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SENATE BILL NO. 1226

Offered January 9, 2019

Prefiled January 4, 2019

A *BILL to amend and reenact §§ 32.1-111.1, 32.1-162.8, and 32.1-325 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 32.1-111.5:2, relating to community paramedics; licensure; services.*

 Patron—Chase

Referred to Committee on Education and Health

Be it enacted by the General Assembly of Virginia:

1. That §§ 32.1-111.1, 32.1-162.8, and 32.1-325 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding a section numbered 32.1-111.5:2 as follows:

§ 32.1-111.1. Definitions.

As used in this article:

"Advisory Board" means the State Emergency Medical Services Advisory Board.

"Automated external defibrillator" means a medical device which combines a heart monitor and defibrillator and (i) has been approved by the United States Food and Drug Administration, (ii) is capable of recognizing the presence or absence of ventricular fibrillation or rapid ventricular tachycardia, (iii) is capable of determining, without intervention by an operator, whether defibrillation should be performed, and (iv) automatically charges and requests delivery of an electrical impulse to an individual's heart, upon determining that defibrillation should be performed.

"Community paramedic" means a certified emergency medical services provider that is licensed by the Commissioner to practice as a community paramedic.

"Emergency medical services" or "EMS" means health care, public health, and public safety services used in the medical response to the real or perceived need for immediate medical assessment, care, or transportation and preventive care or transportation in order to prevent loss of life or aggravation of physiological or psychological illness or injury.

"Emergency medical services agency" or "EMS agency" means any person engaged in the business, service, or regular activity, whether for profit or not, of rendering immediate medical care and providing transportation to persons who are sick, injured, wounded, or otherwise incapacitated or helpless and that holds a valid license as an emergency medical services agency issued by the Commissioner in accordance with § 32.1-111.6.

"Emergency medical services personnel" or "EMS personnel" means individuals who are employed by or members of an emergency medical services agency and who provide emergency medical services pursuant to an emergency medical services agency license issued to that agency by the Commissioner and in accordance with the authorization of that agency's operational medical director.

"Emergency medical services physician" or "EMS physician" means a physician who holds a current endorsement from the Office of Emergency Medical Services (EMS) and may serve as an EMS agency operational medical director or training program physician course director.

"Emergency medical services provider" or "EMS provider" means any person who holds a valid certificate as an emergency medical services provider issued by the Commissioner.

"Emergency medical services system" or "EMS system" means the system of emergency medical services agencies, vehicles, equipment, and personnel; health care facilities; other health care and emergency services providers; and other components engaged in the planning, coordination, and delivery of emergency medical services in the Commonwealth, including individuals and facilities providing communication and other services necessary to facilitate the delivery of emergency medical services in the Commonwealth.

"Emergency medical services vehicle" means any vehicle, vessel, or aircraft that holds a valid emergency medical services vehicle permit issued by the Office of Emergency Medical Services that is equipped, maintained, or operated to provide emergency medical care or transportation of patients who are sick, injured, wounded, or otherwise incapacitated or helpless.

"Office of Emergency Medical Services" means the Office of Emergency Medical Services of the Department.

"Operational medical director" or "OMD" means an EMS physician, currently licensed to practice medicine or osteopathic medicine in the Commonwealth, who is formally recognized and responsible for providing medical direction, oversight, and quality improvement to an EMS agency.

§ 32.1-111.5:2. Community paramedic; licensure; practice.

59 A. The Board shall adopt regulations governing the practice of community paramedics. The
60 regulations shall (i) set forth the requirements for licensure to practice as a community paramedic, (ii)
61 provide for appropriate application and renewal fees, and (iii) include requirements for licensure
62 renewal and continuing education.

63 B. It shall be unlawful for a person to practice or hold himself out as a community paramedic
64 without a valid, unrevoked license issued by the Commissioner.

65 C. An applicant for licensure as a community paramedic shall submit evidence satisfactory to the
66 Commissioner that the applicant (i) is currently certified as an emergency medical services provider and
67 has been certified for at least three years, (ii) has successfully completed a community paramedic
68 training program that is approved by the Board or accredited by a Board-approved national
69 accreditation organization and that includes clinical experience provided under the supervision of a
70 physician or EMS agency, and (iii) has obtained Community Paramedic Certification from the
71 International Board of Specialty Certification.

72 D. A community paramedic shall practice in accordance with protocols and supervisory standards
73 established by an operational medical director. No community paramedic shall provide services except
74 as directed by a patient care plan developed by the patient's physician, nurse practitioner, or physician
75 assistant and approved by the community paramedic's supervising operational medical director.

76 E. A community paramedic is subject to all certification, recertification, disciplinary, complaint, and
77 other relevant regulations that apply to emergency medical services providers certified pursuant to this
78 article.

79 **§ 32.1-162.8. Exemptions from article.**

80 The provisions of this article shall not be applicable to:

81 1. A natural person who provides services to a patient or individual on an individual basis if such
82 person is (i) acting alone under a medical plan of care and is licensed to provide such services pursuant
83 to Title 54.1 or (ii) retained by the individual or by another individual acting on the individual's behalf.

84 2. Any organization providing only housekeeping, chore or beautician services.

85 3. Any home care organization located in the Commonwealth that after initial licensure is:

86 a. Certified by the Department of Health under provisions of Title XVIII or Title XIX of the Social
87 Security Act;

88 b. Accredited by any organization recognized by the Centers for Medicare and Medicaid Services for
89 the purposes of Medicare certification; or

90 c. Licensed for hospice services under Article 7 (§ 32.1-162.1 et seq.) of this chapter.

91 4. A community paramedic providing services in accordance with § 32.1-111.5:2 or his affiliated
92 licensed emergency medical services agency.

93 **§ 32.1-325. Board to submit plan for medical assistance services to U.S. Secretary of Health and**
94 **Human Services pursuant to federal law; administration of plan; contracts with health care**
95 **providers.**

96 A. The Board, subject to the approval of the Governor, is authorized to prepare, amend from time to
97 time, and submit to the U.S. Secretary of Health and Human Services a state plan for medical assistance
98 services pursuant to Title XIX of the United States Social Security Act and any amendments thereto.
99 The Board shall include in such plan:

100 1. A provision for payment of medical assistance on behalf of individuals, up to the age of 21,
101 placed in foster homes or private institutions by private, nonprofit agencies licensed as child-placing
102 agencies by the Department of Social Services or placed through state and local subsidized adoptions to
103 the extent permitted under federal statute;

104 2. A provision for determining eligibility for benefits for medically needy individuals which
105 disregards from countable resources an amount not in excess of \$3,500 for the individual and an amount
106 not in excess of \$3,500 for his spouse when such resources have been set aside to meet the burial
107 expenses of the individual or his spouse. The amount disregarded shall be reduced by (i) the face value
108 of life insurance on the life of an individual owned by the individual or his spouse if the cash surrender
109 value of such policies has been excluded from countable resources and (ii) the amount of any other
110 revocable or irrevocable trust, contract, or other arrangement specifically designated for the purpose of
111 meeting the individual's or his spouse's burial expenses;

112 3. A requirement that, in determining eligibility, a home shall be disregarded. For those medically
113 needy persons whose eligibility for medical assistance is required by federal law to be dependent on the
114 budget methodology for Aid to Families with Dependent Children, a home means the house and lot used
115 as the principal residence and all contiguous property. For all other persons, a home shall mean the
116 house and lot used as the principal residence, as well as all contiguous property, as long as the value of
117 the land, exclusive of the lot occupied by the house, does not exceed \$5,000. In any case in which the
118 definition of home as provided here is more restrictive than that provided in the state plan for medical
119 assistance services in Virginia as it was in effect on January 1, 1972, then a home means the house and
120 lot used as the principal residence and all contiguous property essential to the operation of the home

121 regardless of value;

122 4. A provision for payment of medical assistance on behalf of individuals up to the age of 21, who
123 are Medicaid eligible, for medically necessary stays in acute care facilities in excess of 21 days per
124 admission;

125 5. A provision for deducting from an institutionalized recipient's income an amount for the
126 maintenance of the individual's spouse at home;

127 6. A provision for payment of medical assistance on behalf of pregnant women which provides for
128 payment for inpatient postpartum treatment in accordance with the medical criteria outlined in the most
129 current version of or an official update to the "Guidelines for Perinatal Care" prepared by the American
130 Academy of Pediatrics and the American College of Obstetricians and Gynecologists or the "Standards
131 for Obstetric-Gynecologic Services" prepared by the American College of Obstetricians and
132 Gynecologists. Payment shall be made for any postpartum home visit or visits for the mothers and the
133 children which are within the time periods recommended by the attending physicians in accordance with
134 and as indicated by such Guidelines or Standards. For the purposes of this subdivision, such Guidelines
135 or Standards shall include any changes thereto within six months of the publication of such Guidelines
136 or Standards or any official amendment thereto;

137 7. A provision for the payment for family planning services on behalf of women who were
138 Medicaid-eligible for prenatal care and delivery as provided in this section at the time of delivery. Such
139 family planning services shall begin with delivery and continue for a period of 24 months, if the woman
140 continues to meet the financial eligibility requirements for a pregnant woman under Medicaid. For the
141 purposes of this section, family planning services shall not cover payment for abortion services and no
142 funds shall be used to perform, assist, encourage or make direct referrals for abortions;

143 8. A provision for payment of medical assistance for high-dose chemotherapy and bone marrow
144 transplants on behalf of individuals over the age of 21 who have been diagnosed with lymphoma, breast
145 cancer, myeloma, or leukemia and have been determined by the treating health care provider to have a
146 performance status sufficient to proceed with such high-dose chemotherapy and bone marrow transplant.
147 Appeals of these cases shall be handled in accordance with the Department's expedited appeals process;

148 9. A provision identifying entities approved by the Board to receive applications and to determine
149 eligibility for medical assistance, which shall include a requirement that such entities (i) obtain accurate
150 contact information, including the best available address and telephone number, from each applicant for
151 medical assistance, to the extent required by federal law and regulations, and (ii) provide each applicant
152 for medical assistance with information about advance directives pursuant to Article 8 (§ 54.1-2981 et
153 seq.) of Chapter 29 of Title 54.1, including information about the purpose and benefits of advance
154 directives and how the applicant may make an advance directive;

155 10. A provision for breast reconstructive surgery following the medically necessary removal of a
156 breast for any medical reason. Breast reductions shall be covered, if prior authorization has been
157 obtained, for all medically necessary indications. Such procedures shall be considered noncosmetic;

158 11. A provision for payment of medical assistance for annual pap smears;

159 12. A provision for payment of medical assistance services for prostheses following the medically
160 necessary complete or partial removal of a breast for any medical reason;

161 13. A provision for payment of medical assistance which provides for payment for 48 hours of
162 inpatient treatment for a patient following a radical or modified radical mastectomy and 24 hours of
163 inpatient care following a total mastectomy or a partial mastectomy with lymph node dissection for
164 treatment of disease or trauma of the breast. Nothing in this subdivision shall be construed as requiring
165 the provision of inpatient coverage where the attending physician in consultation with the patient
166 determines that a shorter period of hospital stay is appropriate;

167 14. A requirement that certificates of medical necessity for durable medical equipment and any
168 supporting verifiable documentation shall be signed, dated, and returned by the physician, physician
169 assistant, or nurse practitioner and in the durable medical equipment provider's possession within 60
170 days from the time the ordered durable medical equipment and supplies are first furnished by the
171 durable medical equipment provider;

172 15. A provision for payment of medical assistance to (i) persons age 50 and over and (ii) persons
173 age 40 and over who are at high risk for prostate cancer, according to the most recent published
174 guidelines of the American Cancer Society, for one PSA test in a 12-month period and digital rectal
175 examinations, all in accordance with American Cancer Society guidelines. For the purpose of this
176 subdivision, "PSA testing" means the analysis of a blood sample to determine the level of prostate
177 specific antigen;

178 16. A provision for payment of medical assistance for low-dose screening mammograms for
179 determining the presence of occult breast cancer. Such coverage shall make available one screening
180 mammogram to persons age 35 through 39, one such mammogram biennially to persons age 40 through
181 49, and one such mammogram annually to persons age 50 and over. The term "mammogram" means an

182 X-ray examination of the breast using equipment dedicated specifically for mammography, including but
183 not limited to the X-ray tube, filter, compression device, screens, film and cassettes, with an average
184 radiation exposure of less than one rad mid-breast, two views of each breast;

185 17. A provision, when in compliance with federal law and regulation and approved by the Centers
186 for Medicare & Medicaid Services (CMS), for payment of medical assistance services delivered to
187 Medicaid-eligible students when such services qualify for reimbursement by the Virginia Medicaid
188 program and may be provided by school divisions;

189 18. A provision for payment of medical assistance services for liver, heart and lung transplantation
190 procedures for individuals over the age of 21 years when (i) there is no effective alternative medical or
191 surgical therapy available with outcomes that are at least comparable; (ii) the transplant procedure and
192 application of the procedure in treatment of the specific condition have been clearly demonstrated to be
193 medically effective and not experimental or investigational; (iii) prior authorization by the Department of
194 Medical Assistance Services has been obtained; (iv) the patient selection criteria of the specific
195 transplant center where the surgery is proposed to be performed have been used by the transplant team
196 or program to determine the appropriateness of the patient for the procedure; (v) current medical therapy
197 has failed and the patient has failed to respond to appropriate therapeutic management; (vi) the patient is
198 not in an irreversible terminal state; and (vii) the transplant is likely to prolong the patient's life and
199 restore a range of physical and social functioning in the activities of daily living;

200 19. A provision for payment of medical assistance for colorectal cancer screening, specifically
201 screening with an annual fecal occult blood test, flexible sigmoidoscopy or colonoscopy, or in
202 appropriate circumstances radiologic imaging, in accordance with the most recently published
203 recommendations established by the American College of Gastroenterology, in consultation with the
204 American Cancer Society, for the ages, family histories, and frequencies referenced in such
205 recommendations;

206 20. A provision for payment of medical assistance for custom ocular prostheses;

207 21. A provision for payment for medical assistance for infant hearing screenings and all necessary
208 audiological examinations provided pursuant to § 32.1-64.1 using any technology approved by the
209 United States Food and Drug Administration, and as recommended by the national Joint Committee on
210 Infant Hearing in its most current position statement addressing early hearing detection and intervention
211 programs. Such provision shall include payment for medical assistance for follow-up audiological
212 examinations as recommended by a physician, physician assistant, nurse practitioner, or audiologist and
213 performed by a licensed audiologist to confirm the existence or absence of hearing loss;

214 22. A provision for payment of medical assistance, pursuant to the Breast and Cervical Cancer
215 Prevention and Treatment Act of 2000 (P.L. 106-354), for certain women with breast or cervical cancer
216 when such women (i) have been screened for breast or cervical cancer under the Centers for Disease
217 Control and Prevention (CDC) Breast and Cervical Cancer Early Detection Program established under
218 Title XV of the Public Health Service Act; (ii) need treatment for breast or cervical cancer, including
219 treatment for a precancerous condition of the breast or cervix; (iii) are not otherwise covered under
220 creditable coverage, as defined in § 2701 (c) of the Public Health Service Act; (iv) are not otherwise
221 eligible for medical assistance services under any mandatory categorically needy eligibility group; and
222 (v) have not attained age 65. This provision shall include an expedited eligibility determination for such
223 women;

224 23. A provision for the coordinated administration, including outreach, enrollment, re-enrollment and
225 services delivery, of medical assistance services provided to medically indigent children pursuant to this
226 chapter, which shall be called Family Access to Medical Insurance Security (FAMIS) Plus and the
227 FAMIS Plan program in § 32.1-351. A single application form shall be used to determine eligibility for
228 both programs;

229 24. A provision, when authorized by and in compliance with federal law, to establish a public-private
230 long-term care partnership program between the Commonwealth of Virginia and private insurance
231 companies that shall be established through the filing of an amendment to the state plan for medical
232 assistance services by the Department of Medical Assistance Services. The purpose of the program shall
233 be to reduce Medicaid costs for long-term care by delaying or eliminating dependence on Medicaid for
234 such services through encouraging the purchase of private long-term care insurance policies that have
235 been designated as qualified state long-term care insurance partnerships and may be used as the first
236 source of benefits for the participant's long-term care. Components of the program, including the
237 treatment of assets for Medicaid eligibility and estate recovery, shall be structured in accordance with
238 federal law and applicable federal guidelines; and

239 25. A provision for the payment of medical assistance for otherwise eligible pregnant women during
240 the first five years of lawful residence in the United States, pursuant to § 214 of the Children's Health
241 Insurance Program Reauthorization Act of 2009 (P.L. 111-3).

242 26. *A provision for the payment of medical assistance for home health services provided by a*
243 *certified community paramedic in accordance with § 32.1-111.5:2 and exempt from licensure as a home*

health organization pursuant to subdivision 4 of § 32.1-168.2.

B. In preparing the plan, the Board shall:

1. Work cooperatively with the State Board of Health to ensure that quality patient care is provided and that the health, safety, security, rights and welfare of patients are ensured.

2. Initiate such cost containment or other measures as are set forth in the appropriation act.

3. Make, adopt, promulgate and enforce such regulations as may be necessary to carry out the provisions of this chapter.

4. Examine, before acting on a regulation to be published in the Virginia Register of Regulations pursuant to § 2.2-4007.05, the potential fiscal impact of such regulation on local boards of social services. For regulations with potential fiscal impact, the Board shall share copies of the fiscal impact analysis with local boards of social services prior to submission to the Registrar. The fiscal impact analysis shall include the projected costs/savings to the local boards of social services to implement or comply with such regulation and, where applicable, sources of potential funds to implement or comply with such regulation.

5. Incorporate sanctions and remedies for certified nursing facilities established by state law, in accordance with 42 C.F.R. § 488.400 et seq. "Enforcement of Compliance for Long-Term Care Facilities With Deficiencies."

6. On and after July 1, 2002, require that a prescription benefit card, health insurance benefit card, or other technology that complies with the requirements set forth in § 38.2-3407.4:2 be issued to each recipient of medical assistance services, and shall upon any changes in the required data elements set forth in subsection A of § 38.2-3407.4:2, either reissue the card or provide recipients such corrective information as may be required to electronically process a prescription claim.

C. In order to enable the Commonwealth to continue to receive federal grants or reimbursement for medical assistance or related services, the Board, subject to the approval of the Governor, may adopt, regardless of any other provision of this chapter, such amendments to the state plan for medical assistance services as may be necessary to conform such plan with amendments to the United States Social Security Act or other relevant federal law and their implementing regulations or constructions of these laws and regulations by courts of competent jurisdiction or the United States Secretary of Health and Human Services.

In the event conforming amendments to the state plan for medical assistance services are adopted, the Board shall not be required to comply with the requirements of Article 2 (§ 2.2-4006 et seq.) of Chapter 40 of Title 2.2. However, the Board shall, pursuant to the requirements of § 2.2-4002, (i) notify the Registrar of Regulations that such amendment is necessary to meet the requirements of federal law or regulations or because of the order of any state or federal court, or (ii) certify to the Governor that the regulations are necessitated by an emergency situation. Any such amendments that are in conflict with the Code of Virginia shall only remain in effect until July 1 following adjournment of the next regular session of the General Assembly unless enacted into law.

D. The Director of Medical Assistance Services is authorized to:

1. Administer such state plan and receive and expend federal funds therefor in accordance with applicable federal and state laws and regulations; and enter into all contracts necessary or incidental to the performance of the Department's duties and the execution of its powers as provided by law.

2. Enter into agreements and contracts with medical care facilities, physicians, dentists and other health care providers where necessary to carry out the provisions of such state plan. Any such agreement or contract shall terminate upon conviction of the provider of a felony. In the event such conviction is reversed upon appeal, the provider may apply to the Director of Medical Assistance Services for a new agreement or contract. Such provider may also apply to the Director for reconsideration of the agreement or contract termination if the conviction is not appealed, or if it is not reversed upon appeal.

3. Refuse to enter into or renew an agreement or contract, or elect to terminate an existing agreement or contract, with any provider who has been convicted of or otherwise pled guilty to a felony, or pursuant to Subparts A, B, and C of 42 C.F.R. Part 1002, and upon notice of such action to the provider as required by 42 C.F.R. § 1002.212.

4. Refuse to enter into or renew an agreement or contract, or elect to terminate an existing agreement or contract, with a provider who is or has been a principal in a professional or other corporation when such corporation has been convicted of or otherwise pled guilty to any violation of § 32.1-314, 32.1-315, 32.1-316, or 32.1-317, or any other felony or has been excluded from participation in any federal program pursuant to 42 C.F.R. Part 1002.

5. Terminate or suspend a provider agreement with a home care organization pursuant to subsection E of § 32.1-162.13.

6. (Expires January 1, 2020) Provide payments or transfers pursuant to § 457 of the Internal Revenue Code to the deferred compensation plan described in § 51.1-602 on behalf of an individual who is a dentist or an oral and maxillofacial surgeon providing services as an independent contractor pursuant to

305 a Medicaid agreement or contract under this section. Notwithstanding the provisions of § 51.1-600, an
306 "employee" for purposes of Chapter 6 (§ 51.1-600 et seq.) of Title 51.1 shall include an independent
307 contractor as described in this subdivision.

308 For the purposes of this subsection, "provider" may refer to an individual or an entity.

309 E. In any case in which a Medicaid agreement or contract is terminated or denied to a provider
310 pursuant to subsection D, the provider shall be entitled to appeal the decision pursuant to 42 C.F.R.
311 § 1002.213 and to a post-determination or post-denial hearing in accordance with the Administrative
312 Process Act (§ 2.2-4000 et seq.). All such requests shall be in writing and be received within 15 days of
313 the date of receipt of the notice.

314 The Director may consider aggravating and mitigating factors including the nature and extent of any
315 adverse impact the agreement or contract denial or termination may have on the medical care provided
316 to Virginia Medicaid recipients. In cases in which an agreement or contract is terminated pursuant to
317 subsection D, the Director may determine the period of exclusion and may consider aggravating and
318 mitigating factors to lengthen or shorten the period of exclusion, and may reinstate the provider pursuant
319 to 42 C.F.R. § 1002.215.

320 F. When the services provided for by such plan are services which a marriage and family therapist,
321 clinical psychologist, clinical social worker, professional counselor, or clinical nurse specialist is licensed
322 to render in Virginia, the Director shall contract with any duly licensed marriage and family therapist,
323 duly licensed clinical psychologist, licensed clinical social worker, licensed professional counselor or
324 licensed clinical nurse specialist who makes application to be a provider of such services, and thereafter
325 shall pay for covered services as provided in the state plan. The Board shall promulgate regulations
326 which reimburse licensed marriage and family therapists, licensed clinical psychologists, licensed clinical
327 social workers, licensed professional counselors and licensed clinical nurse specialists at rates based
328 upon reasonable criteria, including the professional credentials required for licensure.

329 G. The Board shall prepare and submit to the Secretary of the United States Department of Health
330 and Human Services such amendments to the state plan for medical assistance services as may be
331 permitted by federal law to establish a program of family assistance whereby children over the age of 18
332 years shall make reasonable contributions, as determined by regulations of the Board, toward the cost of
333 providing medical assistance under the plan to their parents.

334 H. The Department of Medical Assistance Services shall:

335 1. Include in its provider networks and all of its health maintenance organization contracts a
336 provision for the payment of medical assistance on behalf of individuals up to the age of 21 who have
337 special needs and who are Medicaid eligible, including individuals who have been victims of child abuse
338 and neglect, for medically necessary assessment and treatment services, when such services are delivered
339 by a provider which specializes solely in the diagnosis and treatment of child abuse and neglect, or a
340 provider with comparable expertise, as determined by the Director.

341 2. Amend the Medallion II waiver and its implementing regulations to develop and implement an
342 exception, with procedural requirements, to mandatory enrollment for certain children between birth and
343 age three certified by the Department of Behavioral Health and Developmental Services as eligible for
344 services pursuant to Part C of the Individuals with Disabilities Education Act (20 U.S.C. § 1471 et seq.).

345 3. Utilize, to the extent practicable, electronic funds transfer technology for reimbursement to
346 contractors and enrolled providers for the provision of health care services under Medicaid and the
347 Family Access to Medical Insurance Security Plan established under § 32.1-351.

348 I. The Director is authorized to negotiate and enter into agreements for services rendered to eligible
349 recipients with special needs. The Board shall promulgate regulations regarding these special needs
350 patients, to include persons with AIDS, ventilator-dependent patients, and other recipients with special
351 needs as defined by the Board.

352 J. Except as provided in subdivision A 1 of § 2.2-4345, the provisions of the Virginia Public
353 Procurement Act (§ 2.2-4300 et seq.) shall not apply to the activities of the Director authorized by
354 subsection I of this section. Agreements made pursuant to this subsection shall comply with federal law
355 and regulation.