LEGISLATIVE ACTION

Senate Comm: RCS 02/20/2024 House

The Appropriations Committee on Agriculture, Environment, and General Government (Perry) recommended the following:

## Senate Amendment

Delete lines 163 - 576

and insert:

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means either:

(a) An application pursuant to 21 U.S.C. s. 387j for a nicotine dispensing device containing or utilizing nicotine derived from tobacco marketed in the United States as of August 8, 2016, which was submitted to the FDA on or before September 9, 2020, and accepted for filing; or

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11	(b) An application pursuant to 21 U.S.C. s. 387j for a
12	nicotine dispensing device containing or utilizing nicotine
13	derived from a non-tobacco source that is not a single use or
14	disposable electronic cigarette, an electronic cigar, an
15	electronic cigarillo, an electronic pipe, or other similar
16	device and that does not use a sealed, prefilled, and disposable
17	cartridge of nicotine in a solution.
18	(14) "Wholesale nicotine products dealer" means the holder
19	of a wholesale nicotine products dealer permit who purchases
20	nicotine dispensing devices or nicotine products from any
21	nicotine product manufacturer.
22	(15) "Wholesale nicotine products dealer permit" means a
23	permit issued by the division under s. 569.316.
24	(1) (9) "Any person under the age of 21" does not include
25	any person under the age of 21 who:
26	(a) Is in the military reserve or on active duty in the
27	Armed Forces of the United States; or
28	(b) Is acting in his or her scope of lawful employment.
29	Section 2. Section 569.311, Florida Statutes, is created to
30	read:
31	569.311 Nicotine dispensing device directory
32	(1) By December 1, 2024, and annually thereafter, every
33	nicotine product manufacturer that sells nicotine dispensing
34	devices to any person for eventual retail sale in this state
35	shall execute and deliver a form, prescribed by the division,
36	under penalty of perjury for each such nicotine dispensing
37	device sold that meets either of the following criteria:
38	(a) The manufacturer of a nicotine dispensing device has
39	submitted a timely filed premarket tobacco product application

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40	for the nicotine dispensing device pursuant to 21 U.S.C. s. 387j
41	and remains stayed by a court order, or the manufacturer has
42	filed a timely request for supervisory review with the FDA which
43	remains under review, or the order has been rescinded by the FDA
44	or vacated by a court; or
45	(b) The nicotine product manufacturer has received a
46	marketing granted order under 21 U.S.C. s. 387j for the nicotine
47	dispensing device from the FDA.
48	(2) The form prescribed by the division pursuant to
49	subsection (1) must require each nicotine product manufacturer
50	to set forth the name under which the nicotine product
51	manufacturer transacts or intends to transact business, the
52	address of the location of the nicotine product manufacturer's
53	principal place of business, the nicotine product manufacturer's
54	e-mail address, and the brand name of the nicotine dispensing
55	device, the device's category (e.g., e-liquid, power unit,
56	device, e-liquid cartridge, e-liquid pod, disposable), the
57	device's name, and any flavor utilized with the device that is
58	sold in this state. The division may allow a nicotine product
59	manufacturer to group its nicotine dispensing devices on its
60	certification.
61	(3) In addition to completing the form prescribed by the
62	division pursuant to subsection (1), each nicotine product
63	manufacturer shall provide a copy of the cover page of the
64	granted marketing order issued by the FDA pursuant to 21 U.S.C.
65	s. 387j for each device; a copy of the acceptance letter issued
66	by the FDA pursuant to 21 U.S.C. s. 387j for a timely filed
67	premarket tobacco product application for each device; or a
68	document issued by the FDA or by a court confirming that the

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69	premarket tobacco product application has been received and
70	denied, but the order is not yet in effect for each device.
71	(4) Any nicotine product manufacturer submitting a
72	certification pursuant to subsection (1) shall notify the
73	division within 30 days after any material change to the
74	certification, including, but not limited to, issuance by the
75	FDA of any of the following:
76	(a) A denial of a market authorization pursuant to 21
77	U.S.C. s. 387j;
78	(b) An order requiring a nicotine product manufacturer to
79	remove a nicotine dispensing device or nicotine product from the
80	market either temporarily or permanently;
81	(c) Any notice of action taken by the FDA affecting the
82	ability of the nicotine dispensing device to be introduced or
83	delivered in this state for commercial distribution;
84	(d) Any change in policy which results in a nicotine
85	dispensing device becoming an FDA enforcement priority; or
86	(e) Any other change deemed material by the division
87	pursuant to a rule of the division.
88	(5) The division shall develop and maintain a directory
89	listing all nicotine product manufacturers that sell nicotine
90	dispensing devices in this state and the nicotine dispensing
91	devices certified by those manufacturers with the division which
92	comply with this section. The division shall make the directory
93	available January 1, 2025, on its or the Department of Business
94	and Professional Regulation's website. The division shall update
95	the directory as necessary. The division shall establish a
96	process to provide retailers, distributors, and wholesalers
97	notice of the initial publication of the directory and changes
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made to the directory in the prior month.	
(6) The division shall establish by rule a process to	
provide a nicotine product manufacturer notice and an	
opportunity to cure deficiencies before removing the	
manufacturer or any of its nicotine dispensing devices from t	he
directory.	
(a) The division may not remove the nicotine product	
manufacturer or any of its nicotine dispensing devices from t	he
directory until at least 30 days after the nicotine product	
manufacturer has been given notice of an intended action. Not	ice
is sufficient and deemed immediately received by a nicotine	
product manufacturer if the notice is sent either electronica	ully
or by facsimile to an e-mail address or facsimile number	
provided by the nicotine product manufacturer in its most red	ent
certification filed under subsection (1).	
(b) The nicotine product manufacturer has 15 days from t	he
date of service of the notice of the division's intended acti	on
to establish that the nicotine product manufacturer or any of	-
its nicotine dispensing devices must be included on the	
directory.	
(c) A determination by the division not to include or no	)t
to remove a nicotine product manufacturer or nicotine dispens	sing
device from the directory is subject to review under chapter	
120. If a nicotine product manufacturer seeks review of remov	<u>ral</u>
from the directory, the division must keep the nicotine	
dispensing device on the directory until entry of a final ord	ler.
(d) If a nicotine dispensing device is removed from the	
directory, each retailer and each wholesaler holding nicotine	<u>}</u>
dispensing devices for eventual sale to a consumer in this st	ate

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127	has 30 days from the day such product is removed from the
128	directory to sell the product or remove the product from its
129	inventory. After 30 days following removal from the directory,
130	the product identified in the notice of removal is contraband
131	and subject to s. 569.345.
132	(7)(a) Except as provided in subsections (b) and (c),
133	beginning March 1, 2025, or on the date that the division first
134	makes the directory available for public inspection on its or
135	the Department of Business and Professional Regulation's
136	website, whichever is later, a nicotine product manufacturer
137	that offers for sale in this state a nicotine dispensing device
138	not listed on the directory is subject to a fine of \$1,000 per
139	day for each individual nicotine dispensing device offered for
140	sale in violation of this section until the offending product is
141	removed from the market or until the offending product is
142	properly listed on the directory.
143	(b) Each retailer shall have 60 days from the date that the
144	division first makes the directory available for inspection on
145	its public website to sell products that were in its inventory
146	and not included on the directory or remove those products from
147	inventory.
148	(c) Each distributor or wholesaler shall have 60 days from
149	the date that the division first makes the directory available
150	for inspection on its public website to remove from inventory
151	those products intended for eventual retail sale to a consumer
152	in this state.
153	(8) A nicotine product manufacturer that falsely represents
154	any of the information required by subsection (1) or subsection
155	(2) commits a felony of the third degree for each false

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156 representation, punishable as provided in s. 775.082 or s. 157 775.083.

158 (9) Each retail nicotine products dealer and wholesale 159 nicotine products dealer is subject to unannounced inspections 160 or audit checks by the division for purposes of enforcing this 161 section. The division shall conduct unannounced follow-up 162 compliance checks of all noncompliant retail nicotine products 163 dealers or wholesale nicotine products dealers within 30 days 164 after any violation of this section. The division shall publish 165 the results of all inspections or audits at least annually and 166 shall make the results available to the public on request. 167 (10) The division may establish by rule a procedure to 168 allow nicotine product manufacturers to renew certifications 169 without having to resubmit all the information required by this 170 section. 171 (11) The failure of a nicotine product manufacturer to provide information or documents required by this section may 172 173 result in a nicotine dispensing device not being included on the 174 directory or the removal of a nicotine dispensing device from 175 the directory. The division may assess an administrative fine of 176 up to \$1,000 for each nicotine dispensing device offered for 177 sale in this state if a nicotine product manufacturer fails to 178 provide notice to the division of a material change to its 179 certification within 30 days after that material change. The 180 division shall deposit all fines collected into the General 181 Revenue Fund. An order imposing an administrative fine becomes 182 effective 15 days after the date of the order.

183 Section 3. Section 569.312, Florida Statutes, is created to 184 read:

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185 569.312 Maintenance and inspection of nicotine dispensing 186 device records.-(1) Each nicotine product manufacturer that sells nicotine 187 188 dispensing devices in this state shall maintain and keep for a 189 period of 3 years, at the address listed on the certification 190 required pursuant to s. 569.311, a complete and accurate record 191 of the number of nicotine dispensing devices sold or delivered 192 to a wholesaler in this state and to which each nicotine dispensing device was sold on a wholesale basis, including the 193 194 business name, license number, shipping and business addresses, 195 e-mail address, and telephone number for the person or entity to which each product was sold. Such records may be kept in an 196 197 electronic or paper format. 198 (2) Each retail nicotine products dealer; wholesale 199 nicotine product dealer; wholesale dealer, as defined in s. 200 210.01(6); and distributing agent, as defined in s. 210.01(14), 201 shall maintain and keep for a period of 3 years at its principal 202 place of business a complete and accurate record of the quantity 203 of each nicotine dispensing device received, delivered, or sold 204 in this state and to which each nicotine dispensing device was 205 sold or delivered or from which the business received each 206 nicotine dispensing device, including the business name, license 207 number, shipping and business addresses, e-mail address, and 2.08 telephone number for the person or entity to which each product 209 was sold or delivered or from which each product was received. 210 Such records may be kept in an electronic or paper format. 211 (3) Nicotine product manufacturers that sell nicotine 212 dispensing devices in this state; retail nicotine products 213 dealers; wholesale nicotine products dealers; wholesale dealers,

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214 as defined in s. 210.01(6); and distributing agents, as defined 215 in s. 210.01(14), who sell or deliver nicotine dispensing 216 devices directly to consumers are not required to keep and 217 maintain the name, address, e-mail address, and telephone number 218 of consumers who purchase or receive nicotine dispensing 219 devices. 220 (4) Within 7 calendar days after receiving a request by the 221 division, a nicotine product manufacturer that sells nicotine 2.2.2 dispensing devices in this state, including a manufacturer 223 selling nicotine dispensing devices directly to consumers; a 224 retail nicotine products dealer; a wholesale nicotine products 225 dealer; a wholesale dealer, as defined in s. 210.01(6); and a distributing agent, as defined in s. 210.01(14), shall provide 226 227 to the division or its duly authorized representative copies of 228 records related to the nicotine dispensing devices received, 229 delivered, or sold in this state and to which those nicotine 230 dispensing devices were sold or delivered or from which they 231 were received. 232 (5) The division, or a designated employee thereof, may 233 examine the records required to be maintained by each nicotine 234 product manufacturer, retail nicotine products dealer, wholesale 235 nicotine products dealer, wholesale dealer, as defined in s. 236 210.01(6), and distributing agent, as defined in s. 210.01(14); 2.37 issue subpoenas to such persons or entities; administer oaths; 238 and take depositions of witnesses within or outside of this 239 state. The civil law of this state regarding enforcing obedience 240 to a subpoena lawfully issued by a judge or other person duly 241 authorized to issue subpoenas under the laws of this state in civil cases applies to a subpoena issued by the division, or any 242

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243	designated employee thereof. The subpoena may be enforced by
244	writ of attachment issued by the division, or any designated
245	employee, for such witness to compel him or her to appear before
246	the division, or any designated employee, and give his or her
247	testimony and to bring and produce such records as may be
248	required for examination. The division, or any designated
249	employee, may bring an action against a witness who refuses to
250	appear or give testimony by citation before the circuit court,
251	which shall punish such witness for contempt as in cases of
252	refusal to obey the orders and process of the circuit court. The
253	division may in such cases pay such attendance and mileage fees
254	as are permitted to be paid to witnesses in civil cases
255	appearing before the circuit court.
256	(6) The division may assess an administrative fine of up to
257	\$1,000 for each violation of this section. The division shall
258	deposit all fines collected into the General Revenue Fund. An
259	order imposing an administrative fine becomes effective 15 days
260	after the date of the order.
261	Section 4. Section 569.313, Florida Statutes, is created to
262	read:
263	569.313 Shipment of unregistered nicotine dispensing
264	devices sold for retail sale in this state
265	(1) A nicotine product manufacturer may not sell, ship, or
266	otherwise distribute a nicotine dispensing device in this state
267	for eventual retail sale to a consumer in this state for which:
268	(a) The FDA has entered an order requiring the nicotine
269	product manufacturer to remove the product from the market
270	either temporarily or permanently, which order has not been
271	stayed by the FDA or a court of competent jurisdiction;

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272	(b) The nicotine product manufacturer has not submitted a
273	timely filed premarket tobacco product application for the
274	nicotine dispensing device;
275	(c) The nicotine product manufacturer's timely filed
276	premarket tobacco product application for the nicotine
277	dispensing device is no longer pending because it was not
278	accepted by the FDA, it was denied by the FDA, or it is subject
279	to any other order or action by the FDA or any court that
280	negatively affects the ability of the product to be introduced
281	or delivered into interstate commerce for commercial
282	distribution in the United States; or
283	(d) The nicotine product manufacturer has not submitted the
284	certification required under this chapter for any of the
285	nicotine dispensing devices intended for eventual retail sale to
286	a consumer in this state.
287	(2) Any person who knowingly ships or receives nicotine
288	dispensing devices in violation of this section commits a
289	misdemeanor of the first degree, punishable as provided in s.
290	775.082 or s. 775.083.
291	(3) The division may also assess an administrative fine of
292	up to \$5,000 for each violation. The division shall deposit all
293	fines collected into the General Revenue Fund. An order imposing
294	an administrative fine becomes effective 15 days after the date
295	of the order.
296	Section 5. Section 569.316, Florida Statutes, is created to
297	read:
298	569.316 Wholesale nicotine products dealer permits;
299	application; qualifications; renewal; duplicates
300	(1) (a) Each person, firm, association, or corporation that

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301 seeks to deal, at wholesale, in nicotine products that will be sold at retail within this state, or to sell nicotine products 302 303 or nicotine dispensing devices to any retail nicotine products 304 dealer who intends to sell those nicotine products in this 305 state, must obtain a wholesale nicotine products dealer permit 306 for each place of business or premises at which nicotine 307 products are sold. 308 (b) Application for a wholesale nicotine products dealer 309 permit must be made on a form furnished by the division and must 310 set forth the name under which the applicant transacts or 311 intends to transact business, the address of the location of the 312 applicant's place of business, the applicant's e-mail address, 313 and any other information the division requires. If the 314 applicant has or intends to have more than one place of business 315 dealing in nicotine products or nicotine dispensing devices, a 316 separate application must be made for each place of business. If 317 the applicant is a firm or an association, the application must set forth the names, e-mail addresses, and addresses of the 318 persons constituting the firm or association. If the applicant 319 320 is a corporation, the application must set forth the names, e-321 mail addresses, and addresses of the principal officers of the 322 corporation. The application must also set forth any other 323 information prescribed by the division for the purpose of 324 identifying the applicant firm, association, or corporation. The 325 application must be signed and verified by oath or affirmation 326 by the owner, if a sole proprietor; if the owner is a firm, 327 association, or partnership, by the members or partners thereof; 328 or, if the owner is a corporation, by an executive officer of 329 the corporation or by a person authorized by the corporation to

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330 sign the application, together with the written evidence of this 331 authority. (2) (a) Wholesale nicotine products dealer permits may be 332 333 issued only to persons who are 21 years of age or older or to 334 corporations the officers of which are 21 years of age or older. 335 (b) The division may refuse to issue a wholesale nicotine 336 products dealer permit to any person, firm, association, or 337 corporation whose permit has been revoked by any jurisdiction; 338 to any corporation an officer of which has had such permit 339 revoked by any jurisdiction; or to any person who is or has been 340 an officer of a corporation whose permit has been revoked by any 341 jurisdiction. The division must revoke any wholesale nicotine 342 products dealer permit issued to a firm, an association, or a 343 corporation prohibited from obtaining such permit under this 344 chapter. 345 (3) Upon approval of an application for a wholesale nicotine products dealer permit, the division shall issue to the 346 347 applicant a wholesale nicotine products dealer permit for the place of business or premises specified in the application. A 348 349 wholesale nicotine products dealer permit is not assignable and 350 is valid only for the person in whose name the wholesale 351 nicotine products dealer permit is issued and for the place 352 designated in the wholesale nicotine products dealer permit. The 353 wholesale nicotine products dealer permit must be conspicuously 354 displayed at all times at the place for which it is issued. 355 (4) A wholesale dealer, as defined in s. 210.01(6), or a 356 distributing agent, as defined in s. 210.01(14), is not required 357 to have a separate or additional wholesale nicotine products 358 dealer permit to deal, at wholesale, in nicotine dispensing

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359	devices within this state. A wholesale dealer, as defined in s.
360	210.01(6), a distributing agent, as defined in s. 210.01(14), or
361	a tobacco products distributor, as defined in s. 210.25(5),
362	which deals, at wholesale, in nicotine dispensing devices is
363	subject to, and must be in compliance with, this chapter.
364	Section 6. Section 569.317, Florida Statutes, is created to
365	read:
366	569.317 Wholesale nicotine products dealer permitholder;
367	administrative penaltiesA wholesale nicotine products dealer
368	permitholder may only purchase and sell for retail sale in this
369	state nicotine dispensing devices contained on the directory
370	created by the division pursuant to s. 569.311. The division may
371	suspend or revoke the wholesale nicotine products dealer permit
372	of a wholesale nicotine products dealer permitholder upon
373	sufficient cause appearing of a violation of this part by a
374	wholesale nicotine products dealer permitholder or its agent or
375	employee. The division may also assess an administrative fine of
376	up to \$5,000 for each violation. The division shall deposit all
377	fines collected into the General Revenue Fund. An order imposing
378	an administrative fine becomes effective 15 days after the date
379	of the order. The division may suspend the imposition of a
380	penalty against a wholesale nicotine products dealer
381	permitholder, conditioned upon compliance with terms the
382	division considers appropriate.
383	Section 7. Section 569.32, Florida Statutes, is amended to
384	read:
385	569.32 Retail nicotine products dealer permits;
386	application; qualifications; renewal; duplicates
387	(1)(a) Each person, firm, association, or corporation that

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388 seeks to deal, at retail, in nicotine products or nicotine 389 dispensing devices within this the state, or to allow a nicotine 390 products vending machine to be located on its premises in this 391 the state, must obtain a retail nicotine products dealer permit 392 for each place of business or premises at which nicotine 393 products or nicotine dispensing devices are sold. Each dealer 394 owning, leasing, furnishing, or operating vending machines 395 through which nicotine products are sold must obtain a permit 396 for each machine and shall post the permit in a conspicuous 397 place on or near the machine; however, if the dealer has more 398 than one vending machine at a single location or if nicotine 399 products or nicotine dispensing devices are sold both over the 400 counter and through a vending machine at a single location, the 401 dealer need obtain only one permit for that location.

402 (b) Application for a permit must be made on a form 403 furnished by the division and must set forth the name under 404 which the applicant transacts or intends to transact business, 405 the address of the location of the applicant's place of business 406 within this the state, and any other information the division 407 requires. If the applicant has or intends to have more than one 408 place of business dealing in nicotine products or nicotine 409 dispensing devices within this the state, a separate application 410 must be made for each place of business. If the applicant is a 411 firm or an association, the application must set forth the names 412 and addresses of the persons constituting the firm or 413 association; if the applicant is a corporation, the application 414 must set forth the names and addresses of the principal officers 415 of the corporation. The application must also set forth any other information prescribed by the division for the purpose of 416



417 identifying the applicant firm, association, or corporation. The 418 application must be signed and verified by oath or affirmation 419 by the owner, if a sole proprietor; or, if the owner is a firm, 420 association, or partnership, by the members or partners thereof; 421 or, if the owner is a corporation, by an executive officer of 422 the corporation or by a person authorized by the corporation to 423 sign the application, together with the written evidence of this 424 authority.

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(c) Permits must be issued annually.

(d) The holder of a permit may renew the permit each year. <u>A dealer that does not timely renew its permit must pay a late</u> <u>fee of \$5 for each month or portion of a month occurring after</u> <u>expiration, and before renewal, of the dealer's permit. The</u> division shall establish by rule a renewal procedure.