SPONSOR: Sen. Blevins & Rep. Maier;
Sens. Cook, Bonini, Bunting, Cloutier, Connor, DeLuca, Henry, Marshall, McDowell, Simpson, Sokola, Sorenson, Venables, Winslow; Reps. DiLiberto, DiPinto, Ewing, Hudson, Price, Viola, Wagner, West

DELAWARE STATE SENATE

141st GENERAL ASSEMBLY

SENATE BILL NO. 181

AN ACT TO AMEND TITLES 16 AND 18 OF THE DELAWARE CODE RELATING TO HEALTH INSURANCE.

WHEREAS Delaware statute, unlike the statutes of many other states, does not require health insurance policies to permit reasonable referrals to specialists at the recommendation of an insured's primary care physician; and

WHEREAS Delaware statute does not expressly require health insurance policies to provide for necessary emergency room services; and

WHEREAS Delaware statute does not require health insurance policies to cover accepted prescription drugs which are recommended by a patient's physician but not listed on the insurance company's list of pre-approved drugs; and

WHEREAS necessary referrals, emergency room care, and necessary prescription drugs are critical to the provision of adequate health care to persons who receive medical care under Delaware health insurance policies; and

WHEREAS current law in Delaware does not require health insurers to offer quick, internal appeals of benefit denials; and

WHEREAS Delaware patients have been unfairly denied coverage for medically necessary and otherwise covered routine patient care costs incurred while participating in important and established clinical trials; and

WHEREAS Senate Bill No. 299, enacted during the 140th General Assembly, provides for the prompt and efficient resolution of health insurance coverage disputes involving medical necessity determinations and other medical issues, but does not provide an efficient mechanism for resolving disputes involving non-medical issues:

NOW THEREFORE:

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

1 Section 1. This Act shall be referred to as the "Delaware Patient's Bill of Rights".

2 Section 2. Amend Title 16, § 9119 of the Delaware Code by adding thereto after subsection (c), new subsections
3 (d) through (f), to read as follows:

4 "(d) For cases in which the denial, reduction, or termination of benefits by the health carrier is based on
5 grounds other than medical necessity or the appropriateness of services, as defined in this Section,
6 review from the final decision of the health carrier, following completion of the health carrier's internal
7 review process, shall be through the Department of Insurance in accordance with the provisions of
8 Section 332 of Title 18 of the Delaware Code.

9 (e) For cases in which a denial, reduction, or termination of benefits should be reviewed by both an
10 IURO and by the Department of Insurance, or where there is ambiguity as to where the review
11 should be conducted, the review shall be conducted by an IURO pursuant to this Section.

12 (f) The Department of Insurance shall refer any appeals that are incorrectly filed with it to the
13 Department of Health and Social Services, where such appeals shall be treated as timely if they
14 were filed with the Department of Insurance within the time restraints imposed by Title 18, Section
15 332 of the Delaware Code. The Department of Health and Social Services shall forward any
16 appeals that are incorrectly filed with it to the Department of Insurance and appeals that are
17 incorrectly filed with the Department of Health and Social Services shall be treated as timely filed
18 if they were filed within the time constraints imposed by Title 16, Section 9119 of the Delaware
19 Code."

20 Section 3. Amend Title 18, Section 102 of the Delaware Code by adding after subsection (10) a new subsection
21 (11), to read as follows:

22 "(11) 'Balance billing' means a health care provider's demand that a patient pay a greater amount for a
23 given service than the amount the individual's insurer, managed care organization, or health service
24 corporation has paid or will pay for the service."
25 Section 4. Amend Title 18 of the Delaware Code by deleting § 332 in its entirety and by replacing it with the
26 following:
27 "§ 332. Arbitration of disputes involving health insurance coverage.
28 (a) The following definitions shall apply with respect to this section:
29 1. 'Adverse determination' means a benefit denial, reduction, or termination, a denial of
30 certification, or both.
31 2. 'Benefit denial' means the denial, in whole or in part, of payment or reimbursement for
32 health care services rendered or health care supplies provided to any person claiming
33 benefits under an insurance policy delivered or issued for delivery in Delaware.
34 3. 'Carrier' in this section shall have the same meaning applied to it at 18 Del.C.
35 §3343(a)(1).
36 4. 'Covered person' means a person who claims to be entitled to receive benefits from a
37 carrier.
38 5. 'Denial of certification' means a determination that an admission or continued stay, or
39 course of treatment, or other covered health care service does not satisfy the insurance
40 policy's clinical requirements for appropriateness, necessity, health care setting and/or
41 level of care.
42 6. 'Emergency review' means an IRP review involving an imminent, emergent, or
43 serious threat to the health of the claimant.
44 7. 'Health plan' shall have the same meaning as 'health benefit plan' as defined at 18
45 Del.C. §3343(a)(2).
46 8. 'Insurance policy' shall have the meaning assigned to it at 18 Del.C. §2702, and shall
47 also include all health plans and policies for the payment for, provision of, or
48 reimbursement for medical services, supplies or both issued by insurers, health
49 services corporations or managed care organizations.

50 9. 'Internal review process' or 'IRP' means the procedure for an internal review of an
51 adverse determination pursuant to subsection (b) of this section.
52 (b) Every carrier shall establish and maintain an IRP approved by the Insurance Commissioner.
53 (c) The Insurance Commissioner shall approve those IRPs that meet the following minimum
54 criteria:
55 1. Written notice. The IRP must provide for written notice of the internal review
56 procedure to covered persons, annually and following any adverse determination;
57 2. Requests for review of adverse determinations. The IRP must permit covered
58 persons to submit requests for internal reviews of adverse determinations
59 ('grievances') orally or in writing. Grievances must be submitted within 30 days
60 of receipt by the covered person of written notice of an adverse determination.
61 The carrier must provide written forms for submission of grievances. Upon
62 receipt of an oral grievance or a written grievance that does not contain sufficient
63 information, the carrier must immediately provide the covered person with a
64 written form upon which to make his grievance, and the carrier may require that
65 an oral or insufficient written grievance be submitted in writing within ten days
66 of the covered person’s receipt of the written form. A grievance shall be
67 considered as received by the carrier when a written form, which the covered
68 person purports to be complete, is received by the carrier.
69 3. Instructions on written form. The written form referred to in subparagraph (c)(2)
70 of this section shall inform the covered person of the information necessary to
71 pursue an internal grievance of an adverse decision.
72 4. Prompt response to written grievances. The IRP shall provide that within five
73 business days of receipt of a written grievance, the carrier shall provide written
74 acknowledgement of the grievance, including the name, address, and telephone
75 number of the individual or department designated by the carrier to respond to the
76 grievance.

77 5. Speedy review of grievances. That IRP shall require that all grievances be
78 decided in an expeditious manner, and in any event, no more than (i) forty-eight
79 hours after the receipt of all necessary information relating to an emergency
80 review, (ii) thirty days after the receipt of all necessary information in the case of
81 requests for referrals or determinations concerning whether a requested benefit is
82 covered pursuant to the contract, and (iii) forty-five days after the receipt of all
83 necessary information in all other instances. A grievance shall be considered
84 decided when the carrier has made its final decision on the subject of the review
85 and has deposited written notice of that decision in the mail, in accordance with
86 subsections (7) and (8) below.
87 6. Assignment of qualified personnel. The IRP shall provide that when the subject
88 of the grievance relates to medical or clinical matters, including medical necessity
89 and appropriateness of treatment, the health carrier shall assign licensed, certified,
90 or registered health care personnel with expertise in the field implicated by the
91 request for review to conduct the review. The review shall be conducted by
92 personnel other than those who made the initial adverse determination.
93 7. Written notice of decisions. The IRP shall provide that within five days after a
94 grievance is decided in the manner described above, the insured shall be provided
95 with written notice of the disposition of that grievance. In cases where the
96 grievance has been decided in a manner that does not pay the claim in its entirety,
97 the carrier shall provide the insured with a letter fully stating the reasons for the
98 disposition (including specific policy language relied upon and any other
99 documents relied upon), and the clinical rationale for the determination in cases
100 where the determination has a clinical basis. The carrier's written notice shall
101 also inform the insured of the appropriate manner for the insured to pursue an
102 external review of the carrier's decision. Finally, the carrier's written notice shall
103 inform the insured of the mediation services offered by the Department of
104 Insurance, but shall clearly inform the insured in layman's terms that mediation

105 does not change the deadlines imposed by 16 Del.C. § 9119 or 18 Del.C. § 332.
106 The Department of Insurance shall inform any person with rights under 16 Del.C.
107 § 9119 or 18 Del.C. § 332 of those rights.
108 8. Manner of notice of decisions. Written notice of the review decision shall be
109 deposited in the mail, addressed to the last known address of the covered person.
110 In the case of emergency reviews, the carrier shall also make reasonable efforts to
111 notify the covered person immediately following the determination of the
112 grievance and the written notice of determination shall be deposited in the mail,
113 addressed to the last known address of the claimant, within 48 hours after the
114 receipt of all information necessary to complete the review.
115 (d) Every carrier shall submit a report on its internal review process on an annual basis to the
116 Insurance Commissioner in accordance with regulations established by the Department.
117 (e) With respect to adverse determinations that are subject to review by the Department of
118 Insurance pursuant to 16 Del.C. § 9119(d), the Insurance Commissioner shall develop
119 regulations providing for arbitration of such adverse determinations. Such regulations
120 shall contain the following provisions:
121 1. Requests for arbitration shall be in writing and mailed to the Commissioner
122 within 60 days of the receipt of the written statement referred to in subsection
123 (c)(7) of this section.
124 2. Arbitrators shall be chosen from an appropriate panel of arbitrators, and hearings
125 shall be conducted according to rules established by the Department of Insurance.
126 3. The arbitrator shall review written arbitration requests prior to holding any
127 hearing or allowing any exchange of information between the parties, in order to
128 determine whether a written arbitration request is meritless on its face, and may
129 summarily dismiss meritless requests for arbitration.
130 4. Neither party shall be held to have waived any of its rights to seek relief in a
131 court of law with respect to a covered person's legal rights to benefits by an act
132 relating to arbitration or the rendering of an arbitration decision.

133 5. Arbitration decisions shall be rendered within 45 days of the Commissioner's
134 receipt of an arbitration request.
135 (f) The Insurance Commissioner shall establish a schedule of fees for arbitration. Fees chargeable
136 to covered persons shall not exceed $75 per arbitration. The carrier shall be responsible for all
137 costs of arbitration which exceed this fee regardless of the final ruling, and shall reimburse the
138 Commissioner for the expenses related to the arbitration process. Funds paid to the Insurance
139 Commissioner under this subsection shall be placed in the arbitration fund and shall be used
140 exclusively for the payment of appointed arbitrators. The Insurance Commissioner may, in her
141 discretion, impose a schedule of maximum fees that can be charged by an arbitrator for a given
142 type of arbitration.
143 (g) If the arbitrator makes a decision in favor of the carrier, that decision shall give rise to a
144 rebuttable presumption to that effect in any subsequent action brought by or on behalf of the
145 covered person with respect to the decision. Should the decision favor the covered person the
146 carrier shall have the right to appeal the matter to the Court, in accordance with Court rules.
147 The outcome of that appeal, however, shall have no effect on the covered person, as to whom
148 the decision of the arbitrator shall control. The assignment of counsel for an appeal by the
149 carrier and the payment of expenses of that assigned counsel shall be as set forth in 16 Del.C. §
150 9119(a).
151 (h) Nothing in this section shall be construed to affect policies or contracts to the extent that those
152 policies or contracts are exempt from state regulation under federal law or regulation, nor shall
153 anything in this section be read to restrict any affirmative rights granted to patients or insureds
154 under any other provision of the Delaware Code or the common law of the State of Delaware.
155 (i) Notwithstanding any other language in the Delaware Code, the Department of Health and
156 Social Services shall have the authority to carry out all duties assigned to it by this Section."
157 Section 5. Amend Title 18, Chapter 33 of the Delaware Code by adding a new §3347, to read as follows:
158 "§ 3347. Referrals.
159 (a) This section applies to every policy or contract of health insurance which is delivered or issued for
160 delivery in this state, including each policy or contract issued by a health service corporation, and which

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161 designates network physicians or providers or preferred physicians or providers (hereinafter referred to
162 collectively as 'network providers').
163 (b) All individual and group health insurance policies shall provide that if medically necessary covered
164 services are not available through network providers, or the network providers are not available within a
165 reasonable period of time, the insurer, on the request of a network provider, within a reasonable period,
166 shall allow referral to a non-network physician or provider and shall reimburse the non-network
167 physician or provider at an agreed-upon or negotiated rate. In such circumstances, the non-network
168 physician or provider may not balance bill the insured. Such a referral shall not be refused by the
169 insurer absent a decision by a physician in the same or a similar specialty as the physician to whom a
170 referral is sought that the referral is not reasonably related to the provision of medically necessary
171 services.
172 (c) All individual and group health insurance policies which do not allow insureds to have direct access to
173 health care specialists shall establish and implement a procedure by which insureds can obtain a
174 standing referral to a health care specialist.
175 (d) The procedure established under subsection (c) of this section:
176 1. Shall provide for a standing referral to a specialist if the insured's network provider
177 determines that the insured needs continuing care from the specialist; and
178 2. May require the insurer's approval of an initial treatment plan designed by the
179 specialist containing (i) a limit on the number of visits to the specialist, (ii) a time
180 limit on the duration of the referral, and (iii) mandatory updates on the insured's
181 condition. Such approval shall not be withheld absent a decision by a qualified
182 physician that the treatment sought in the treatment plan is not reasonably related to
183 the appropriate treatment of the insured's condition.
184 3. Within the treatment period referred to in subsection (d)(2) of this section, the
185 specialist shall be permitted to treat the insured without a further referral from the
186 insured's network provider and may authorize such further referrals, procedures, tests,
187 and other medical services as the individual's network provider would otherwise be
188 permitted to provide or authorize.

189 4. Referrals, procedures, tests, and other medical services referred to in this subsection
190 (d) shall be provided by network providers unless such services are not available
191 through network providers, or the network providers are not available within a
192 reasonable period of time. If services are not available through network providers, or
193 the network providers are not available within a reasonable period of time, the out-of-
194 network provider shall be reimbursed at an agreed-upon or negotiated rate. In such
195 circumstances, the non-network provider may not balance bill the insured.
196 (e) Nothing in this Section shall prevent the operation of policy provisions involving deductibles or co-
197 payments."
198 Section 6. Amend Title 18, Chapter 33 of the Delaware Code by adding a new §3348, to read as follows:
199 "§3348. Emergency Care.
200 (a) This section applies to every policy or contract of health insurance, including each policy or
201 contract issued by a health service corporation, which is delivered or issued for delivery in this
202 state, and which designates network physicians or providers or preferred physicians or providers
203 (hereinafter referred to collectively as 'network providers'). However, this section applies only to
204 conditions for which coverage is provided by those policies or contracts.
205 (b) All individual and group health insurance policies shall provide that persons covered under those
206 policies will be insured for emergency care services performed by non-network providers at an
207 agreed-upon or negotiated rate, regardless of whether the physician or provider furnishing the
208 services has a contractual or other arrangement with the insurer to provide items or services to
209 persons covered under the policies. Said rate shall be no less than the rate paid to network
210 providers. In such circumstances, the non-network provider may not balance bill the insured.
211 (c) Plans described in subsections (a) and (b) of this section shall cover:
212 1. any medical screening examination or other evaluation medically required to
213 determine whether an emergency medical condition exists;
214 2. necessary emergency care services, including treatment and stabilization of an
215 emergency medical condition; and

216 3. services originated in a hospital emergency facility or comparable facility following
217 treatment or stabilization of an emergency medical condition as approved by the
218 insurer with respect to services performed by non-network providers, provided that
219 the insurer is required to approve or disapprove coverage of poststabilization care as
220 requested by a treating physician or provider within the time appropriate to the
221 circumstances relating to the delivery of services and the condition of the patient, but
222 in no case to exceed one hour from the time of the request.
223 (d) Nothing in this Section shall prevent the operation of policy provisions involving deductibles or co-
224 payments. As used in this section 'emergency medical condition' means a medical or behavioral
225 condition, the onset of which is sudden, that manifests itself by symptoms of sufficient severity,
226 including, but not limited to, severe pain, that a prudent layperson, possessing an average
227 knowledge of medicine and health, could reasonably expect the absence of immediate medical
228 attention to result in (a) placing the health of the person afflicted with such condition in serious
229 jeopardy, or in the case of a behavioral condition, placing the health of such person or others in
230 serious jeopardy; (b) serious impairment to such person's bodily functions, (c) serious impairment
231 or dysfunction of any bodily organ or part of such person, or (d) serious disfigurement of such
232 person."
233 Section 7. Amend Title 18, Chapter 33 of the Delaware Code by adding a new §3349, to read as follows:
234 "§3349. Prescription Medication.
235 (a) This section applies to every policy or contract of health insurance, including each policy or contract
236 issued by a health service corporation, which is delivered or issued for delivery in this state and which
237 provides coverage for outpatient prescription drugs.
238 (b) Every policy or contract of health insurance described in subsection (a) shall provide coverage for any
239 outpatient drug prescribed to treat a covered person for a covered chronic, disabling, or life-threatening
240 illness if the drug:
241 1. has been approved by the Food and Drug administration for at least one indication;
242 and
243 2. is recognized for treatment of the indication for which the drug is prescribed in:

244 a. a prescription drug reference compendium approved by the Insurance
245 Commissioner for purposes of this section, or
246 b. substantially accepted peer reviewed medical literature.
247 (c) Coverage of a drug required by this section shall include coverage of medically necessary services
248 associated with administration of the drug.
249 (d) This section does not require coverage for:
250 1. experimental drugs not otherwise approved for the proposed use or indication by the
251 Food and Drug Administration, or
252 2. any disease, condition, service, or treatment that is excluded from coverage under the
253 policy.
254 (e) Nothing in this Section shall prevent the operation of policy provisions involving deductibles, co-
255 insurance, allowable charge limitations, maximum dollar policy limitations, or coordination of
256 benefits."
257 Section 8. Amend Title 18, Chapter 35 of the Delaware Code by adding a new §3559D, to read as follows:
258 "§3559D. Referrals.
259 (a) This section applies to every group or blanket policy or contract of health insurance, including each policy
260 or contract issued by a health service corporation, which is delivered or issued for delivery in this state, and
261 which designates network physicians or providers or preferred physicians or providers (hereinafter referred
262 to collectively as 'network providers').
263 (b) All individual and group health insurance policies shall provide that if medically necessary covered services
264 are not available through network providers, or the network providers are not available within a reasonable
265 period of time, the insurer, on the request of a network provider, within a reasonable period, shall allow
266 referral to a non-network physician or provider and shall reimburse the non-network physician or provider at
267 an agreed-upon or negotiated rate. In such circumstances, the non-network physician or provider may not
268 balance bill the insured. Such a referral shall not be refused by the insurer absent a decision by a physician
269 in the same or a similar specialty as the physician to whom a referral is sought that the referral is not
270 reasonably related to the provision of medically necessary services.

271 (c) All individual and group health insurance policies which do not allow insureds to have direct access to
272 health care specialists shall establish and implement a procedure by which insureds can obtain a standing
273 referral to a health care specialist.
274 (d) The procedure established under subsection (c) of this section:
275 1. Shall provide for a standing referral to a specialist if the insured's network
276 provider determines that the insured needs continuing care from the specialist;
277 and
278 2. May require the insurer's approval of an initial treatment plan designed by the
279 specialist containing (i) a limit on the number of visits to the specialist, (ii) a time
280 limit on the duration of the referral, and (iii) mandatory updates on the insured's
281 condition. Such approval shall not be withheld absent a decision by a qualified
282 physician that the treatment sought in the treatment plan is not reasonably related
283 to the appropriate treatment of the insured's condition.
284 3. Within the treatment period referred to in subsection (d)(2) of this section, the
285 specialist shall be permitted to treat the insured without a further referral from the
286 insured's network provider and may authorize such further referrals, procedures,
287 tests, and other medical services as the individual's network provider would
288 otherwise be permitted to provide or authorize.
289 4. Referrals, procedures, tests, and other medical services referred to in this
290 subsection (d) shall be provided by network providers unless such services are
291 not available through network providers, or the network providers are not
292 available within a reasonable period of time. If services are not available through
293 network providers, or the network providers are not available within a reasonable
294 period of time, the out-of-network provider shall be reimbursed at an agreed-upon
295 or negotiated rate. In such circumstances, the non-network provider may not
296 balance bill the insured.
297 (e) Nothing in this Section shall prevent the operation of policy provisions involving deductibles or co-
298 payments."

299 Section 9. Amend Title 18, Chapter 35 of the Delaware Code by adding a new §3559E, to read as follows:

300 "§3559E. Emergency Care.

301 (a) This section applies to every group or blanket policy or contract of health insurance, including each policy
302 or contract issued by a health service corporation, which is delivered or issued for delivery in this state, and
303 which designates network physicians or providers or preferred physicians or providers (hereinafter referred
304 to collectively as 'network providers'). However, this section applies only to conditions for which coverage
305 is provided by those policies or contracts.

306 (b) All individual and group health insurance policies shall provide that persons covered under those policies
307 will be insured for emergency care services performed by non-network providers at an agreed-upon or
308 negotiated rate, regardless of whether the physician or provider furnishing the services has a contractual or
309 other arrangement with the insurer to provide items or services to persons covered under the policies. Said
310 rate shall be no less than the rate paid to network providers. In such circumstances, the non-network
311 provider may not balance bill the insured.

312 (c) Plans described in subsections (a) and (b) of this section shall cover:

313 1. any medical screening examination or other evaluation medically required to
314 determine whether an emergency medical condition exists;

315 2. necessary emergency care services, including treatment and stabilization of an
316 emergency medical condition; and

317 3. services originated in a hospital emergency facility or comparable facility following
318 treatment or stabilization of an emergency medical condition as approved by the
319 insurer with respect to services performed by non-network providers, provided that
320 the insurer is required to approve or disapprove coverage of poststabilization care as
321 requested by a treating physician or provider within the time appropriate to the
322 circumstances relating to the delivery of services and the condition of the patient, but
323 in no case to exceed one hour from the time of the request.

324 (d) Nothing in this Section shall prevent the operation of policy provisions involving deductibles or co-
325 payments. As used in this section 'emergency medical condition' means a medical or behavioral condition,
326 the onset of which is sudden, that manifests itself by symptoms of sufficient severity, including, but not

327 limited to, severe pain, that a prudent layperson, possessing an average knowledge of medicine and health,
328 could reasonably expect the absence of immediate medical attention to result in (a) placing the health of the
329 person afflicted with such condition in serious jeopardy, or in the case of a behavioral condition, placing the
330 health of such person or others in serious jeopardy; (b) serious impairment to such person's bodily functions,
331 (c) serious impairment or dysfunction of any bodily organ or part of such person, or (d) serious
332 disfigurement of such person."

333 Section 10. Amend Title 18, Chapter 35 of the Delaware Code by adding a new §3559F, to read as follows:

334 "§3559F. Prescription Medication.

335 (a) This section applies to every group or blanket policy or contract of health insurance, including each
336 policy or contract issued by a health service corporation, which is delivered or issued for delivery in this
337 state and which provides coverage for outpatient prescription drugs.

338 (b) Every group or blanket policy or contract of health insurance described in subsection (a) shall provide
339 coverage for any outpatient drug prescribed to treat a covered person for a covered chronic, disabling, or
340 life-threatening illness if the drug:

341 1. has been approved by the Food and Drug administration for at least one indication;
342 and

343 2. is recognized for treatment of the indication for which the drug is prescribed in:

344 a. a prescription drug reference compendium approved by the Insurance
345 Commissioner for purposes of this section, or

346 b. substantially accepted peer reviewed medical literature.

347 (c) Coverage of a drug required by this section shall include coverage of medically necessary services
348 associated with administration of the drug.

349 (d) This section does not require coverage for:

350 1. experimental drugs not otherwise approved for the proposed use or indication by the
351 Food and Drug Administration, or

352 2. any disease, condition, service or treatment that is excluded from coverage under the
353 policy.

354 (e) Nothing in this Section shall prevent the operation of policy provisions involving deductibles, co-
355 insurance, allowable charge limitations, maximum dollar policy limitations, or coordination of
356 benefits."

357 Section 11. Amend Title 18, Delaware Code by adding a new Section 3559G, to read as follows:

358 "§3559G. Clinical Trials.

359 (a) Definitions.

360 (1) 'Routine patient care costs,' as used in this Section, include all items and services that are
361 otherwise generally available to a qualified individual that are provided in the clinical trial
362 except:

363 a. the investigational items or service itself;
364 b. items and services provided solely to satisfy data collection and analysis
365 needs and that are not used in the direct clinical management of the patients,
366 and
367 c. items and services customarily provided by the research sponsors free of
368 charge for any enrollee in the trial.

369 (2) 'Clinical trials' for purposes of this section include clinical trials that are approved or funded
370 by use of the following entities:

371 a. One of the National Institutes of Health (NIH);
372 b. An NIH Cooperative Group or center which is a formal network of facilities
373 that collaborate or research projects and have an established NIH-approval
374 peer review program operating within the group. This includes, but is not
375 limited to, the NCI Clinical Cooperative Group and the NCI Community
376 Clinical Oncology program.
377 c. The federal Departments of Veterans' Affairs or Defense;
378 d. An institutional review board of an institution in this State that has a multiple
379 project assurance contract approval by the Office of Protection for the
380 Research Risks of the NIH; and

381 e. A qualified research entity that meets the criteria for NIH Center Support
382 grant eligibility.
383 (3) Any clinical trial receiving coverage for routine costs under the provisions of this act must
384 meet the following requirements:
385 a. The subject or purpose of the trial must be the evaluation of an item or
386 service that falls within the covered benefits of the policy and is not
387 specifically excluded from coverage;
388 b. The trial must not be designed exclusively to test toxicity or disease
389 pathophysiology.
390 c. The trial must have therapeutic intent.
391 d. Trials of therapeutic interventions must enroll patients with diagnosed
392 disease.
393 e. The principal purpose of the trial is to test whether the intervention
394 potentially improves the participant's health outcomes.
395 f. The trial is well supported by available scientific and medical information or
396 it is intended to clarify or establish the health outcomes of interventions
397 already in common clinical use.
398 g. The trial does not unjustifiably duplicate existing studies.
399 h. The trial is in compliance with Federal regulations relating to the protection
400 of human subjects.
401 (b) Every group or blanket policy of health insurance which is delivered or issued for delivery in this
402 state, including each policy or contract issued by a health service corporation, shall provide
403 coverage for routine patient care costs as defined in paragraph (a)(1) of this Section for covered
404 persons engaging in clinical trials for treatment of life threatening diseases. Nothing in this
405 Section, however, independently requires coverage for expense of such clinical trials which are
406 otherwise not covered under the policy or contract."
407 Section 12. Not later than October 1, 2001, the Secretary of the Department of Health and Social Services and
408 the Delaware Insurance Commissioner shall adopt rules and regulations necessary to carry out the purposes of this Act.

409 Section 13. The provisions of this bill shall apply to all insurance policies, contracts, and plans delivered, issued
410 for delivery, reissued, renewed, or extended on or after January 1, 2002, or at any time when any term of any such policy,
411 contract or plan is changed or any premium adjustment is made on or after January 1, 2002.
412 Section 14. If any provision of this Act or the application thereof to any person or circumstances is held invalid,
413 such invalidity shall not affect other provisions or applications of this Act which can be given effect without the invalid
414 provisions or application, and to this end the provisions of this Act are severable.

SYNOPSIS

This Bill would amend the Delaware code to ensure that persons covered under health insurance policies receive the right to (a) appropriate referrals, (b) necessary prescription drugs, (c) speedy internal appeals of adverse decisions, (d) appropriate emergency room care, and (e) benefits for clinical trials.

Author: Senator Blevins