatment and supported by the program; that under the~~
110 ~~detoxification protocol the strength of maintenance doses of methadone should decrease over~~
111 ~~time, the treatment should be limited to a defined period of time, and participants are required to~~
112 ~~work toward a drug-free lifestyle.~~

113 ~~(v) That each opioid treatment program shall report and provide statistics to the~~
114 ~~Department of Health and Human Resources at least semiannually which includes the total~~
115 ~~number of patients; the number of patients who have been continually receiving methadone~~
116 ~~treatment in excess of two years, including the total number of months of treatment for each such~~
117 ~~patient; the state residency of each patient; the number of patients discharged from the program,~~
118 ~~including the total months in the treatment program prior to discharge and whether the discharge~~
119 ~~was for:~~

120 ~~(A) Termination or disqualification;~~

121 ~~(B) Completion of a program of detoxification;~~

122 ~~(C) Voluntary withdrawal prior to completion of all requirements of detoxification as~~
123 ~~determined by the opioid treatment program;~~

124 ~~(D) Successful completion of the individualized treatment care plan; or~~

125 ~~(E) An unexplained reason.~~

126 ~~(vi) That random drug testing of all patients shall be conducted during the course of~~
127 ~~treatment at least monthly. For purposes of these rules, "random drug testing" means that each~~
128 ~~patient of an opioid treatment program facility has a statistically equal chance of being selected~~
129 ~~for testing at random and at unscheduled times. Any refusal to participate in a random drug test~~
130 ~~shall be considered a positive test. Nothing contained in this section or the legislative rules~~
131 ~~promulgated in conformity herewith will preclude any opioid treatment program from administering~~
132 ~~such additional drug tests as determined necessary by the opioid treatment program.~~

133 ~~(vii) That all random drug tests conducted by an opioid treatment program shall, at a~~
134 ~~minimum, test for the following:~~

135 ~~(A) Opiates, including oxycodone at common levels of dosing; (B) Methadone and any~~
136 ~~other medication used by the program as an intervention;~~

137 ~~(C) Benzodiazepine including diazepam, lorazepam, clonazepam and alprazolam;~~

138 ~~(D) Cocaine;~~

139 ~~(E) Methamphetamine or amphetamine;~~

140 ~~(F) Tetrahydrocannabinol, delta-9-tetrahydrocannabinol or dronabinol or other similar~~
141 ~~substances; or~~

142 ~~(G) Other drugs determined by community standards, regional variation or clinical~~
143 ~~indication.~~

144 ~~(viii) That a positive drug test is a test that results in the presence of any drug or substance~~
145 ~~listed in this schedule and any other drug or substance prohibited by the opioid treatment program.~~

146 ~~A positive drug test result after the first six months in an opioid treatment program shall result in~~
147 ~~the following:~~

148 ~~(A) Upon the first positive drug test result, the opioid treatment program shall:~~

149 ~~(1) Provide mandatory and documented weekly counseling of no less than thirty minutes~~
150 ~~to the patient, which shall include weekly meetings with a counselor who is licensed, certified or~~
151 ~~enrolled in the process of obtaining licensure or certification in compliance with the rules and on~~
152 ~~staff at the opioid treatment program;~~

153 ~~(2) Immediately revoke the take home methadone privilege for a minimum of thirty days;~~
154 ~~and~~

155 ~~(B) Upon a second positive drug test result within six months of a previous positive drug~~
156 ~~test result, the opioid treatment program shall:~~

157 ~~(1) Provide mandatory and documented weekly counseling of no less than thirty minutes,~~
158 ~~which shall include weekly meetings with a counselor who is licensed, certified or enrolled in the~~
159 ~~process of obtaining licensure or certification in compliance with the rules and on staff at the opioid~~
160 ~~treatment program;~~

161 ~~(2) Immediately revoke the take-home methadone privilege for a minimum of sixty days;~~

162 and

163 ~~(3) Provide mandatory documented treatment team meetings with the patient.~~

164 ~~(C) Upon a third positive drug test result within a period of six months the opioid treatment~~
165 ~~program shall:~~

166 ~~(1) Provide mandatory and documented weekly counseling of no less than thirty minutes,~~
167 ~~which shall include weekly meetings with a counselor who is licensed, certified or enrolled in the~~
168 ~~process of obtaining licensure or certification in compliance with the rules and on staff at the opioid~~
169 ~~treatment program;~~

170 ~~(2) Immediately revoke the take-home methadone privilege for a minimum of one hundred~~
171 ~~twenty days; and~~

172 ~~(3) Provide mandatory and documented treatment team meetings with the patient which~~
173 ~~will include, at a minimum: The need for continuing treatment; a discussion of other treatment~~
174 ~~alternatives; and the execution of a contract with the patient advising the patient of discharge for~~
175 ~~continued positive drug tests.~~

176 ~~(D) Upon a fourth positive drug test within a six-month period, the patient shall be~~
177 ~~immediately discharged from the opioid treatment program or, at the option of the patient, shall~~
178 ~~immediately be provided the opportunity to participate in a twenty-one day detoxification plan,~~
179 ~~followed by immediate discharge from the opioid treatment program: *Provided*, That testing~~
180 ~~positive solely for tetrahydrocannabinol, delta-9-tetrahydrocannabinol or dronabinol or similar~~
181 ~~substances shall not serve as a basis for discharge from the program.~~

182 ~~(ix) That the opioid treatment program must report and provide statistics to the Department~~
183 ~~of Health and Human Resources demonstrating compliance with the random drug test rules,~~
184 ~~including:~~

185 ~~(A) Confirmation that the random drug tests were truly random in regard to both the~~
186 ~~patients tested and to the times random drug tests were administered by lottery or some other~~

187 ~~objective standard so as not to prejudice or protect any particular patient;~~

188 ~~(B) Confirmation that the random drug tests were performed at least monthly for all~~
189 ~~program participants;~~

190 ~~(C) The total number and the number of positive results; and~~

191 ~~(D) The number of expulsions from the program.~~

192 ~~(x) That all opioid treatment facilities be open for business seven days per week; however,~~
193 ~~the opioid treatment center may be closed for eight holidays and two training days per year. During~~
194 ~~all operating hours, every opioid treatment program shall have a health care professional as~~
195 ~~defined by rule promulgated by the secretary actively licensed in this state present and on duty at~~
196 ~~the treatment center and a physician actively licensed in this state available for consultation.~~

197 ~~(xi) That the Office of Health Facility Licensure and Certification develop policies and~~
198 ~~procedures in conjunction with the Board of Pharmacy that will allow physicians treating patients~~
199 ~~through an opioid treatment program access to the Controlled Substances Monitoring Program~~
200 ~~database maintained by the Board of Pharmacy at the patient's intake, before administration of~~
201 ~~methadone or other treatment in an opioid treatment program, after the initial thirty days of~~
202 ~~treatment, prior to any take-home medication being granted, after any positive drug test, and at~~
203 ~~each ninety-day treatment review to ensure the patient is not seeking prescription medication~~
204 ~~from multiple sources. The results obtained from the Controlled Substances Monitoring Program~~
205 ~~database shall be maintained with the patient records.~~

206 ~~(xii) That each opioid treatment program shall establish a peer review committee, with at~~
207 ~~least one physician member, to review whether the program is following guidelines established~~
208 ~~by a nationally recognized authority approved by the secretary. The secretary shall prescribe the~~
209 ~~procedure for evaluation by the peer review. Each opioid treatment program shall submit a report~~
210 ~~of the peer review results to the secretary on a quarterly basis.~~

211 ~~(xiii) The secretary shall propose a rule for legislative approval in accordance with the~~
212 ~~provisions of article three, chapter twenty-nine-a of this code for the distribution of state aid to~~
213 ~~local health departments and basic public health services funds.~~

214 ~~The rule shall include the following provisions:~~

215 (10) The distribution of state aid to local health departments and basic public health:

216 Base allocation amount for each county;

217 Establishment and administration of an emergency fund of no more than two percent of
218 the total annual funds of which unused amounts are to be distributed back to local boards of health
219 at the end of each fiscal year;

220 A calculation of funds utilized for state support of local health departments;

221 Distribution of remaining funds on a per capita weighted population approach which
222 factors coefficients for poverty, health status, population density and health department
223 interventions for each county and a coefficient which encourages counties to merge in the
224 provision of public health services;

225 A hold-harmless provision to provide that each local health department receives no less
226 in state support for a period of four years beginning in the 2009 budget year.

227 ~~The Legislature finds that an emergency exists and, therefore, the secretary shall file an
228 emergency rule to implement the provisions of this section pursuant to the provisions of section
229 fifteen, article three, chapter twenty-nine-a of this code. The emergency rule is subject to the prior
230 approval of the Legislative Oversight Commission on Health and Human Resources
231 Accountability prior to filing with the Secretary of State.~~

232 ~~(xiv) Other health-related matters which the department is authorized to supervise and for
233 which the rule-making authority has not been otherwise assigned.~~

ARTICLE 5Y. REGULATION OF METHADONE.

§16-5Y-1. Proposal of rules by the secretary.

1 (a) The secretary shall regulate opioid treatment programs. The Secretary shall review the
2 effectiveness of opioid treatment programs.

3 (b) An opioid treatment program shall be licensed and operated under the requirements
4 of chapter twenty-seven of this code.

5 (c) The Health Care Authority shall develop new certificate of need standards, pursuant
6 to the provisions of article two-d of this chapter, that are specific for opioid treatment program
7 facilities.

8 (1) No applications for a certificate of need for opioid treatment programs may be approved
9 by the Health Care Authority.

10 (2) There is a moratorium on the licensure of new opioid treatment programs that do not
11 have a certificate of need as of June 1, 2007, which shall continue until the Legislature determines
12 that there is a necessity for additional opioid treatment facilities in West Virginia.

13 (3) Any opioid treatment program facility that has received a certificate of need pursuant
14 to article two-d, of this chapter by the Health Care Authority shall be permitted to be licensed and
15 operate the facility.

16 (d) Opioid treatment programs shall be subject to monitoring by the secretary. All staff
17 working or volunteering at opioid treatment programs shall complete the minimum education,
18 reporting and safety training criteria established by the secretary.

19 (e) The secretary shall propose rules in accordance with the provisions of article three,
20 chapter twenty-nine-a of this code that are necessary and proper to effectuate the purposes of
21 this chapter. The legislative rules shall provide at a minimum:

22 (1) That the initial assessment prior to admission for entry into the opioid treatment
23 program shall include an initial drug test to determine whether an individual is either opioid
24 addicted or presently receiving methadone for an opioid addiction from another opioid treatment
25 program.

26 (2) The patient may be admitted to the opioid treatment program if there is a positive test
27 for either opioids or methadone or there are objective symptoms of withdrawal, or both, and all
28 other criteria set forth in the rule for admission into an opioid treatment program are met.
29 Admission to the program may be allowed to the following groups with a high risk of relapse
30 without the necessity of a positive test or the presence of objective symptoms: Pregnant women

31 with a history of opioid abuse, prisoners or parolees recently released from correctional facilities,
32 former clinic patients who have successfully completed treatment but who believe themselves to
33 be at risk of imminent relapse and HIV patients with a history of intravenous drug use.

34 (3) Within seven days of the admission of a patient, the opioid treatment program shall
35 complete an initial assessment and an initial plan of care.

36 (4) Within thirty days after admission of a patient, the opioid treatment program shall
37 develop an individualized treatment plan of care and attach the plan to the patient's chart no later
38 than five days after the plan is developed. The opioid treatment program shall follow guidelines
39 established by a nationally recognized authority approved by the secretary and include a recovery
40 model in the individualized treatment plan of care. The treatment plan is to reflect that
41 detoxification is an option for treatment and supported by the program; that under the
42 detoxification protocol the strength of maintenance doses of methadone should decrease over
43 time, the treatment should be limited to a defined period of time, and participants are required to
44 work toward a drug-free lifestyle.

45 (5) Random drug testing of all patients shall be conducted during the course of treatment
46 at least on a monthly basis. For purposes of these rules, "random drug testing" means that each
47 patient of an opioid treatment program facility has a statistically equal chance of being selected
48 for testing at random and at unscheduled times. Any refusal to participate in a random drug test
49 shall be considered a positive test. Nothing contained in this section or the legislative rules
50 promulgated in conformity herewith will preclude any opioid treatment program from administering
51 such additional drug tests as determined necessary by the opioid treatment program.

52 (6) Random drug tests conducted by an opioid treatment program shall, at a minimum,
53 test for the following:

54 (A) Opiates, including oxycodone at common levels of dosing;

55 (B) Methadone and any other medication used by the program as an intervention;

56 (C) Benzodiazepine including diazepam, lorazepam, clonazepam and alprazolam;

57 (D) Cocaine;

58 (E) Methamphetamine or amphetamine;

59 (F) Tetrahydrocannabinol, delta-9-tetrahydrocannabinol or dronabinol or other similar
60 substances; or

61 (G) Other drugs determined by community standards, regional variation or clinical
62 indication.

63 (7) A positive drug test is a test that results in the presence of any drug or substance listed
64 in this schedule and any other drug or substance prohibited by the opioid treatment program. A
65 positive drug test result after the first six months in an opioid treatment program shall result in the
66 following:

67 (A) Upon the first positive drug test result, the opioid treatment program shall:

68 (1) Provide mandatory and documented weekly counseling of no less than thirty minutes
69 to the patient, which shall include weekly meetings with a counselor who is licensed, certified or
70 enrolled in the process of obtaining licensure or certification in compliance with the rules and on
71 staff at the opioid treatment program;

72 (2) Immediately revoke the take home methadone privilege for a minimum of thirty days;
73 and

74 (B) Upon a second positive drug test result within six months of a previous positive drug
75 test result, the opioid treatment program shall:

76 (1) Provide mandatory and documented weekly counseling of no less than thirty minutes,
77 which shall include weekly meetings with a counselor who is licensed, certified or enrolled in the
78 process of obtaining licensure or certification in compliance with the rules and on staff at the opioid
79 treatment program;

80 (2) Immediately revoke the take-home methadone privilege for a minimum of sixty days;
81 and

82 (3) Provide mandatory documented treatment team meetings with the patient.

83 (C) Upon a third positive drug test result within a period of six months the opioid treatment
84 program shall:

85 (1) Provide mandatory and documented weekly counseling of no less than thirty minutes,
86 which shall include weekly meetings with a counselor who is licensed, certified or enrolled in the
87 process of obtaining licensure or certification in compliance with the rules and on staff at the opioid
88 treatment program;

89 (2) Immediately revoke the take-home methadone privilege for a minimum of one hundred
90 twenty days; and

91 (3) Provide mandatory and documented treatment team meetings with the patient which
92 will include, at a minimum: The need for continuing treatment; a discussion of other treatment
93 alternatives; and the execution of a contract with the patient advising the patient of discharge for
94 continued positive drug tests.

95 (D) Upon a fourth positive drug test within a six-month period, the patient shall be
96 immediately discharged from the opioid treatment program or, at the option of the patient, shall
97 immediately be provided the opportunity to participate in a twenty-one day detoxification plan,
98 followed by immediate discharge from the opioid treatment program: *Provided*, That testing
99 positive solely for tetrahydrocannabinol, delta-9-tetrahydrocannabinol or dronabinol or similar
100 substances shall not serve as a basis for discharge from the program.

101 (8) Opioid treatment programs must report and provide statistics on a quarterly basis to
102 the Department of Health and Human Resources and to the Legislative Oversight Commission
103 on Health and Human Resources including:

104 (A) The total number of patients;

105 (B) The number of patients who have been continually receiving methadone treatment in
106 excess of two years, including the total number of months of treatment for each such patient;

107 (C) The state residency of each patient;

108 (D) The number of patients discharged from the program, including the total months in the
109 treatment program prior to discharge and whether the discharge was for:

- 110 (i) Termination or disqualification;
111 (ii) Completion of a program of detoxification;
112 (iii) Voluntary withdrawal prior to completion of all requirements of detoxification as
113 determined by the opioid treatment program;
114 (iv) Successful completion of the individualized treatment care plan; or
115 (v) An unexplained reason.
116 (E) Confirmation that the random drug tests were truly random in regard to both the
117 patients tested and to the times random drug tests were administered by lottery or some other
118 objective standard so as not to prejudice or protect any particular patient;
119 (F) Confirmation that the random drug tests were performed at least monthly for all
120 program participants;
121 (G) The total number and the number of positive results; and
122 (H) The number of expulsions from the program.
123 (9) Effective March 31, 2017, opioid treatment facilities shall be open for business seven
124 days per week; however, the opioid treatment center may be closed for eight holidays and two
125 training days per year. During all operating hours, opioid treatment programs shall have:
126 (A) An advanced practice registered nurse, certified as an addiction specialist or
127 equivalent certification that may be established by legislative rule, that is actively licensed in this
128 state present and on duty at the treatment center;
129 (B) A physician actively licensed in this state, present and on duty at the treatment center,
130 certified as an addictions specialist by the American Board of Addiction Medicine or a psychiatrist
131 certified by the American Board of Psychiatry and Neurology, or equivalent certification that may
132 be established by legislative rule, available for consultation; and
133 (C) A licensed professional counselor or licensed social worker certified as an addiction
134 specialist or equivalent certification that may be established by legislative rule, for each twenty-
135 five patients.

136 (10) An opioid treatment program shall provide a patient with an hour of individual
137 substance abuse counseling weekly.

138 (11) The Office of Health Facility Licensure and Certification shall develop policies and
139 procedures in conjunction with the Board of Pharmacy that will allow physicians treating patients
140 through an opioid treatment program access to the Controlled Substances Monitoring Program
141 database maintained by the Board of Pharmacy at the patients intake, before administration of
142 methadone or other treatment in an opioid treatment program, after the initial thirty days of
143 treatment, prior to any take-home medication being granted, after any positive drug test, and at
144 each ninety-day treatment review to ensure the patient is not seeking prescription medication
145 from multiple sources. The results obtained from the Controlled Substances Monitoring Program
146 database shall be maintained with the patient records.

147 (12) Opioid treatment programs shall establish a peer review committee, with at least one
148 physician member, to review whether the program is following guidelines established by a
149 nationally recognized authority approved by the secretary. The secretary shall prescribe the
150 procedure for evaluation by the peer review. Each opioid treatment program shall submit a report
151 of the peer review results to the secretary on a quarterly basis.

NOTE: The purpose of this bill is to provide a mechanism for methadone regulation and administering treatment and counseling to opioid addicted individuals. In furtherance of these objectives the bill contains provisions (1) requiring the secretary of Health and Human Resources to propose legislative rules for the regulation of opioid treatment programs; (2) requiring the Health Care Authority to develop new certificate of need standards; (3) prohibiting the Health Care Authority from approving applications of certificate of need for opioid treatment programs; (4) imposing a moratorium on licensure of certain new opioid treatment programs; (5) providing the secretary monitor opioid treatment programs; (6) requiring program staff to receive minimum training; (7) setting forth standards for initial assessment to admission to a program; (8) setting forth criteria to be admitted to a treatment program; (9) requiring a program to develop individualized treatment plans; (10) providing for random drug testing for program patients; (11) enunciating consequences for positive drug tests of patients in opioid treatment programs, including mandatory counseling; (12) requiring mandatory statistical reporting to the Department of Health and Human Resources and the Legislative Oversight Commission on Health and Human Resources; (13) prescribing times programs must be open; (14) setting forth certain staff requirements for programs; (15) requiring programs to establish peer review committees that include a physician member; and (16) requiring the secretary to prescribe the procedure for peer review.

Strike-throughs indicate language that would be stricken from a heading or the present law and underscoring indicates new language that would be added.