

26 and to certain adverse determinations; requiring such
 27 process to be posted on the entities' websites;
 28 providing an effective date.

29
 30 Be It Enacted by the Legislature of the State of Florida:

31
 32 Section 1. Subsection (2) of section 409.905, Florida
 33 Statutes, is amended to read:

34 409.905 Mandatory Medicaid services.—The agency may make
 35 payments for the following services, which are required of the
 36 state by Title XIX of the Social Security Act, furnished by
 37 Medicaid providers to recipients who are determined to be
 38 eligible on the dates on which the services were provided. Any
 39 service under this section shall be provided only when medically
 40 necessary and in accordance with state and federal law.

41 Mandatory services rendered by providers in mobile units to
 42 Medicaid recipients may be restricted by the agency. Nothing in
 43 this section shall be construed to prevent or limit the agency
 44 from adjusting fees, reimbursement rates, lengths of stay,
 45 number of visits, number of services, or any other adjustments
 46 necessary to comply with the availability of moneys and any
 47 limitations or directions provided for in the General
 48 Appropriations Act or chapter 216.

49 (2) EARLY AND PERIODIC SCREENING, DIAGNOSIS, AND TREATMENT
 50 SERVICES; BIOMARKER TESTING.—

51 (a) The agency shall pay for early and periodic screening
52 and diagnosis of a recipient under age 21 to ascertain physical
53 and mental problems and conditions and all services determined
54 by the agency to be medically necessary for the treatment,
55 correction, or amelioration of these problems and conditions,
56 including personal care, private duty nursing, durable medical
57 equipment, physical therapy, occupational therapy, speech
58 therapy, respiratory therapy, and immunizations.

59 (b) Subject to the approval of the Centers for Medicare
60 and Medicaid Services, the agency shall pay for biomarker
61 testing for the purposes of diagnosis, treatment, appropriate
62 management, or ongoing monitoring of a recipient's disease or
63 condition.

64 1. The biomarker testing covered under this paragraph must
65 be supported by medical and scientific evidence. Such evidence
66 includes, but is not limited to:

67 a. Labeled indications for a United States Food and Drug
68 Administration-approved or Food and Drug Administration-cleared
69 test;

70 b. Indicated tests for a Food and Drug Administration-
71 approved drug;

72 c. Warnings and precautions on Food and Drug
73 Administration-approved drug labels;

74 d. The Centers for Medicare and Medicaid Services national
75 coverage determinations or Medicare Administrative Contractor

76 local coverage determinations; or

77 e. Nationally recognized clinical practice guidelines and
78 consensus statements.

79 2. The biomarker testing covered under this paragraph must
80 be provided in a manner that limits disruptions in care,
81 including tests to remove multiple biopsies or biospecimen
82 samples.

83 3. If utilization review, including, but not limited to,
84 prior authorization, is required, the utilization review
85 committee or any third party acting on behalf of the agency must
86 approve or deny a utilization review request, including, but not
87 limited to, a prior authorization request, and must notify the
88 recipient, the recipient's health care provider, and any entity
89 requesting authorization of the biomarker testing within 72
90 hours for a nonurgent request and within 24 hours for an urgent
91 request after receipt of the request.

92 4. The recipient and the prescribing health care provider
93 must have access to a clear, readily accessible, and convenient
94 process to request an exception to the coverage or an adverse
95 utilization review determination of the agency. The process
96 shall be made readily accessible on the agency's website.

97 5. As used in this paragraph, the terms "biomarker,"
98 "biomarker testing," "consensus statements," and "nationally
99 recognized practice guidelines" have the same meanings as in s.
100 627.64094.

101 Section 2. Paragraph (dd) is added to subsection (1) of
 102 section 409.973, Florida Statutes, to read:

103 409.973 Benefits.—

104 (1) MINIMUM BENEFITS.—Managed care plans shall cover, at a
 105 minimum, the following services:

106 (dd) Biomarker testing, as defined in s. 627.64094.

107 Section 3. Section 627.64094, Florida Statutes, is created
 108 to read:

109 627.64094 Coverage for biomarker testing.—

110 (1) As used in this section, the term:

111 (a) "Biomarker" means a characteristic that is objectively
 112 measured and evaluated as an indicator of normal biological
 113 processes, pathogenic processes, or pharmacologic responses to a
 114 specific therapeutic intervention, including known gene-drug
 115 interactions for medications being considered for use or already
 116 being administered. The term includes, but is not limited to,
 117 gene mutations, characteristics of genes, and protein
 118 expression.

119 (b) "Biomarker testing" is the analysis of a patient's
 120 tissue, blood, or other biospecimen for the presence of a
 121 biomarker. The term includes, but is not limited to, single-
 122 analyte tests, multiplex panel tests, protein expression, and
 123 whole exome, whole genome, and whole transcriptome sequencing.

124 (c) "Consensus statements" means statements developed by
 125 an independent, multidisciplinary panel of experts using a

126 transparent methodology and reporting structure and with a
127 conflict of interest policy. These statements are aimed at
128 specific clinical circumstances and base the statements on the
129 best available evidence for the purpose of optimizing the
130 outcomes of clinical care.

131 (d) "Nationally recognized clinical practice guidelines"
132 means evidence-based clinical practice guidelines developed by
133 independent organizations or medical professional societies
134 using a transparent methodology and reporting structure and with
135 a conflict of interest policy. The guidelines establish
136 standards of care informed by a systematic review of evidence
137 and an assessment of the benefits and risks of alternative care
138 options and include recommendations intended to optimize patient
139 care.

140 (2) A health insurance policy, a nonprofit health services
141 plan or nonprofit health care plan, as defined in s. 628.703,
142 and a health benefit plan, as defined in s. 627.6699(3), issued,
143 amended, delivered, or renewed in this state, or providing
144 prepaid health care in this state, on or after July 1, 2023,
145 must include coverage for biomarker testing for the purposes of
146 diagnosis, treatment, appropriate management, or ongoing
147 monitoring of an insured's disease or condition.

148 (a) The biomarker testing covered under this subsection
149 must be supported by medical and scientific evidence. Such
150 evidence includes, but is not limited to:

- 151 1. Labeled indications for a United States Food and Drug
 152 Administration-approved or Food and Drug Administration-cleared
 153 test;
- 154 2. Indicated tests for a Food and Drug Administration-
 155 approved drug;
- 156 3. Warnings and precautions on Food and Drug
 157 Administration-approved drug labels;
- 158 4. The Centers for Medicare and Medicaid Services national
 159 coverage determinations or Medicare Administrative Contractor
 160 local coverage determinations; or
- 161 5. Nationally recognized clinical practice guidelines and
 162 consensus statements.
- 163 (b) The biomarker testing covered under this subsection
 164 must be provided in a manner that limits disruptions in care,
 165 including tests to remove multiple biopsies or biospecimen
 166 samples.
- 167 (c) If utilization review, including, but not limited to,
 168 prior authorization, is required, the utilization review
 169 committee or any third party acting on behalf of the health
 170 insurer, the nonprofit health services plan or nonprofit health
 171 care plan, and the health benefit plan subject to this
 172 subsection must approve or deny a utilization review request,
 173 including, but not limited to, a prior authorization request,
 174 and must notify the insured, the insured's health care provider,
 175 and any entity requesting authorization of the biomarker testing

176 within 72 hours for a nonurgent request and within 24 hours for
177 an urgent request after receipt of the request.

178 (e) The insured and the prescribing health care provider
179 must have access to a clear, readily accessible, and convenient
180 process to request an exception to the policy coverage or an
181 adverse utilization review determination of the health insurer,
182 the nonprofit health services plan or nonprofit health care
183 plan, and the health benefit plan. The process shall be made
184 readily accessible on the website of the health insurer, the
185 nonprofit health services plan or nonprofit health care plan,
186 and the health benefit plan.

187 Section 4. Section 627.65742, Florida Statutes, is created
188 to read:

189 627.65742 Coverage for biomarker testing.-

190 (1) As used in this section, the term:

191 (a) "Biomarker" means a characteristic that is objectively
192 measured and evaluated as an indicator of normal biological
193 processes, pathogenic processes, or pharmacologic responses to a
194 specific therapeutic intervention, including known gene-drug
195 interactions for medications being considered for use or already
196 being administered. The term includes, but is not limited to,
197 gene mutations, characteristics of genes, and protein
198 expression.

199 (b) "Biomarker testing" is the analysis of a patient's
200 tissue, blood, or other biospecimen for the presence of a

201 biomarker. The term includes, but is not limited to, single-
202 analyte tests, multiplex panel tests, protein expression, and
203 whole exome, whole genome, and whole transcriptome sequencing.

204 (c) "Consensus statements" means statements developed by
205 an independent, multidisciplinary panel of experts using a
206 transparent methodology and reporting structure and with a
207 conflict of interest policy. These statements are aimed at
208 specific clinical circumstances and base the statements on the
209 best available evidence for the purpose of optimizing the
210 outcomes of clinical care.

211 (d) "Nationally recognized clinical practice guidelines"
212 means evidence-based clinical practice guidelines developed by
213 independent organizations or medical professional societies
214 using a transparent methodology and reporting structure and with
215 a conflict of interest policy. The guidelines establish
216 standards of care informed by a systematic review of evidence
217 and an assessment of the benefits and risks of alternative care
218 options and include recommendations intended to optimize patient
219 care.

220 (2) A health insurance policy, a nonprofit health services
221 plan or nonprofit health care plan, as defined in s. 628.703,
222 and a health benefit plan, as defined in s. 627.6699(3), issued,
223 amended, delivered, or renewed in this state, or providing
224 prepaid health care in this state, on or after July 1, 2023,
225 must include coverage for biomarker testing for the purposes of

HB 805

2023

226 diagnosis, treatment, appropriate management, or ongoing
227 monitoring of an insured's disease or condition.

228 (a) The biomarker testing covered under this subsection
229 must be supported by medical and scientific evidence. Such
230 evidence includes, but is not limited to:

231 1. Labeled indications for a United States Food and Drug
232 Administration-approved or Food and Drug Administration-cleared
233 test;

234 2. Indicated tests for a Food and Drug Administration-
235 approved drug;

236 3. Warnings and precautions on Food and Drug
237 Administration-approved drug labels;

238 4. The Centers for Medicare and Medicaid Services national
239 coverage determinations or Medicare Administrative Contractor
240 local coverage determinations; or

241 5. Nationally recognized clinical practice guidelines and
242 consensus statements.

243 (b) The biomarker testing covered under this subsection
244 must be provided in a manner that limits disruptions in care,
245 including tests to remove multiple biopsies or biospecimen
246 samples.

247 (c) If utilization review, including, but not limited to,
248 prior authorization, is required, the utilization review
249 committee or any third party acting on behalf of the health
250 insurer, the nonprofit health services plan or nonprofit health

251 care plan, and the health benefit plan subject to this
 252 subsection must approve or deny a utilization review request,
 253 including, but not limited to, a prior authorization request,
 254 and must notify the insured, the insured's health care provider,
 255 and any entity requesting authorization of the biomarker testing
 256 within 72 hours for a nonurgent request and within 24 hours for
 257 an urgent request after receipt of the request.

258 (e) The insured and the prescribing health care provider
 259 must have access to a clear, readily accessible, and convenient
 260 process to request an exception to the policy coverage or an
 261 adverse utilization review determination of the health insurer,
 262 the nonprofit health services plan or nonprofit health care
 263 plan, and the health benefit plan. The process shall be made
 264 readily accessible on the website of the health insurer, the
 265 nonprofit health services plan or nonprofit health care plan,
 266 and the health benefit plan.

267 Section 5. Section 641.31078, Florida Statutes, is created
 268 to read:

269 641.31078 Coverage for biomarker testing.-

270 (1) As used in this section, the term:

271 (a) "Biomarker" means a characteristic that is objectively
 272 measured and evaluated as an indicator of normal biological
 273 processes, pathogenic processes, or pharmacologic responses to a
 274 specific therapeutic intervention, including known gene-drug
 275 interactions for medications being considered for use or already

276 being administered. The term includes, but is not limited to,
277 gene mutations, characteristics of genes, and protein
278 expression.

279 (b) "Biomarker testing" is the analysis of a patient's
280 tissue, blood, or other biospecimen for the presence of a
281 biomarker. The term includes, but is not limited to, single-
282 analyte tests, multiplex panel tests, protein expression, and
283 whole exome, whole genome, and whole transcriptome sequencing.

284 (c) "Consensus statements" means statements developed by
285 an independent, multidisciplinary panel of experts using a
286 transparent methodology and reporting structure and with a
287 conflict of interest policy. These statements are aimed at
288 specific clinical circumstances and base the statements on the
289 best available evidence for the purpose of optimizing the
290 outcomes of clinical care.

291 (d) "Nationally recognized clinical practice guidelines"
292 means evidence-based clinical practice guidelines developed by
293 independent organizations or medical professional societies
294 using a transparent methodology and reporting structure and with
295 a conflict of interest policy. The guidelines establish
296 standards of care informed by a systematic review of evidence
297 and an assessment of the benefits and risks of alternative care
298 options and include recommendations intended to optimize patient
299 care.

300 (2) A health maintenance contract, a nonprofit health

301 services plan or nonprofit health care plan, as defined in s.
 302 628.703, and a health benefit plan, as defined in s.
 303 627.6699(3), issued, amended, delivered, or renewed in this
 304 state, or providing prepaid health care in this state, on or
 305 after July 1, 2023, must include coverage for biomarker testing
 306 for the purposes of diagnosis, treatment, appropriate
 307 management, or ongoing monitoring of a subscriber's disease or
 308 condition.

309 (a) The biomarker testing covered under this subsection
 310 must be supported by medical and scientific evidence. Such
 311 evidence includes, but is not limited to:

312 1. Labeled indications for a United States Food and Drug
 313 Administration-approved or Food and Drug Administration-cleared
 314 test;

315 2. Indicated tests for a Food and Drug Administration-
 316 approved drug;

317 3. Warnings and precautions on Food and Drug
 318 Administration-approved drug labels;

319 4. The Centers for Medicare and Medicaid Services national
 320 coverage determinations or Medicare Administrative Contractor
 321 local coverage determinations; or

322 5. Nationally recognized clinical practice guidelines and
 323 consensus statements.

324 (b) The biomarker testing covered under this subsection
 325 must be provided in a manner that limits disruptions in care,

326 including tests to remove multiple biopsies or biospecimen
327 samples.

328 (c) If utilization review, including, but not limited to,
329 prior authorization, is required, the utilization review
330 committee or any third party acting on behalf of the health
331 maintenance organization, the nonprofit health services plan or
332 nonprofit health care plan, and the health benefit plan subject
333 to this subsection must approve or deny a utilization review
334 request, including, but not limited to, a prior authorization
335 request, and must notify the subscriber, the subscriber's health
336 care provider, and any entity requesting authorization of the
337 biomarker testing within 72 hours for a nonurgent request and
338 within 24 hours for an urgent request after receipt of the
339 request.

340 (e) The subscriber and the prescribing health care
341 provider must have access to a clear, readily accessible, and
342 convenient process to request an exception to the contract
343 coverage or an adverse utilization review determination of the
344 health maintenance organization, the nonprofit health services
345 plan or nonprofit health care plan, and the health benefit plan.
346 The process shall be made readily accessible on the website of
347 the health maintenance organization, the nonprofit health
348 services plan or nonprofit health care plan, and the health
349 benefit plan.

350 Section 6. Section 641.5143, Florida Statutes, is created

351 to read:

352 641.5143 Coverage for biomarker testing.-

353 (1) As used in this section, the term:

354 (a) "Biomarker" means a characteristic that is objectively
355 measured and evaluated as an indicator of normal biological
356 processes, pathogenic processes, or pharmacologic responses to a
357 specific therapeutic intervention, including known gene-drug
358 interactions for medications being considered for use or already
359 being administered. The term includes, but is not limited to,
360 gene mutations, characteristics of genes, and protein
361 expression.

362 (b) "Biomarker testing" is the analysis of a patient's
363 tissue, blood, or other biospecimen for the presence of a
364 biomarker. The term includes, but is not limited to, single-
365 analyte tests, multiplex panel tests, protein expression, and
366 whole exome, whole genome, and whole transcriptome sequencing.

367 (c) "Consensus statements" means statements developed by
368 an independent, multidisciplinary panel of experts using a
369 transparent methodology and reporting structure and with a
370 conflict of interest policy. These statements are aimed at
371 specific clinical circumstances and base the statements on the
372 best available evidence for the purpose of optimizing the
373 outcomes of clinical care.

374 (d) "Nationally recognized clinical practice guidelines"
375 means evidence-based clinical practice guidelines developed by

376 independent organizations or medical professional societies
377 using a transparent methodology and reporting structure and with
378 a conflict of interest policy. The guidelines establish
379 standards of care informed by a systematic review of evidence
380 and an assessment of the benefits and risks of alternative care
381 options and include recommendations intended to optimize patient
382 care.

383 (2) A prepaid health clinic contract issued, amended,
384 delivered, or renewed in the state on or after July 1, 2023,
385 must include coverage for biomarker testing for the purposes of
386 diagnosis, treatment, appropriate management, or ongoing
387 monitoring of a subscriber's disease or condition.

388 (a) The biomarker testing covered under this subsection
389 must be supported by medical and scientific evidence. Such
390 evidence includes, but is not limited to:

391 1. Labeled indications for a United States Food and Drug
392 Administration-approved or Food and Drug Administration-cleared
393 test;

394 2. Indicated tests for a Food and Drug Administration-
395 approved drug;

396 3. Warnings and precautions on Food and Drug
397 Administration-approved drug labels;

398 4. The Centers for Medicare and Medicaid Services national
399 coverage determinations or Medicare Administrative Contractor
400 local coverage determinations; or

401 5. Nationally recognized clinical practice guidelines and
402 consensus statements.

403 (b) The biomarker testing covered under this subsection
404 must be provided in a manner that limits disruptions in care,
405 including tests to remove multiple biopsies or biospecimen
406 samples.

407 (c) If utilization review, including, but not limited to,
408 prior authorization, is required, the utilization review
409 committee or any third party acting on behalf of the prepaid
410 health clinic subject to this subsection must approve or deny a
411 utilization review request, including, but not limited to, a
412 prior authorization request, and must notify the subscriber, the
413 subscriber's health care provider, and any entity requesting
414 authorization of the biomarker testing within 72 hours for a
415 nonurgent request and within 24 hours for an urgent request
416 after receipt of the request.

417 (e) The subscriber and the prescribing health care
418 provider must have access to a clear, readily accessible, and
419 convenient process to request an exception to the contract
420 coverage or an adverse utilization review determination of the
421 prepaid health clinic. The process shall be made readily
422 accessible on the prepaid health clinic's website.

423 Section 7. This act shall take effect July 1, 2023.