Health Care General Committee

Wednesday, March 8, 2006
10:00 AM – 12:00 PM
306 HOB

COMMITTEE MEETING PACKET

Revised

Allan G. Bense
Speaker

Gayle B. Harrell
Chair

AGENDA
Health Care General Committee
March 8, 2006
10:00 a.m. – 12:00 p.m.
306 HOB

I. Call to order/Roll Call

II. Opening Remarks

III. Consideration of the following bill:

- HB 1027 - - Biomedical Research by Hasner, Coley

IV. Workshop on the following:

- HB 645 - - Nursing Home Facilities by Gelber

V. Presentation of OPPAGA Report No. 06-07
Inflated Pricing, Confidential Information Prevent Medicaid from Ensuring Lowest Prescription Drug Prices

VI. Presentation by the Department of Health
Crohn's Disease and Ulcerative Colitis Report

VII. Presentation by the Florida Council for Community Mental Health
Mental Health and Hospital Emergency Care

VIII. Closing Remarks and Adjournment

1 A bill to be entitled
2 An act relating to biomedical research; providing
3 legislative intent; amending s. 215.5602, F.S.; revising
4 the method for appointing members to the Biomedical
5 Research Advisory Council; authorizing the Legislature to
6 annually appropriate funds to the James and Esther King
7 Biomedical Research Program; providing for transition to
8 new appointments; amending s. 381.855, F.S.; revising the
9 purpose of the Florida Center for Universal Research to
10 Eradicate Disease; requiring the center to provide grants
11 for cancer research; revising membership of the center's
12 advisory council; providing for terms of office and the
13 filling of vacancies; providing for officers, meetings,
14 and procedure; providing procedures for awarding of cancer
15 research grants; providing for peer review panels;
16 providing requirements with respect to ethical conduct and
17 conflicts of interest; providing for public records and
18 meetings; authorizing the Legislature to annually
19 appropriate funds to the Florida Center for Universal
20 Research to Eradicate Disease; providing for transition to
21 new appointments; amending s. 381.921, F.S.; revising a
22 goal of the Florida Cancer Council; creating s. 381.922,
23 F.S.; establishing the William G. "Bill" Bankhead, Jr.,
24 and David Coley Cancer Research Program within the
25 Department of Health; providing the purpose of the
26 program; requiring an annual report; amending s. 561.121,
27 F.S.; redistributing certain funds collected from taxes on
28 alcoholic beverages; amending s. 1004.445, F.S.; revising

29 the method of appointing and filling vacancies on the
30 board of directors of the Johnnie B. Byrd, Sr.,
31 Alzheimer's Center and Research Institute; requiring
32 certain information in the annual report; requiring an
33 annual operating budget; providing procedures for awarding
34 of Alzheimer's disease research grants; providing for peer
35 review panels; providing requirements with respect to
36 ethical conduct, conflicts of interest, and
37 confidentiality; providing for public records and
38 meetings; authorizing the Legislature to annually
39 appropriate funds to the Johnnie B. Byrd, Sr., Alzheimer's
40 Center and Research Institute; providing for transition to
41 new appointments; providing appropriations; providing
42 effective dates.
43
44 Be It Enacted by the Legislature of the State of Florida:
45
46 Section 1. It is the intent of the Legislature to provide
47 funding to support grants for biomedical research in this state
48 with the anticipation that sustained funding for biomedical
49 research over a period of years will lead to an alleviation of
50 human suffering from diseases such as cancer and Alzheimer's
51 disease. It is the intent of the Legislature to dramatically
52 reduce this state's inordinately high cancer burden, reducing
53 both cancer incidence and mortality, while advancing scientific
54 endeavors in this state, making this state a world-class leader
55 in cancer research and treatment. Further, it is the intent of
56 the Legislature to address the debilitating and deadly effects

57 of Alzheimer's disease by supporting research in Alzheimer's
58 disease statewide through the awarding of research grants on a
59 competitive basis. Additionally, it is the intent of the
60 Legislature to stimulate dramatic economic development,
61 particularly in the biotechnology industry, through investment
62 in this state's biomedical research.
63 Section 2. Subsection (3) of section 215.5602, Florida
64 Statutes, is amended, and subsection (11) is added to that
65 section, to read:
66 215.5602 James and Esther King Biomedical Research
67 Program.--
68 (3) There is created within the Department of Health the
69 Biomedical Research Advisory Council.
70 (a) The council shall consist of nine members, including:
71 the chief executive officer of the Florida Division of the
72 American Cancer Society, or a designee; the chief executive
73 officer of the Florida/Puerto Rico Affiliate of the American
74 Heart Association, or a designee; and the chief executive
75 officer of the American Lung Association of Florida, or a
76 designee. The ~~Governor shall appoint the~~ remaining six members
77 of the council~~,~~ shall be appointed as follows:
78 1. The Governor shall appoint two members with expertise
79 in the field of biomedical research, one member from a research
80 university in the state, and one member representing the general
81 population of the state.
82 2. The President of the Senate shall appoint one member
83 with expertise in the field of behavioral or social research.

84 3. The Speaker of the House of Representatives shall
85 appoint one member from a professional medical organization.
86 ~~4. One member from a research university in the state.~~
87 ~~5. One member representing the general population of the~~
88 ~~state.~~
89
90 In making these ~~his or her~~ appointments, the Governor, the
91 President of the Senate, and the Speaker of the House of
92 Representatives shall select primarily, but not exclusively,
93 Floridians with biomedical and lay expertise in the general
94 areas of cancer, cardiovascular disease, stroke, and pulmonary
95 disease. The ~~Governor's~~ appointments shall be for a 3-year term
96 and shall reflect the diversity of the state's population. An
97 appointed ~~A council~~ member ~~appointed by the Governor~~ may not
98 serve more than two consecutive terms.
99 (b) The council shall adopt internal organizational
100 procedures as necessary for its efficient organization.
101 (c) The department shall provide such staff, information,
102 and other assistance as is reasonably necessary to assist the
103 council in carrying out its responsibilities.
104 (d) Members of the council shall serve without
105 compensation, but may receive reimbursement as provided in s.
106 112.061 for travel and other necessary expenses incurred in the
107 performance of their official duties.
108 (11) The Legislature may annually appropriate funds to the
109 James and Esther King Biomedical Research Program for the
110 purposes of this section.

111 Section 3. All appointments to the Biomedical Research
112 Advisory Council for the James and Esther King Biomedical
113 Research Program that were not made in accordance with s.
114 215.5602, Florida Statutes, as amended by this act, shall expire
115 June 30, 2006, but such appointees may continue to serve until
116 their successors are appointed. This section shall take effect
117 upon this act becoming a law.
118 Section 4. Subsections (3) and (5) of section 381.855,
119 Florida Statutes, are amended, and subsections (6), (7), (8),
120 and (9) are added to that section, to read:
121 381.855 Florida Center for Universal Research to Eradicate
122 Disease.--
123 (3) There is established within the Department of Health
124 the Florida Center for Universal Research to Eradicate Disease,
125 which shall be known as "CURED."
126 (a) The purpose of the center is to coordinate, improve,
127 expand, and monitor all biomedical research programs within the
128 state, facilitate funding opportunities, including providing
129 grants for cancer research through the William G. "Bill"
130 Bankhead, Jr., and David Coley Cancer Research Program created
131 in s. 381.922, and foster improved technology transfer of
132 research findings into clinical trials and widespread public
133 use.
134 (b) The goal of the center is to find cures for diseases
135 such as cancer, heart disease, lung disease, diabetes,
136 autoimmune disorders, and neurological disorders, including
137 Alzheimer's disease, epilepsy, and Parkinson's disease.

138 (c) The center shall hold an annual biomedical technology
139 summit in Florida to which biomedical researchers, biomedical
140 technology companies, business incubators, pharmaceutical
141 manufacturers, and others around the nation and world are
142 invited to share biomedical research findings in order to
143 expedite the discovery of cures. Summit attendees shall cover
144 the costs of such attendance or obtain sponsorship for such
145 attendance.
146 (d) The center shall encourage clinical trials in this
147 state on research that holds promise of curing a disease or
148 condition. The center shall facilitate partnerships between
149 researchers, treating physicians, and community hospitals for
150 the purpose of sharing new techniques and new research findings,
151 as well as coordinating voluntary donations to ensure an
152 adequate supply of adult stem cells, placentas, or cord blood.
153 (e) The center shall facilitate the formation of
154 partnerships between researchers in this state and institutions
155 in other states and countries where research with rare plants or
156 animals could lead to cures.
157 (f) The center shall encourage agricultural colleges and
158 agricultural businesses in this state to be active in the search
159 for cures and in providing information to the public about
160 disease prevention.
161 (g) The center shall facilitate partnerships among
162 researchers working to cure all types of diseases, including
163 those that are prevalent in developed countries and those that
164 occur mainly in developing countries.

165 (h) The center shall also encourage the discovery and
166 production in Florida of vaccines that prevent disease.
167 (i) The center shall monitor the supply and demand needs
168 of researchers relating to stem cell research and other types of
169 human tissue research. If the center determines that there is a
170 need for increased donation of human tissue, it shall notify
171 hospitals licensed pursuant to chapter 395 which have entered
172 into partnership agreements with research institutes conducting
173 stem cell research located in the same geographic region as the
174 researchers demanding the stem cells or other tissues. Such
175 hospitals shall implement programs that encourage voluntary
176 donations of cord blood or other needed adult tissue.
177 (j) The center shall be funded through private, state, and
178 federal sources.
179 (k) The center shall serve as a registry of all known
180 opportunities for biomedical grants ~~and may assist any public or~~
181 ~~private biomedical research program in this state in preparing~~
182 ~~grant requests~~.
183 (l) The center shall provide grants for cancer research to
184 further the search for cures for cancer.
185 1. Emphasis shall be given to the goals enumerated in s.
186 381.921, as those goals support the advancement of such cures.
187 2. Preference may be given to grant proposals that foster
188 collaborations between institutions, researchers, and community
189 practitioners, as such proposals support the advancement of
190 cures through basic or applied research, including cancer
191 clinical trials and related networks.

192 (m) ~~(l)~~ The center shall maintain a website with links to
193 peer-reviewed biomedical research. The website shall also
194 contain a list of all known biomedical research being conducted
195 in Florida and shall facilitate communication among researchers
196 and other interested parties.
197 (n) ~~(m)~~ The center shall submit an annual report to the
198 Governor, the President of the Senate, and the Speaker of the
199 House of Representatives no later than January 15 which contains
200 recommendations for legislative change necessary to foster a
201 positive climate for biomedical research in this state.
202 (5) There is established within the center an advisory
203 council that shall meet at least annually.
204 (a) The council shall consist of one representative from a
205 Florida not-for-profit institution engaged in basic and clinical
206 biomedical research and education which receives more than $10
207 million in annual grant funding from the National Institutes of
208 Health, to be appointed by the Secretary of Health from a
209 different institution each term, and ~~the members of the board of~~
210 ~~directors of the Florida Research Consortium and at least~~ one
211 representative from and appointed by each of the following
212 entities:
213 1. The Emerging Technology Commission.
214 2. Enterprise Florida, Inc.
215 3. BioFlorida.
216 4. The Biomedical Research Advisory Council.
217 5. The Florida Medical Foundation.
218 6. Pharmaceutical Research and Manufacturers of America.
219 7. The Florida Tri-Agency Coalition on Smoking OR Health.

220 8. The Florida Cancer Council.
221 9. The American Cancer Society, Florida Division, Inc.
222 10. The American Heart Association.
223 11. The American Lung Association of Florida.
224 12. The American Diabetes Association, South Coastal
225 Region.
226 13. The Alzheimer's Association.
227 14. The Epilepsy Foundation.
228 15. The National Parkinson Foundation.
229 16. The Florida Public Health Foundation, Inc.
230 17. The Florida Research Consortium ~~Scripps Florida or the~~
231 ~~entity formed in this state by The Scripps Research Institute~~.
232 (b) Members of the council shall serve without
233 compensation, and each organization represented shall cover all
234 expenses of its representative.
235 (6) Members shall be appointed to 4-year terms of office.
236 The members of the advisory council shall annually elect a chair
237 from among the members of the advisory council. Any vacancy on
238 the advisory council shall be filled in the same manner as the
239 original appointment.
240 (7) The advisory council shall meet at least annually, but
241 may meet as often as it deems necessary to carry out its duties
242 and responsibilities. The advisory council may take official
243 action by a majority vote of the members present at any meeting
244 at which a quorum is present.
245 (8)(a) Applications for cancer research funding may be
246 submitted from any university or established research institute
247 in the state. All qualified investigators in the state,

248 regardless of institutional affiliation, shall have equal access
249 and opportunity to compete for the research funding.
250 Collaborative proposals, including those that advance the
251 center's goals enumerated in paragraph (3)(l), may be given
252 preference. Grants shall be awarded by the Secretary of Health,
253 after consultation with the council, on the basis of scientific
254 merit, as determined by an open, competitive peer review process
255 that ensures objectivity, consistency, and high quality. The
256 following types of applications shall be considered for funding:
257 1. Investigator-initiated research grants.
258 2. Institutional research grants.
259 3. Collaborative research grants, including those that
260 advance the finding of cures through basic or applied research.
261 (b) To ensure that all proposals for research funding are
262 appropriate and are evaluated fairly on the basis of scientific
263 merit, the Secretary of Health, in consultation with the
264 council, shall appoint a peer review panel of independent,
265 scientifically qualified individuals to review the scientific
266 content of each proposal and establish its scientific priority
267 score. The priority scores shall be forwarded to the council and
268 must be considered in determining which proposals shall be
269 recommended for funding.
270 (c) The council and the peer review panel shall establish
271 and follow rigorous guidelines for ethical conduct and adhere to
272 a strict policy with regard to conflict of interest. A member of
273 the council or panel may not participate in any discussion or
274 decision with respect to a research proposal by any firm,
275 entity, or agency with which the member is associated as a

276 member of the governing body or as an employee or with which the
277 member has entered into a contractual arrangement. Meetings of
278 the council and the peer review panels are subject to chapter
279 119, s. 286.011, and s. 24, Art. I of the State Constitution.
280 (9) The Legislature may annually appropriate funds to the
281 Florida Center for Universal Research to Eradicate Disease for
282 research grants and for operating costs.
283 Section 5. All appointments to the advisory council for
284 the Florida Center for Universal Research to Eradicate Disease
285 that were not made in accordance with s. 381.855, Florida
286 Statutes, as amended by this act, shall expire June 30, 2006,
287 but such appointees may continue to serve until their successors
288 are appointed. This section shall take effect upon this act
289 becoming a law.
290 Section 6. Subsection (1) of section 381.921, Florida
291 Statutes, is amended to read:
292 381.921 Florida Cancer Council mission and duties.--The
293 council, which shall work in concert with the Florida Center for
294 Universal Research to Eradicate Disease to ensure that the goals
295 of the center are advanced, shall endeavor to dramatically
296 improve cancer research and treatment in this state through:
297 (1) Efforts to significantly expand cancer research
298 capacity in the state by:
299 (a) Identifying ways to attract new research talent and
300 attendant national grant-producing researchers to ~~Florida-based~~
301 cancer research facilities in this state;

302 (b) Implementing a peer-reviewed, competitive process to
303 identify and fund the best proposals to expand cancer research
304 institutes in this state;
305 (c) Funding through available resources for those
306 proposals that demonstrate the greatest opportunity to attract
307 federal research grants and private financial support;
308 (d) Encouraging the employment of bioinformatics in order
309 to create a cancer informatics infrastructure that enhances
310 information and resource exchange and integration through
311 researchers working in diverse disciplines, to facilitate the
312 full spectrum of cancer investigations;
313 (e) Facilitating the technical coordination, business
314 development, and support of intellectual property as it relates
315 to the advancement of cancer research; and
316 (f) Aiding in other multidisciplinary research-support
317 activities as they inure to the advancement of cancer research.
318 Section 7. Section 381.922, Florida Statutes, is created
319 to read:
320 381.922 William G. "Bill" Bankhead, Jr., and David Coley
321 Cancer Research Program.--
322 (1) The William G. "Bill" Bankhead, Jr., and David Coley
323 Cancer Research Program, which may be otherwise cited as the
324 "Bankhead-Coley Program," is created within the Department of
325 Health. The purpose of the program shall be to advance progress
326 towards cures for cancer through grants awarded through a peer-
327 reviewed, competitive process pursuant to s. 381.855.
328 (2) By December 15 of each year, the Department of Health
329 shall submit to the Governor, the President of the Senate, and

330 the Speaker of the House of Representatives a report indicating
331 progress towards the program's mission and making
332 recommendations that further its purpose.
333 Section 8. Subsection (1) of section 561.121, Florida
334 Statutes, is amended to read:
335 561.121 Deposit of revenue.--
336 (1) All state funds collected pursuant to ss. 563.05,
337 564.06, and 565.12 shall be paid into the State Treasury and
338 disbursed in the following manner:
339 (a)~~1.~~ Two percent of monthly collections of the excise
340 taxes on alcoholic beverages established in ss. 563.05, 564.06,
341 and 565.12 shall be deposited into the Alcoholic Beverage and
342 Tobacco Trust Fund to meet the division's appropriation for the
343 state fiscal year.
344 ~~2. Beginning July 1, 2004, there is annually distributed~~
345 ~~$15 million to the Grants and Donations Trust Fund within the~~
346 ~~Department of Elderly Affairs, and these funds are annually~~
347 ~~appropriated to support a contract with the Johnnie B. Byrd,~~
348 ~~Sr., Alzheimer's Center and Research Institute at the University~~
349 ~~of South Florida for the purposes of conducting research,~~
350 ~~developing and operating integrated data projects, and providing~~
351 ~~assistance to memory disorder clinics as established in s.~~
352 ~~430.502.~~
353 ~~3. Beginning July 1, 2004, there is annually distributed~~
354 ~~$6 million to the Biomedical Research Trust Fund within the~~
355 ~~Department of Health, and these funds are annually appropriated~~
356 ~~to the James and Esther King Biomedical Research Program. From~~
357 ~~these funds, up to $250,000 shall be available annually for the~~

358 ~~operating costs of the Florida Center for Universal Research to~~
359 ~~Eradicate Disease.~~
360 ~~4. Beginning July 1, 2004, there is annually distributed~~
361 ~~$9 million to be paid by warrant drawn by the Chief Financial~~
362 ~~Officer upon the State Treasury to Florida State University for~~
363 ~~the School of Chiropractic Medicine. Notwithstanding the~~
364 ~~provisions of chapter 216, until the School of Chiropractic~~
365 ~~Medicine is completely staffed and fully operational, these~~
366 ~~funds may be used for any purpose by the university.~~
367 (b) The remainder of the funds collected pursuant to ss.
368 563.05, 564.06, and 565.12 ~~collection~~ shall be credited to the
369 General Revenue Fund.
370 Section 9. Subsections (2) and (6) of section 1004.445,
371 Florida Statutes, are amended, present subsections (8), (9), and
372 (10) are renumbered as subsections (9), (10), and (11),
373 respectively, and new subsections (8) and (12) are added to that
374 section, to read:
375 1004.445 Johnnie B. Byrd, Sr., Alzheimer's Center and
376 Research Institute.--
377 (2)(a) The State Board of Education shall enter into an
378 agreement for the utilization of the facilities on the campus of
379 the University of South Florida to be known as the Johnnie B.
380 Byrd, Sr., Alzheimer's Center and Research Institute, including
381 all furnishings, equipment, and other chattels used in the
382 operation of those facilities, with a Florida not-for-profit
383 corporation organized solely for the purpose of governing and
384 operating the Johnnie B. Byrd, Sr., Alzheimer's Center and
385 Research Institute. This not-for-profit corporation, acting as

386 an instrumentality of the state, shall govern and operate the
387 Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute
388 in accordance with the terms of the agreement between the State
389 Board of Education and the not-for-profit corporation. The not-
390 for-profit corporation may, with the prior approval of the State
391 Board of Education, create either for-profit or not-for-profit
392 corporate subsidiaries, or both, to fulfill its mission. The
393 not-for-profit corporation and its subsidiaries are authorized
394 to receive, hold, invest, and administer property and any moneys
395 acquired from private, local, state, and federal sources, as
396 well as technical and professional income generated or derived
397 from practice activities of the institute, for the benefit of
398 the institute and the fulfillment of its mission.
399 (b)~~1.~~ The affairs of the not-for-profit corporation shall
400 be managed by a board of directors who shall serve without
401 compensation. The board of directors shall consist of the
402 President of the University of South Florida and the chair of
403 the State Board of Education, or their designees, five ~~5~~
404 representatives of the state universities, and nine ~~no fewer~~
405 ~~than 9 nor more than 14~~ representatives of the public who are
406 neither medical doctors nor state employees. Each director who
407 is a representative of a state university or of the public shall
408 be appointed to serve a term of 3 years. The chair of the board
409 of directors shall be selected by a majority vote of the
410 directors. Each director shall have only one vote.
411 ~~2. The initial board of directors shall consist of the~~
412 ~~President of the University of South Florida and the chair of~~
413 ~~the State Board of Education, or their designees; the~~ Of the

414 five university representatives, ~~of whom~~ one shall be appointed
415 by the Governor, two by the President of the Senate, and two by
416 the Speaker of the House of Representatives; and of the nine
417 public representatives, ~~of whom~~ three shall be appointed by the
418 Governor, three by the President of the Senate, and three by the
419 Speaker of the House of Representatives. ~~Upon the expiration of~~
420 ~~the terms of the initial appointed directors, all directors~~
421 ~~subject to 3-year terms of office under this paragraph shall be~~
422 ~~appointed by a majority vote of the directors and the board may~~
423 ~~be expanded to include additional public representative~~
424 ~~directors up to the maximum number allowed.~~ Any vacancy in
425 office shall be filled in the same manner as the original
426 appointment ~~for the remainder of the term by majority vote of~~
427 ~~the directors~~. Any director may be reappointed.
428 (6) The institute shall be administered by a chief
429 executive officer, who shall be appointed by and serve at the
430 pleasure of the board of directors of the not-for-profit
431 corporation, and who shall exercise the following powers and
432 duties, subject to the approval of the board of directors:
433 (a) The chief executive officer shall establish programs
434 that fulfill the mission of the institute in research,
435 education, treatment, prevention, and early detection of
436 Alzheimer's disease; however, the chief executive officer may
437 not establish academic programs for which academic credit is
438 awarded and which culminate in the conferring of a degree,
439 without prior approval of the State Board of Education.
440 (b) The chief executive officer shall have control over
441 the budget and the moneys appropriated or donated to the

442 institute from private, local, state, and federal sources, as
443 well as technical and professional income generated or derived
444 from practice activities of the institute. However, professional
445 income generated by university faculty from practice activities
446 at the institute shall be shared between the institute and the
447 university as determined by the chief executive officer and the
448 appropriate university dean or vice president.
449 (c) The chief executive officer shall appoint
450 representatives of the institute to carry out the research,
451 patient care, and educational activities of the institute and
452 establish the compensation, benefits, and terms of service of
453 such representatives. Representatives of the institute shall be
454 eligible to hold concurrent appointments at affiliated academic
455 institutions. University faculty shall be eligible to hold
456 concurrent appointments at the institute.
457 (d) The chief executive officer shall have control over
458 the use and assignment of space and equipment within the
459 facilities.
460 (e) The chief executive officer shall have the power to
461 create the administrative structure necessary to carry out the
462 mission of the institute.
463 (f) The chief executive officer shall have a reporting
464 relationship to the Commissioner of Education.
465 (g) The chief executive officer shall provide a copy of
466 the institute's annual report to the Governor and Cabinet, the
467 President of the Senate, the Speaker of the House of
468 Representatives, and the chair of the State Board of Education.
469 <u>The annual report shall describe the expenditure of all funds</u>

470 and shall provide information regarding research that has been
471 conducted or funded by the center, as well as the expected and
472 actual results of such research.
473 (h) By August 1 of each year, the chief executive officer
474 shall develop and submit to the Governor and Cabinet, the
475 President of the Senate, the Speaker of the House of
476 Representatives, and the chair of the State Board of Education
477 an annual operating budget detailing the planned use of state,
478 federal, and private funds for the fiscal year.
479 (8)(a) Applications for Alzheimer's disease research
480 funding may be submitted from any university or established
481 research institute in the state. All qualified investigators in
482 the state, regardless of institutional affiliation, shall have
483 equal access and opportunity to compete for the research
484 funding. Grants shall be awarded by the board of directors of
485 the not-for-profit corporation, after consultation with the
486 CURED advisory council created under s. 381.855, on the basis of
487 scientific merit, as determined by an open, competitive peer
488 review process that ensures objectivity, consistency, and high
489 quality. The following types of applications shall be considered
490 for funding:
491 1. Investigator-initiated research grants.
492 2. Institutional research grants.
493 (b) To ensure that all proposals for research funding are
494 appropriate and are evaluated fairly on the basis of scientific
495 merit, the board of directors of the not-for-profit corporation,
496 in consultation with the council of scientific advisors, shall
497 appoint a peer review panel of independent, scientifically

498 qualified individuals to review the scientific content of each
499 proposal and establish its scientific priority score. The
500 priority scores shall be forwarded to the council and must be
501 considered in determining which proposals shall be recommended
502 for funding.
503 (c) The council of scientific advisors and the peer review
504 panel shall establish and follow rigorous guidelines for ethical
505 conduct and adhere to a strict policy with regard to conflict of
506 interest and confidentiality which shall comply with National
507 Institutes of Health standards. All employees, members of the
508 board of directors, and affiliates of the not-for-profit
509 corporation shall follow the same rigorous guidelines for
510 ethical conduct and shall adhere to the same strict policy with
511 regard to conflict of interest and confidentiality. A member of
512 the council or panel may not participate in any discussion or
513 decision with respect to a research proposal by any firm,
514 entity, or agency with which the member is associated as a
515 member of the governing body or as an employee or with which the
516 member has entered into a contractual arrangement. Meetings of
517 the council and the peer review panels are subject to chapter
518 119, s. 286.011, and s. 24, Art. I of the State Constitution.
519 (12) The Legislature may annually appropriate funds to the
520 Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute
521 at the University of South Florida for the purposes of this
522 section.
523 Section 10. All appointments to the board of directors of
524 the not-for-profit corporation for the Johnnie B. Byrd, Sr.,
525 Alzheimer's Center and Research Institute that were not made in

526 accordance with s. 1004.445, Florida Statutes, as amended by
527 this act, shall expire June 30, 2006, but such appointees may
528 continue to serve until their successors are appointed. This
529 section shall take effect upon this act becoming a law.
530 Section 11. (1) The sum of $6 million is appropriated
531 from the General Revenue Fund to the Biomedical Research Trust
532 Fund in the Department of Health for fiscal year 2006-2007 for
533 purposes of the James and Esther King Biomedical Research
534 Program pursuant to s. 215.5602, Florida Statutes.
535 (2) The sum of $9 million is appropriated from the General
536 Revenue Fund to the Florida Center for Universal Research to
537 Eradicate Disease within the Department of Health for fiscal
538 year 2006-2007 to be distributed pursuant to s. 381.855, Florida
539 Statutes, to provide grants to researchers seeking cures for
540 cancer, with emphasis given to the goals enumerated in s.
541 381.921, Florida Statutes.
542 (3) The sum of $15 million is appropriated from the
543 General Revenue Fund to the Johnnie B. Byrd, Sr., Alzheimer's
544 Center and Research Institute at the University of South Florida
545 for fiscal year 2006-2007 for the purposes of conducting
546 research, developing and operating integrated data projects, and
547 providing assistance to memory disorder clinics as provided
548 under s. 430.502, Florida Statutes. Not less than 80 percent of
549 these funds shall be distributed by the center as institutional
550 research grants or investigator-initiated research grants.
551 Section 12. Except as otherwise expressly provided in this
552 act and except for this section, which shall take effect upon

553 this act becoming a law, this act shall take effect July 1,
554 2006.

Workshop
HB 645

1 A bill to be entitled
2 An act relating to nursing home facilities; creating s.
3 400.0627, F.S.; providing legislative intent; requiring
4 the Agency for Health Care Administration to reimburse
5 nursing home facilities for the cost of building or
6 modifying their emergency electrical power systems to
7 fully operate during and after an emergency; providing
8 eligibility criteria for reimbursement; providing an
9 appropriation; providing an effective date.
10
11 Be It Enacted by the Legislature of the State of Florida:
12
13 Section 1. Section 400.0627, Florida Statutes, is created
14 to read:
15 400.0627 Emergency electrical power system capacity.--
16 (1) It is the intent of the Legislature that each nursing
17 home facility in this state be encouraged to have an emergency
18 electrical power system capacity that is sufficient to remain
19 fully operational during and after an emergency in order to
20 maintain the safety and health of the residents of the nursing
21 home facility and, if necessary, to provide care to residents
22 evacuated from other nursing home facilities.
23 (2) The agency shall reimburse an eligible nursing home
24 facility for the costs of building or modifying its emergency
25 electrical power system capacity to fully operate the facility
26 during and after an emergency. To be eligible for reimbursement,
27 a nursing home facility must:
28 (a) Not have been cited for any class I deficiency within

29 the 30 months preceding the application for reimbursement;
30 (b) Not be located within the hurricane evacuation zone of
31 the county in which it is located;
32 (c) Have the capacity, as determined by the agency, to
33 care for residents evacuated from other nursing home facilities
34 during an emergency; and
35 (d) Agree to receive residents who are transferred from
36 other nursing home facilities.
37 (3) This section does not require a nursing home facility
38 to modify its existing emergency electrical power system
39 capacity.
40 Section 2. The sum of $ is appropriated from the
41 General Revenue Fund to the Agency for Health Care
42 Administration for the purpose of reimbursing eligible nursing
43 home facilities for the costs of building or modifying their
44 emergency electrical power system capacity to fully operate the
45 facility during and after an emergency during the 2006-2007
46 fiscal year.
47 Section 3. This act shall take effect upon becoming a law.

OPPAGA Report
No. 06-07

oppaga

Inflated Pricing & Confidential Information Prevent Medicaid from Ensuring Lowest Prescription Drug Prices

A Presentation to the House Health Care General Committee

March 8, 2006

Jennifer Johnson, Senior Legislative Analyst

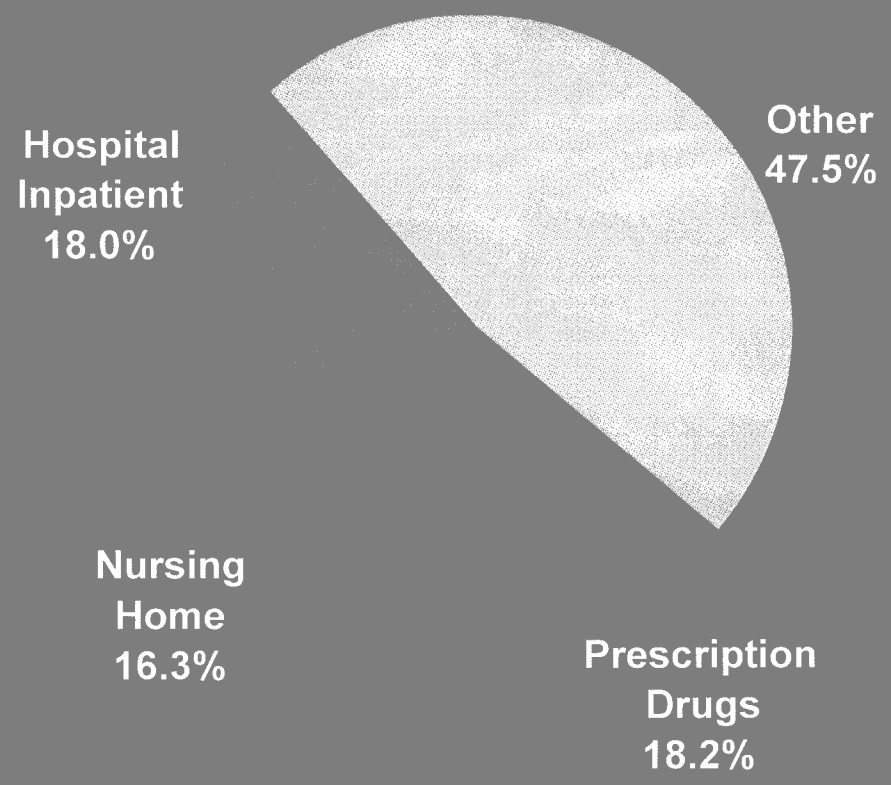
Florida Legislature Office of Program Policy Analysis & Government Accountability

Presentation Overview

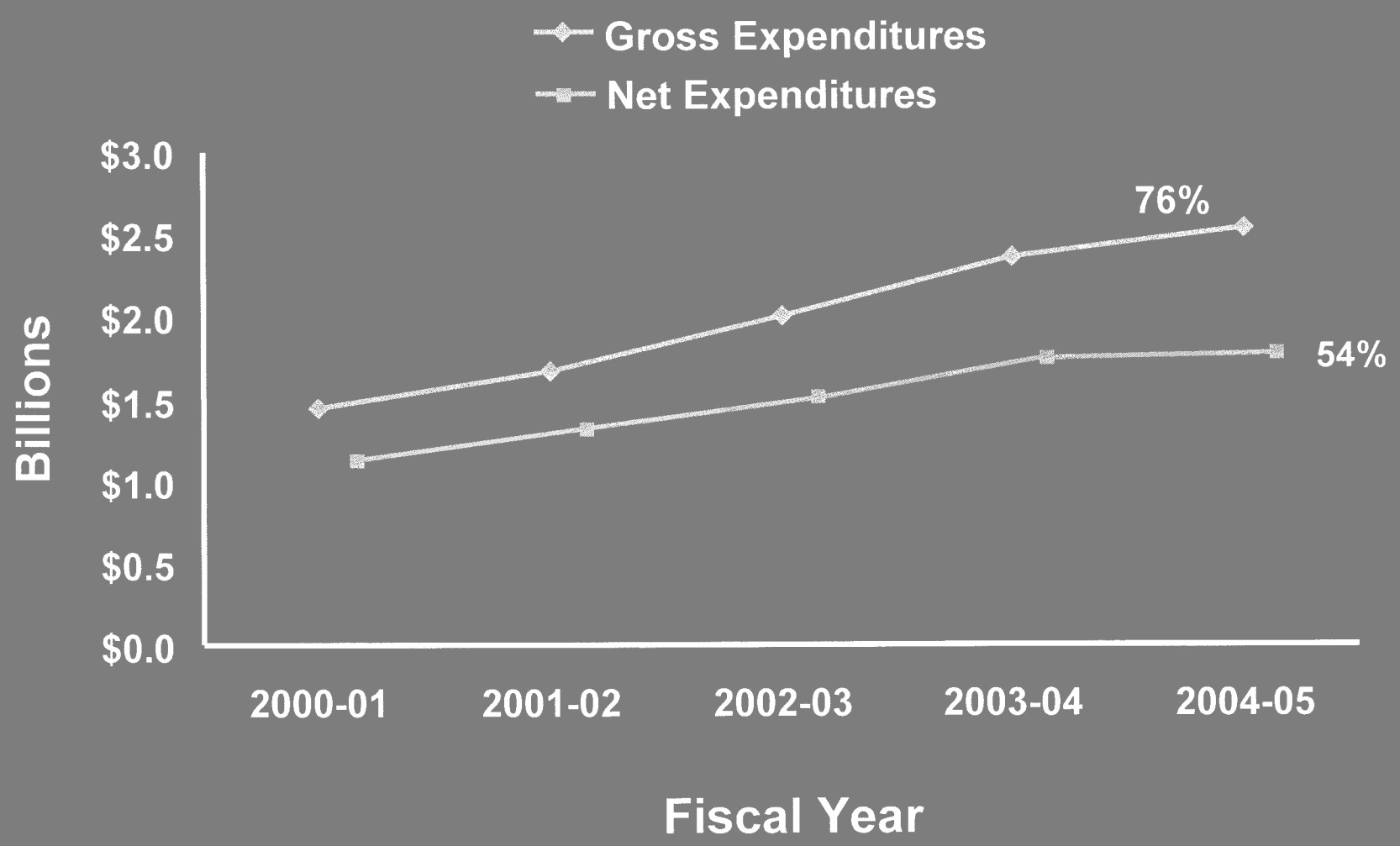
- Medicaid drug expenditures
- Medicaid drug pricing in Florida
- Flaws in Medicaid pricing
- Recommendations

Prescription Drugs Accounted for 18.2% of Medicaid Spending

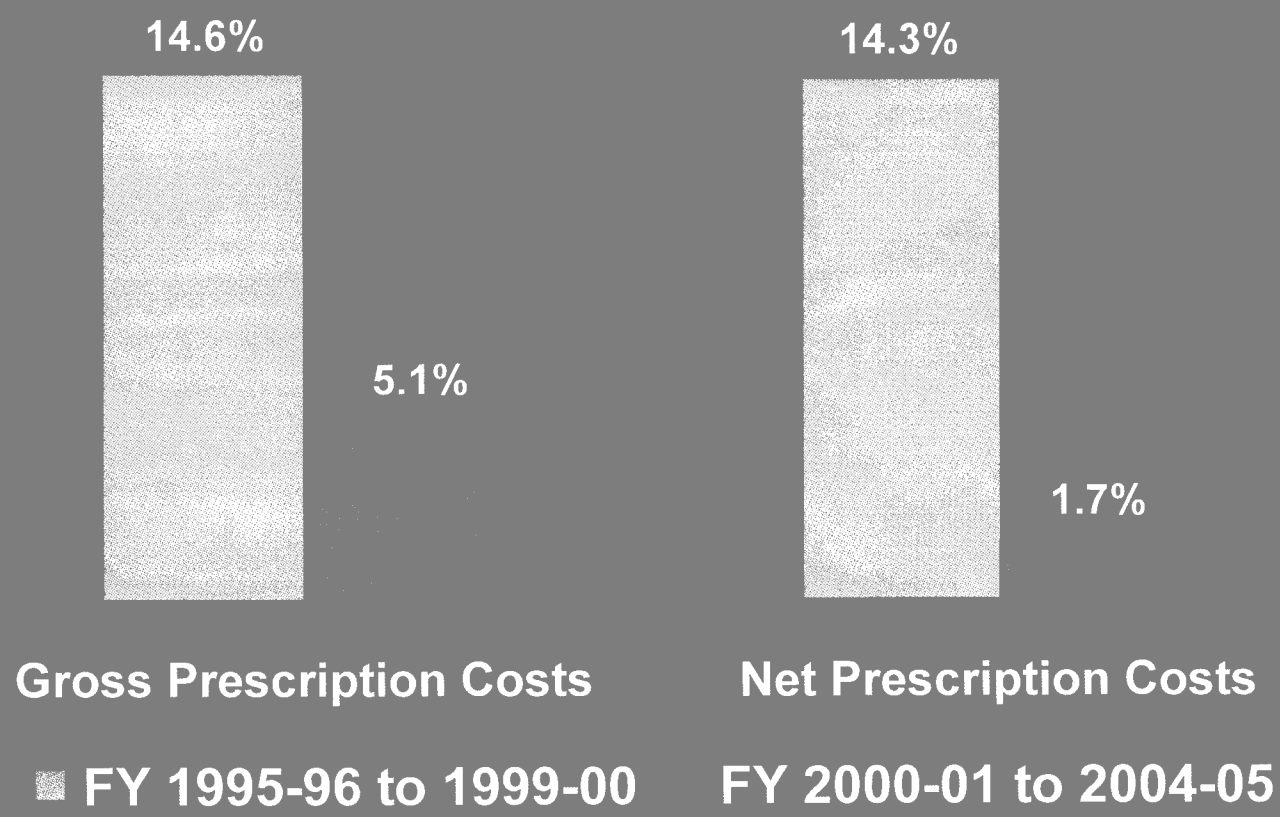
Fiscal Year 2004-05



Medicaid Drug Expenditures



Average Prescription Cost Increased at a Slower Rate



Florida Medicaid Drug Prices

Pharmacy reimbursements

Federal and state supplemental rebates

Pharmacy Reimbursements

Federal guidelines direct states to reimburse pharmacies the lower of the:

- *Estimated acquisition cost* plus dispensing fee, or
- Usual and customary price

Estimated Acquisition Cost

AHCA determines *estimated acquisition costs* by calculating and selecting the lowest of the following:

- Average Wholesale Price (AWP) - 15.4%
- Wholesale Acquisition Cost (WAC) + 5.75%
- The Federal Upper Limit (FUL)
- The State Maximum Allowable Cost (SMAC)

Rebates

- **Federal rebates**
  - Brand name drugs
    - 15.1% of Average Manufacturer Price (AMP) or the difference between the AMP and best price
    - Additional rebate based on inflation
  - Generic drugs
    - 11 % of Average Manufacturer Price (AMP)
- **State supplemental rebates**
  - At least 14% of AMP unless federal or state rebate, or both, equal or exceed 29% of AMP

Fundamental Flaws with Medicaid Pricing

- **Federal research reports:**
  - AWP and WAC are often significantly higher than the prices pharmacies actually pay
- **U.S. Department of Justice and state attorney general investigations reveal intentional inflation by some manufacturers**

Fundamental Flaws (cont.)

This is particularly problematic with the generic drug market

$95.30	$14.00	$14.98	None	$4.36	$10.62	244%
$74.90	$9.31	$9.96	$27.60	$4.49	$5.47	122%
$2,687	$712.50	$2,330.97	$683.00	$97.88	$585.12	598%

Fundamental Flaws (cont.)

- Average Manufacturer Price is a better benchmark for estimating acquisition costs
- However, it is confidential and most states do not have access to it

Recommendations

- Require manufacturers to submit AMP and 'Net Wholesaler Price' and direct AHCA to use information to reimburse pharmacies
  - Federal legislation passed by Congress will allow states access to AMP for Medicaid pricing
  - Texas requires manufacturers to submit AMP and 'net wholesaler prices'

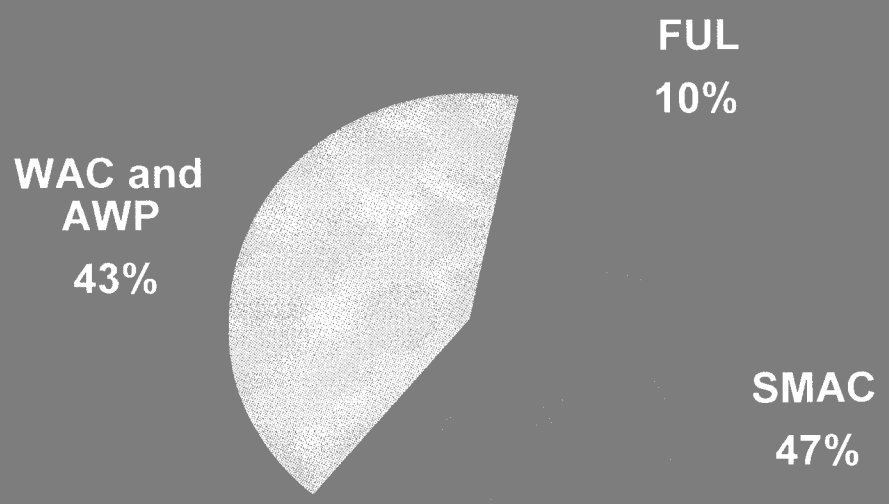
Recommendations

Modify formulas for estimating pharmacy acquisition costs

Drug	AWP-17%	$ 4.6 million
Generics[1]	AWP-40%	20.0 million
Total		$24.6 million

Recommendations

Expand state maximum allowable costs for generic drugs and update more frequently



In the fourth quarter of FY 2004-05, the SMAC price was the lowest price for only 47% of drugs with a SMAC price

Recommendations

- Negotiate supplemental rebates for generic drugs
  - Adjust dispensing fee to encourage pharmacies to dispense generic drugs that receive rebates
- Evaluate joining a purchasing pool
  - Medicare Part D may affect ability to negotiate supplemental rebates

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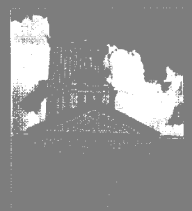
Report available online at:
www.oppaga.state.fl.us/reports/govt/r06-07s.html

Thank you



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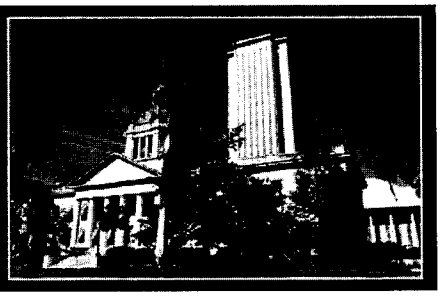


January 2006 Report No. 06-07

Inflated Pricing and Confidential Information Prevent Medicaid from Ensuring Lowest Prescription Drug Prices

at a glance

Medicaid prescription drug expenditures, which were $2.5 billion in Fiscal Year 2004-05, have nearly doubled since Fiscal Year 2000-01, growing an average of 15.1% per year. Legislative actions have helped to slow the growth rate of these expenditures, which rose at an average rate of 21.2% annually during the previous five-year period (Fiscal Years 1995-96 to 1999-00). Much of this slowed growth has been the result of specific cost-containment actions directed at lowering the price that Medicaid pays for drugs.

However, the state's ability to obtain the lowest possible prices for prescription drugs is hindered by inflated manufacturer pricing information and lack of access to confidential information. The Legislature should consider requiring pharmaceutical manufacturers to submit more accurate pricing information to the Agency for Health Care Administration (AHCA) as well as requiring AHCA to strengthen cost-containment strategies to achieve lower prescription drug prices.

Scope

As required by Chapter 2005-133, *Laws of Florida,* this report discusses Medicaid prescription drug pricing, issues that contribute to inflated prescription drug prices, and options for obtaining savings in Medicaid's prescription drug program by paying prices that are closer to pharmacy costs.

Background

Florida's Medicaid program, administered by the Agency for Health Care Administration (AHCA), is among the largest in the country, serving approximately 2.3 million persons each month. Medicaid provides health care coverage to low-income persons who meet federal and state eligibility requirements, including low-income families and children, elderly persons who need long-term care services, and persons with disabilities.

For Fiscal Year 2005-06, the Legislature appropriated $15.6 billion, including nearly $4.5 billion in general revenue, to operate the Medicaid program.[1] Most of these funds ($15.4 billion) will pay for health care services for Medicaid recipients, while $225 million (1.4%) will pay for administrative functions such as program planning, data processing, and contract management.

Florida provides prescription drug coverage as part of its Medicaid program.[2] For outpatient services, Medicaid pays for most prescription drugs and selected over-the-counter medicines.[3]

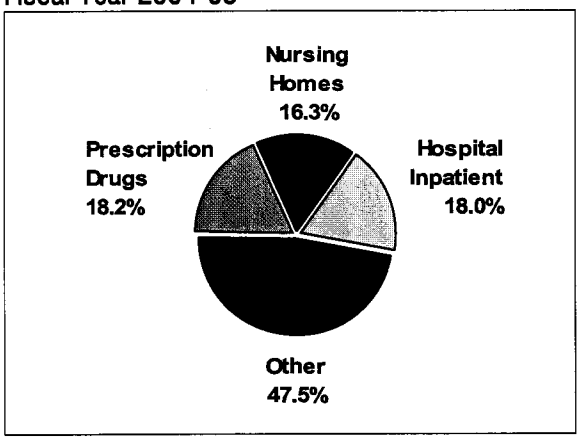
[1] The remaining $11.1 billion comes from trust funds that include federal matching funds as well as other state funds from hospital taxes, drug rebates, and county contributions.

[2] The prescription drug program is an optional Medicaid service, but all states provide prescription drug coverage.

[3] Medicaid does not make specific prescription drug payments to health maintenance organizations and hospitals as prescription drug costs are included as part of their reimbursement.

In Fiscal Year 2004-05, the Florida Medicaid program paid $2.5 billion for prescription drugs. As shown in Exhibit 1, this represented 18.2% of the expenditures for all Medicaid services that year.

Exhibit 1
Prescription Drugs Accounted for 18.2% of Total Expenditures for Medicaid Services in Fiscal Year 2004-05



Source: OPPAGA analysis of AHCA expenditure data.

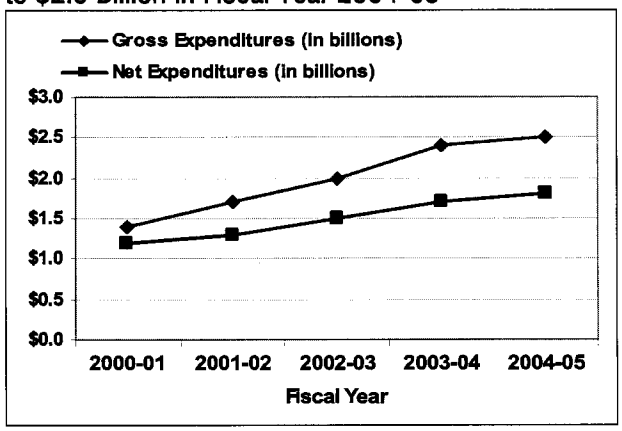
Findings

Prescription drug expenditures have continued to increase, but legislative actions have slowed the growth of these expenditures

Prescription drug expenditures have been one of the fastest growing components of health care and continue to increase annually. To address this rapid growth in the Medicaid program, the Legislature has directed AHCA to implement several cost-containment strategies to slow increases in the price of prescription drugs. These strategies have been successful in slowing both the rate of growth in drug expenditures and the average price per prescription.

Exhibit 2 shows that Medicaid gross prescription drug expenditures increased from around $1.4 billion in Fiscal Year 2000-01 to $2.5 billion in Fiscal Year 2004-05 (or 76%). [4] This represents an average annual growth rate of 15.1% compared to 21.2% annually during the prior five-year period (Fiscal Year 1995-96 to Fiscal Year 1999-00).

Exhibit 2
Medicaid Gross Prescription Drug Expenditures Increased from $1.4 Billion in Fiscal Year 2000-01 to $2.5 Billion in Fiscal Year 2004-05



Source: OPPAGA analysis of AHCA expenditure data.

Net drug expenditures, which take into account federal and state rebates, grew by 54% between Fiscal Year 2000-01 and Fiscal Year 2004-05. (See Exhibit 2.) The annual growth rate during this period was 11.4% which is substantially lower than the 20.9% average net cost increase experienced between Fiscal Years 1995-96 to 1999-00.

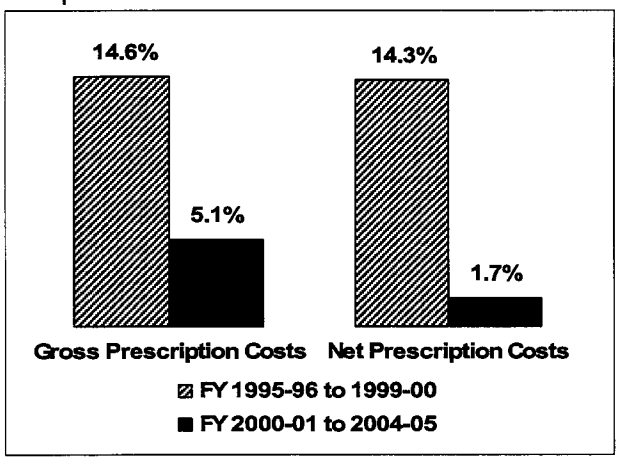
This slower rate of expenditure growth likely resulted from legislatively mandated strategies to control drug price increases. In recent years, the Legislature has mandated that AHCA implement a preferred drug list, which shifts utilization to lower cost drugs and requires brand name drug manufacturers to pay additional cash rebates to the state. The Legislature also has directed AHCA to adjust its pharmacy reimbursement formulas to yield greater discounts and to establish state maximum prices for generic drugs.

The slowed growth in the average price per prescription over the last five years demonstrates the overall success of these strategies. The average price per prescription, without considering rebates, grew by 5.1% during the past five years compared to 14.6% for

[4] Gross expenditures represent total reimbursements to providers and do not account for federal and state rebates. Both Fiscal Year 2004-05 gross and net pharmacy expenditures may change as providers submit final invoices and the state reconciles federal and state rebates.

the previous five-year period. Due to savings achieved from federal and state supplemental rebates, the net cost per prescription grew at a much slower average rate (1.7%) over the past five years compared to the previous five-year period (14.3%). (See Exhibit 3.)

Exhibit 3
Average Prescription Costs Grew at a Slower Rate Between Fiscal Years 2000-01 and 2004-05 Compared to the Prior Five Years



Source: OPPAGA analysis of AHCA drug expenditure data.

Appendix A summarizes Florida's strategies to control Medicaid prescription drug costs and how they have slowed the rate of price increases.

Fundamental flaws related to manufacturer pricing information prevent the state from ensuring that it pays the lowest possible price for prescription drugs

Florida, like all states, seeks to obtain the lowest possible prices for Medicaid prescription drugs. [5] Pricing for prescription drugs is highly complex and is based on the prices paid to pharmacies as well as manufacturer rebates that are required by the federal and some state governments. However, Florida's ability to ensure that it is paying the lowest possible cost for Medicaid prescription drugs is hindered because it must establish pharmacy reimbursement rates using manufacturers' published prices that are inflated and unreliable. While the federal government collects data on manufacturer prices based on actual sales transactions, this information is confidential. As a result, Florida's Medicaid program can not be certain that it obtains the lowest possible prices for prescription drugs.

Pharmacy reimbursements and manufacturer rebates determine how much Florida's Medicaid program pays for prescription drugs. The amount that Florida's Medicaid program spends for prescription drugs depends on two factors: (1) how much Medicaid pays pharmacies for these drugs, and (2) how much Medicaid receives from drug manufacturers in cash rebates. Each state's Medicaid program determines, within federal guidelines, what to pay pharmacies for dispensed drugs. In addition, all states receive manufacturer rebates that are prescribed by federal law, and some states, including Florida, also negotiate with manufacturers for additional rebates (state supplemental rebates). Florida's gross expenditures for Medicaid drugs are reduced by the amount of these manufacturer rebates. In Fiscal Year 2004-05, Florida received $735 million in federal and state manufacturer rebates. [6]

Florida's Medicaid program pays pharmacies the lower of two costs: (1) what it estimates pharmacies pay for drugs (referred to as acquisition costs) plus a $4.23 dispensing fee, or (2) the pharmacy's usual and customary price for the drug. [7] As illustrated in Exhibit 4, AHCA's prescription drug pricing algorithm first selects the lowest estimated acquisition cost and adds the dispensing fee. The algorithm then compares this price to the pharmacy's usual and customary price and pays the lower of these prices. AHCA estimates acquisition costs using two nationally published prices, the Average Wholesale Price (AWP) and the Wholesale Acquisition Cost (WAC); and two maximum prices, the federal upper limit (FUL) and the state maximum

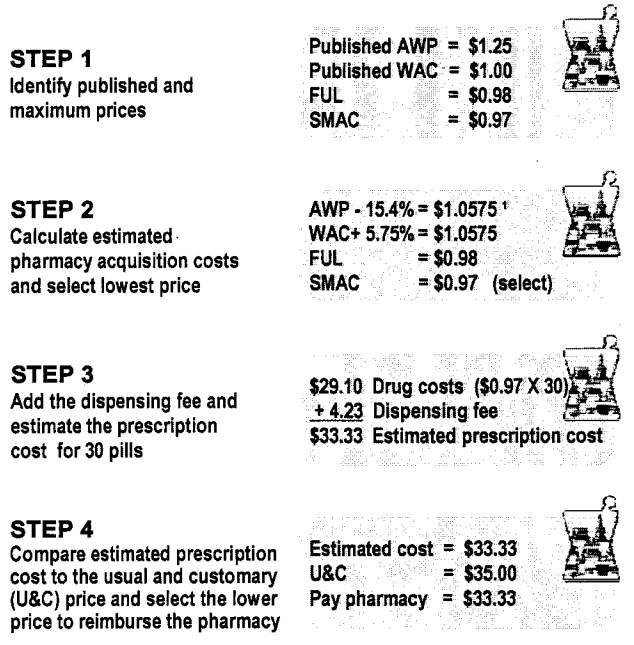
[5] Federal legislation intends for the Department of Veteran's Affairs, the Department of Defense, the Public Health Service, and the U.S. Coast Guard to receive the lowest prices for prescription drug purchases.

[6] Final rebates for Fiscal Year 2004-05 could change as rebates are received and reconciled.

[7] The usual and customary charge reflects the prescription price for persons without insurance.

allowable cost (SMAC).[8] Appendix B provides a glossary of prescription drug pricing terms, and Appendix C details the agency's methods for estimating pharmacy acquisition costs. Appendix D describes the federal and state rebate processes.

Exhibit 4
AHCA Reimburses Pharmacies by Paying the Lower of AHCA's Estimated Prescription Cost or the Usual and Customary Price



Definitions

- Average Wholesale Price (**AWP**). Retail list price (sticker price) or the average price manufacturers recommend that wholesalers sell to physicians, pharmacies, and others.
- Wholesale Acquisition Cost (**WAC**). The average cost at which a manufacturer sells a drug to wholesalers.
- Federal Upper Limit (**FUL**). The maximum amount that the federal government establishes for selected multi-source generic drugs.
- State Maximum Allowable Cost (**SMAC**). The maximum amount a particular state establishes for payment of selected multi-source generic drugs; these can be lower than FUL prices.

[1] Because AWP prices are generally 25% over WAC prices, the state's pricing formulas create equivalent AWP and WAC price estimates.

Source: OPPAGA.

Both federal law and Florida law require manufacturers to provide cash rebates in order for Medicaid to cover their products. These rebates must reach a minimum percentage of the average manufacturer price (AMP).[9] The AMP reflects the average price at which manufacturers sell their products, after accounting for purchasers' discounts and rebates. The Centers for Medicare and Medicaid Services (CMS) calculates federal rebates using AMP information, which manufacturers report quarterly to CMS. Florida statute also requires AHCA to establish state supplemental rebates for brand name drugs based on a minimum percentage of the AMP.

Unreliable information, inflated prices, and confidential manufacturer prices prevent Medicaid from ensuring that it pays the lowest price. To estimate the price that pharmacies pay for drugs, Florida, as most states, generally uses published prices (AWP and WAC) provided by manufacturers that are reported in commercial publications.[10] However, pharmacies' actual purchase prices are sometimes significantly lower than these published prices. Research conducted by the Congressional Budget Office and the U.S. Department of Health and Human Services' Office of the Inspector General suggests that pharmacies sometimes purchase drugs at prices significantly lower than published prices. Since states set pharmacy reimbursements by estimating acquisition costs using published prices, states could sometimes reimburse pharmacies at rates that are high relative to pharmacy costs.

Recently settled federal and state lawsuits have shown that some manufacturers have intentionally inflated the AWP and WAC prices reported to companies that publish manufacturer prices. For example, in September 2005, the United States Department of Justice settled with one manufacturer for $150 million for fraudulent and inflated pricing of two drugs. Florida's Attorney General has subpoenaed six manufacturers for reporting inflated AWP and WAC prices. The results of these suits are pending but could represent over $100 million in

[8] AHCA obtains manufacturer prices from First DataBank, a supplier of electronic drug information that publishes AWP and WAC prices, which represent manufacturers' published list prices to wholesalers and pharmacies.

[9] Federal rule stipulates that manufactures pay rebates at a minimum of 15.1% of the AMP for brand name drugs and 11% for generic drugs. State law requires that total federal and state rebates for brand name drugs reach a minimum of 29% of the AMP. Florida does not negotiate generic rebates.

[10] In addition to *First DataBank*, other industry publications include the *Red Book*, the *Blue Book*, and *Medi-Span*.

overpayments plus additional fines. In addition, at least 16 states besides Florida have filed lawsuits against manufacturers for inflated pricing practices. [11]

Manufacturers that inflate AWP and WAC published prices do so to encourage pharmacies to purchase their products. By selling drugs to pharmacies at much lower prices, manufacturers achieve higher sales volume and pharmacies achieve a greater profit margin. However, this occurs at the expense of the Medicaid program which pays more than it should for prescription drugs. For example, in an April 2005 Florida lawsuit, the Attorney General's Office charged one manufacturer with reporting prices nearly 600% higher than a pharmacy's actual cost to purchase the drug. One instance cited in this lawsuit showed that Florida's Medicaid program reimbursed a pharmacy based on an inflated AWP published price, resulting in the state paying $683 for a drug that only cost the pharmacy $97.88. While such price inflation can occur in both brand name and generic markets, the competitive nature of the generic market is much more susceptible to this practice. [12]

A more ideal benchmark for Florida to use when estimating pharmacy drug purchase costs is the Average Manufacturer Price (AMP). This price takes into account available discounts and rebates, and policy experts generally consider it to be the most accurate market price. However, manufacturers generally keep these prices confidential except to the federal government which uses them to determine rebates. Thus, states cannot use AMP information to estimate pharmacy costs unless they require such access in state law. The U.S. Congress is currently considering making AMP information available to states. If this legislation passes, states would have access to AMP information without having to require access in state law. [13]

Texas state law requires manufacturers to submit AMP information to its Medicaid program quarterly. The Texas Medicaid program retains the confidentiality of manufacturer information but uses this data to compare against the 'net wholesaler price' that Texas also requires manufacturers to report. Texas uses this 'net wholesaler price' instead of the published WAC to estimate wholesaler acquisition costs. The 'net wholesaler price' differs from the commonly published WAC as it includes all forms of manufacturer discounts. In instances when an AMP is significantly lower than the 'net wholesaler price,' the Texas Medicaid program, in conjunction with the Texas Attorney General's Office, requires the manufacturer to revise the 'net wholesaler price.' By doing this, Texas can better ensure that it reimburses pharmacies at prices that more appropriately reflect pharmacy costs.

Despite pricing flaws, Florida should continue efforts to reduce the cost of Medicaid prescription drugs

Even though current pricing information is flawed, Florida can work toward achieving even lower Medicaid prescription drug prices by modifying its formula for reimbursing both brand and generic drugs, expanding its maximum pricing for generic drugs, negotiating supplemental rebates for generic drugs, and/or forming or joining a multi-state purchasing pool to retain its negotiating leverage after Medicare Part D becomes effective.

The state could modify its formulas for estimating acquisition costs that use published AWP and WAC prices. The Legislature could reduce pharmacy reimbursements for some drugs by mandating a higher discount off the AWP, a lower markup on the WAC, and/or that AHCA develop separate formulas to estimate the acquisition costs for brand name and generic drugs. AHCA currently reimburses pharmacies

[11] These states are Alabama, Arizona, Arkansas, California, Connecticut, Illinois, Kentucky, Massachusetts, Minnesota, Mississippi, Missouri, Montana, New York, Ohio, West Virginia, and Wisconsin.

[12] Unlike brand name drugs in which only one manufacturer produces and markets, numerous manufacturers produce and market generic drugs. Thus, generic drug manufacturers must compete for market share, and therefore, are more likely to offer pharmacies deep discounts to purchase their products.

[13] This issue is expected to be voted on when Congress reconvenes at the end of January 2006.

at AWP-15.4% for both brand name and generic drugs. However, as of March 2005, other states were reimbursing pharmacies for brand name drugs using AWP discounts ranging from 5% to 17%. In addition, six states reimbursed pharmacies for generic drugs using AWP discounts ranging from 20% to 40%. [14] If Florida had reimbursed pharmacies at the high end of these ranges, Medicaid could have saved $24.6 million in Fiscal Year 2004-05. [15] (See Exhibit 5.)

Exhibit 5
Medicaid Could Have Saved $24.6 Million in Pharmacy Expenditures by Increasing the Discount Off the AWP in Fiscal Year 2004-05

Drug Type	Revised Discount Price	Approximate Savings Against Fiscal Year 2004-05 Expenditures
Brand Name Drug	AWP-17%	$ 4.6 million
Generics[1]	AWP-40%	20.0 million
Total		**$24.6 million**

[1]These estimates were developed only for those drugs in which the 'lowest price' would have been derived by using AWP-17% for brand named drugs and AWP-40% for generics.

Source: OPPAGA analysis using AHCA drug expenditure data.

Increasing the discount off the AWP to 17% and 40% for brand and generic drugs, respectively, would enable AHCA to reimburse pharmacies at a price that is closer to what they actually pay to purchase drugs while still allowing pharmacies to make a profit. [16] Florida could set even more aggressive discounts for estimating acquisition costs. Recent research conducted by the U.S. Department of Health and Human Services stated that manufacturer prices are on average equal to AWP-23% and AWP-70% for brand name drugs and generics, respectively. [17]

The agency should continue to expand state maximum pricing for generic drugs and update these prices more frequently. Florida sets state maximum allowable costs (SMAC) for some generic drugs that meet specific criteria, and these SMAC prices should be lower than federal upper limit prices and estimated acquisition costs using published prices. [18] As directed by the Legislature, AHCA has increased efforts to set SMAC prices for generic drugs. In the last quarter of Fiscal Year 2004-05, the SMAC price was the lowest price for 17% more generic products compared to the first quarter of that fiscal year. [19] AHCA updates SMAC prices quarterly and, between June and December 2005, nearly doubled the number of products with maximum prices. [20]

Because the generic drug market operates like a commodities market, maximum prices should be updated often. According to an industry source, generic drug prices can change frequently, with up to 25% of the prices changing weekly mainly due to competition for market share. As shown in Exhibit 6, in the last quarter of Fiscal Year 2004-05, the state maximum price was not the lowest price for over half (53%) of these products, indicating that Florida may benefit from changing SMAC prices more often than quarterly.

[14] One additional state, Washington, reimburses generics produced by five or more manufacturers at AWP minus 50%.

[15] This analysis does not estimate savings for Fiscal Year 2005-06, because implementation of the Medicare Part D Prescription Drug Plan will significantly change Medicaid drug expenditures.

[16] An equivalent adjustment also could be made to the WAC price by reducing its markup from the current 5.75%.

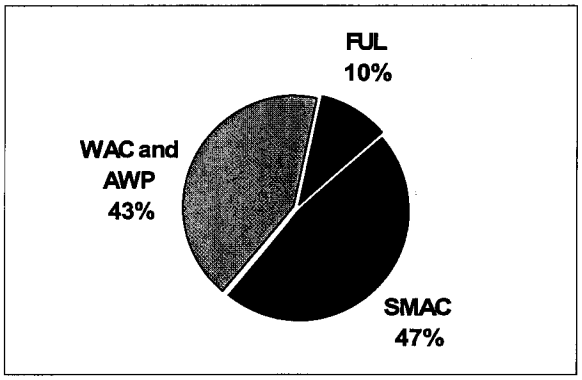
[17] *Medicaid Drug Price Comparisons: Average Manufacturer Price to Published Prices,* June 2005, U.S. Department of Health and Human Services, Office of Inspector General.

[18] The specific criteria are related to the number of manufacturers that produce the generic drug. Unlike the federal government, states are not limited to a percentage of published prices when setting maximum prices.

[19] As directed by the 2004 Legislature, AHCA expanded the SMAC program during the last quarter of the fiscal year after contracting with Provider Synergies in October 2004. Prior to contracting with Provider Synergies, AHCA set maximum prices on an ad hoc basis.

[20] The number of products refers to the total number of unique drug formulations based on characteristics such as forms (capsules, pills, liquids, etc.), dosages (50 mg, 100 mg, etc.), manufacturer, and package size.

Exhibit 6
The SMAC Price Was the Lowest Price for Only 47% of Drugs With SMAC Prices During the Last Quarter of Fiscal Year 2004-05



Source: OPPAGA analysis using AHCA drug expenditure data.

Michigan contracts with a vendor for daily price surveillance. By doing so, it has established maximum prices on two and one-half times as many drug products as Florida and changes maximum prices to follow market fluctuations. These efforts saved Michigan's Medicaid program an estimated $47 million in the first year of the contract with the vendor.

The agency could negotiate generic drug supplemental rebates. In addition to setting maximum prices for generic drugs, AHCA could negotiate supplemental rebates for generic drugs. The Legislature has authorized AHCA to negotiate generic rebates, but it has not done so. [21] In contrast, Texas has negotiated rebates for generic drugs since December 2004. The Texas Medicaid program increased its dispensing fee by $0.50 to encourage pharmacies to fill prescriptions with generic drugs for which Texas receives a supplemental rebate. Texas Medicaid officials estimate that every 1% shift from brand name to generic drugs generates about $15 million in savings. [22]

ACHA should evaluate forming or joining a purchasing pool to preserve negotiating power. In January 2006 with the implementation of the Medicare Part D Prescription Drug Plan, approximately 377,000 Medicaid 'dual eligibles' will transition onto the Medicare plan thereby reducing Medicaid prescription drug volume and shifting drug purchasing patterns. [23] Overall state expenditures are expected to decrease by nearly $1.2 billion representing 19.1 million prescriptions or 50% of the expenditures, with purchases in some therapeutic classes likely to decrease by up to 75%. This change in spending could reduce Florida's ability to continue negotiating the same level of supplemental rebates.

Some states have increased their negotiating power with drug manufacturers by forming multi-state purchasing pools. [24] For example, Michigan is part of a nine-state pool that contracts with a pharmacy benefit manager to manage their pool. The vendor negotiates supplemental rebates based on the total number of lives covered in the pool. Should Florida's Medicaid program lose negotiating power with supplemental rebates after implementation of Medicare Part D, AHCA should evaluate the possible benefits of joining or creating a multi-state purchasing pool.

[21] Section 409.912(39)(a)6., *F.S.* To accomplish this, the agency might need to establish an administrative structure to negotiate and invoice these rebates.

[22] While Florida Medicaid generic prescription drugs comprise only 15% of the total drug expenditures, they comprise almost 50% of total drug claims.

[23] Medicaid dual eligibles are Medicaid recipients who qualify for Medicare and Medicaid and have relied on Medicaid to pay for prescription drugs.

[24] There are currently two multi-state purchasing pools. One includes Louisiana, West Virginia, Wisconsin and Maryland. A second pool includes Michigan Alaska, Hawaii, Minnesota, Montana, Nevada, New Hampshire, Tennessee, and Kentucky.

Recommendations

To achieve lower Medicaid prescription drug prices, we recommend that the Legislature take the actions discussed below.

- **Require manufacturers to report 'net wholesaler prices' and average manufacturer prices (AMP) to AHCA and direct the agency to use this information to reimburse pharmacies.** Texas uses 'net wholesaler prices' which take into account all discounts to more accurately estimate pharmacy acquisition costs and, thereby, reduce its Medicaid prescription drug costs. Texas also uses AMP information to ensure that 'net wholesaler prices' reported by manufacturers are reasonable.
- **Direct AHCA to lower pharmacy reimbursements by modifying its formulas for estimating pharmacy acquisition costs.** AHCA currently reimburses pharmacies at AWP-15.4% for both brand name and generic drugs. Revising these formulas by increasing the discount off the AWP, reducing the markup on the WAC, and/or developing different formulas for brand name and generic drugs would estimate pharmacy costs that are closer to what pharmacies actually pay for drugs.
- **Direct AHCA to continue expanding state maximum pricing for generic drugs and update the maximum pricing list more frequently.** To improve maximum pricing efforts for generic drugs, AHCA should continue to increase the number of generic drugs for which it sets a maximum price. To ensure that a greater percentage of the maximum prices are the lowest price, AHCA should consider adjusting maximum prices more often than quarterly in order to respond to frequent price fluctuations in the generic drug market.
- **Direct AHCA to negotiate generic drug supplemental rebates.** Current Florida law authorizes the agency to negotiate generic rebates, but it has not done so. AHCA could model Texas' generic rebate program which allows pharmacies to dispense any generic drug without prior authorization, but encourages pharmacies to dispense rebated generics by increasing the dispensing fee for these drugs.
- **Direct AHCA to evaluate participation in a purchasing pool.** Under Medicare Part D, the state will reduce prescription drug purchases by nearly 50%, which may affect the state's ability to negotiate the current level of state supplemental rebates. Because of changes in volume and purchasing patterns due to Medicare Part D, AHCA should evaluate the benefits of joining or creating a multi-state purchasing pool.

Appendix A

Medicaid Pharmacy Cost-Containment Strategies Have Slowed Price Increases for Prescription Drugs

Two major factors contribute to increases in Medicaid prescription drug expenditures, price and volume. Volume takes into account utilization (or the number of prescriptions used per person), and enrollment (or the number of persons participating in the Medicaid program). Since 2000, Florida has implemented many strategies to slow growth in Medicaid prescription drug expenditures. Many of these strategies have focused specifically on controlling drug prices. For example, the Legislature required the Agency for Health Care Administration (AHCA) to take the actions described below.

- **Implement a mandatory Preferred Drug List (PDL).** The 2001 Legislature directed the agency to develop a mandatory PDL and negotiate state supplemental rebates with manufacturers. OPPAGA found that the PDL saved $81 million in its first year of implementation. [25] The PDL includes drugs by therapeutic class that are efficacious and have a low cost relative to other drugs in the class. Brand name drug manufacturers can have their drugs placed on the PDL by offering the state cash rebates, which lowers the net cost of their drugs to the state. The PDL essentially shifts utilization to lower cost drugs that are equally effective which lowers Medicaid's overall cost for prescription drugs. The Legislature has continued to strengthen the PDL, including requiring the agency to negotiate only *cash* supplemental rebates and including previously exempt mental health drugs on the preferred drug list.
- **Expand the State Maximum Allowable Cost Program (SMAC).** In Fiscal Years 2003-04 and 2004-05, the Legislature directed the agency to expand the SMAC program and reduced the agency's budget $11.8 million and $25 million, respectively, in anticipation of savings. Because pharmacies receive deep discounts from wholesalers or manufacturers of generic drugs, states set maximum prices below the price that would be paid using the standard discount off published prices. In October 2004, AHCA contracted with a private vendor to develop a more comprehensive state maximum pricing program. By the fourth quarter of Fiscal Year 2004-05, the lowest price for approximately 17% of generic drugs was the SMAC price compared to less than 1% during the first quarter of Fiscal Year 2004-05.
- **Modify formulas that estimate pharmacy acquisition costs.** In both 2000 and 2004 the Legislature directed AHCA to modify its formulas for estimating acquisition costs. The most recent modification lowered pharmacy reimbursements by (1) increasing the discount off the Average Wholesale Price (AWP) from AWP-13.25% to AWP-15.4% and (2) reducing the markup to the Wholesale Acquisition Cost (WAC) from WAC+7% to WAC + 5.75%. [26]

[25] *Progress Report: Changes to Medicaid Preferred Drug List Requirements and Competitive Bidding Pharmacy Contracts Could Save an Additional $86.6 Million in 2003-04,* Report No. 03-27, April 2003.

[26] In 2000, the Legislature directed AHCA to increase the discount off the AWP from AWP-11.5% to AWP-13.25%.

Together, these efforts have slowed the rate of price increases for Medicaid prescription drugs. An analysis of the relative contribution of price and volume shows that efforts to control prices have been effective. Table A-1 shows that over the past five years, only 15.4% of the increase in prescription drug spending was due to increases in the cost of prescriptions, while 84.6% was due to increases in volume. In contrast, during the five years prior to the Legislature taking these price control actions, 70.3% of expenditure increases were due to higher drug prices, with the remaining 29.7% due to volume.

Table A-1
Relative Contribution of Price and Volume to Drug Expenditures Has Reversed

Source of Increase	Fiscal Year 1995 -96 to Fiscal Year 1999-00	Fiscal Year 2000– 01 to Fiscal Year 2004-05
Price	70.32%	15.41%
Volume	29.68%	84.59%
Utilization	29.12%	68.91%
Enrollment	0.56%	15.68%

Source: OPPAGA analysis of AHCA pharmacy summary data.

Appendix B

Medicaid Pharmaceutical Pricing Includes Many Terms

The table below provides an alphabetical listing of terms that define the different pharmaceutical prices. The table also includes a description of how each price is used as well as the advantages, limitations, or other considerations associated with the price.

Table B-1
Pharmaceutical Pricing Terms Reflect Different Calculation Methods for Different Uses

Short Title	Pricing Term	Definition	Use	Advantages, Limitations, or Other Issues	Publicly Available
AMP	Average Manufacturer Price	The average price at which manufacturers sell drugs to wholesalers and other purchasers that distribute to pharmacies. The AMP is net of customary prompt pay discounts and rebates.	Used by the federal government to calculate rebates that drug manufacturers are required to give to state Medicaid programs	This price is defined as the average price paid to manufacturers by wholesalers for drugs distributed to retail pharmacies. This price is generally considered the most accurate market price, as it accounts for discounts and rebates.	No
ASP	Average Sales Price	The weighted average price manufacturers sell drugs to all purchasers excluding government entities. The ASP is net of all price concessions for volume, prompt pay, cash discounts, and rebates.	As of January 2005, used by the federal government to reimburse providers for drugs covered under Medicare Part B that are not covered on a cost or prospective payment basis	This price is considered to be closely aligned with the actual costs of drugs because it accounts for all discounts and rebates. However, while it is collected on a quarterly basis, there is a three- to six-month time lag.	Yes
AWP	Average Wholesale Price	Retail list price (sticker price) or the average price that manufacturers recommend wholesalers sell to physicians, pharmacies and others, such as hospitals.	Used by states to estimate pharmacy acquisition costs.	This price is not defined in law or statute and is developed by manufacturers. This price does not accurately reflect actual market prices because it excludes discounts available to various purchasers.	Yes
Best Price	Best Price	The lowest price available from the manufacturer to any purchaser, excluding certain government purchasers.	Used by the federal government to calculate rebates that manufacturers are required to give to state Medicaid programs	This price should reflect the lowest price paid by any private-sector purchaser and must include certain discounts, such as volume discounts, that are available to purchasers.	No
EAC	Estimated Acquisition Cost	State Medicaid programs' best estimate of what a pharmacy pays for a drug.	Federal Medicaid law directs states to use an estimated acquisition cost to reimburse pharmacies.	States develop formulas that try to account for likely discounts and rebates. Research suggests that pharmacies generally receive larger discounts than those estimated, so states pay significantly more than actual pharmacy acquisition costs.	Yes

Short Title	Pricing Term	Definition	Use	Advantages, Limitations, or Other Issues	Publicly Available
FUL	Federal Upper Limit	The maximum amount that states should pay pharmacies for selected multi-source generic drugs.	Ensures that all states pay no more that the established maximum price for both the generic and brand name version of a drug.	The Centers for Medicare and Medicaid Services (CMS) sets maximum prices for generic drugs that are available from at least three manufacturers and provides this information to states. However, CMS has not set maximum prices for all eligible drugs and research suggests FUL prices are still too high.	Yes
NWAC	Net Wholesale Acquisition Cost	This is the net price that manufacturers quote to wholesalers, distributors, and direct purchasers, such as nursing homes and chain warehouses. The prices must be the net of all discounts and rebates.	The Texas Medicaid program uses this information to estimate acquisition costs.	This price is only available in Texas, as mandated by Texas state law. By requiring manufacturers to submit accurate purchaser costs, the Medicaid program can estimate acquisition costs more accurately.	Yes
SMAC	State Maximum Allowable Cost	The maximum amount a state will pay for selected multi-source generic drugs.	Ensures that the state pays no more than the state-established maximum price for both the generic and brand name version of a drug.	States set prices for selected generic drugs. Prices can be lower than the federal maximum price. Maximum price programs are difficult to develop and maintain, because generic drug prices change frequently and pharmacy purchase prices are not readily accessible.	Yes
U&C	Usual and Customary	The full retail price that individuals without insurance would pay a pharmacy for a particular drug.	Used in determining pharmacy reimbursement by comparing to the states' estimated acquisition costs and selecting the lowest price.	This price is seldom used to reimburse pharmacies for Medicaid prescription drugs as it is rarely the lowest price.	Yes
WAC	Wholesale Acquisition Cost	The average price at which a manufacturer sells a drug to wholesalers.	Used by states to estimate pharmacy acquisition costs.	This price is developed by manufacturers. It does not include prompt pay or other discounts, rebates or reductions.	Yes

Source: OPPAGA analysis of Medicaid pharmaceutical pricing terms, 2005.

Appendix C

Florida Reimburses Pharmacies the Lowest Estimated Cost

Federal Medicaid rules require states to reimburse pharmacies the lower of the estimated acquisition cost or the usual and customary cost that a pharmacy charges for a drug. [27] To estimate pharmacy acquisition costs, states use one or both of two prices reported by manufacturers to commercial companies such as First Data Bank. However, because these prices do not include the discounts and rebates that manufacturers provide to purchasers, a pharmacy's actual purchase price is lower than published prices. [28] Florida uses several approaches to estimate acquisition costs taking into account anticipated discounts.

- **Average Wholesale Price (AWP)** is the suggested or sticker price and represents the average price manufacturers suggest to wholesalers for selling prescription drugs to physicians, pharmacies, and others. Florida estimates that pharmacies purchase drugs at AWP-15.4%.
- **Wholesale Acquisition Cost (WAC)** is the reported average cost at which the manufacturer sells the drug to wholesalers. Florida estimates that pharmacies purchase drugs at WAC+5.75%
- **Federal Upper Limit (FUL)** is a maximum price set by the Centers for Medicare and Medicaid Services for some generic drugs. In general, the FUL price is 150% of the lowest price available nationally for a drug.
- **State Maximum Allowable Cost (SMAC)** is a state set maximum price for some generic drugs. Florida sets SMAC prices at the mid-range or average of several manufacturer prices.
- Florida also pays a **dispensing fee** of $4.23 for every prescription to cover pharmacy overhead costs for filling the order.

Florida compares each price estimate and pays pharmacies the lowest price plus the dispensing fee or the usual and customary price, whichever is lower.

[27] The usual and customary charge reflects the full retail price that a person without insurance would pay a pharmacy.

[28] Discounts and rebates may be awarded for prompt payment, volume purchasing, and other factors.

Appendix D

Federal and State Rebates Reduce Prescription Drug Costs

Rebates do not affect the price Medicaid pays to pharmacies but reduce state costs because manufacturers refund part of the payment price. Florida receives mandatory federal rebates and state supplemental rebates which manufacturers must pay to have their drugs included on the state's Medicaid preferred drug list. Together these rebates can substantially reduce state costs. Receiving these federal and state supplemental rebates resulted in net prescription drug expenditures for Fiscal Year 2004-05 of $1.77 billion, approximately 29.5% less than Florida's gross expenditures ($2.5 billion).

Federal rebates. The federal government requires both brand and generic drug manufacturers to provide rebates to states in order to participate in the Medicaid program. [29] Drug manufacturers report price information to the Centers for Medicare and Medicaid Services (CMS) quarterly. For each brand name drug, manufacturers report the average manufacturer price (AMP) which reflects the **average** price manufacturers receive from wholesalers **after** discounts and rebates and the Best Price, which represents the **lowest** price charged to any private purchaser **after** discounts and rebates.

For both single source and multiple source brand name drugs, manufacturers pay a basic rebate of 15.1% of the AMP or the difference between the AMP and Best Price, whichever is greater. In addition to the basic rebate, manufacturers must pay an additional rebate if the AMP price increases faster than the consumer price index for urban consumers. CMS uses a baseline AMP determined by the drug's original market date as a reference point for calculating any inflation-adjusted rebate. Because prices for many brand name drugs have increased faster than inflation, the additional rebate can be substantial. For generic drugs, manufacturers pay rebates equal to 11% of the AMP. Currently, manufacturers are not required to pay additional rebates for generic drugs based on an inflation adjustment.

Using the quarterly price information provided by manufacturers, CMS calculates and then sends states a list containing the unit rebate amount for each drug. Medicaid programs invoice each manufacturer with whom they do business. The invoice amount is determined by multiplying the number of units reimbursed by Medicaid by the unit rebate.

State supplemental rebates. The 2001 Florida Legislature directed AHCA to establish a mandatory preferred drug list (PDL) and negotiate state supplemental rebates. The PDL includes drugs by therapeutic classes that have a low cost relative to other similar drugs. Brand name drug manufacturers can get their drugs placed on the PDL by offering the state cash rebates, which lowers the net cost of the drugs to the state. The PDL essentially shifts utilization to lower cost drugs and lowers the cost of all drugs provided by the Medicaid program.

[29] The Omnibus Budget Reconciliation Act of 1990, created the federal Medicaid Drug Rebate Program, which was implemented in 1991.

To have their products considered for the PDL, manufacturers must negotiate state supplemental rebates with AHCA. According to state law, the supplemental rebate must equal no less than 14% of the AMP unless the federal or supplemental rebate, or both, equal at least 29% of the AMP. [30] AHCA contracts with Providers Synergies to negotiate a guaranteed net price for manufacturers' drugs to achieve, at a minimum, 29% of the AMP. After the state reimburses pharmacies and receives the federal rebate, manufacturers then pay the state any additional amount necessary to reach the guaranteed net price. For some drugs, the federal rebate alone almost achieves the negotiated guaranteed net price, so the state may receive a minimal supplemental rebate from manufacturers. Other times, the federal rebate is a fairly small amount compared to the negotiated price, so the supplemental rebate owed by the manufacturer will be significant.

Once AHCA and Provider Synergies negotiate the guaranteed net unit prices, the Pharmaceutical and Therapeutics Committee reviews the medical efficacy and pricing of the drugs. [31] For all drugs within a therapeutic category that are clinically similar, the committee recommends that AHCA include the lower priced drugs on the PDL. Drugs with high prices relative to peer drugs are excluded.

Since 2001, the state has expanded the PDL to cover more therapeutic classes and now requires that all supplemental rebates be cash rebates. [32] The most recent change to the PDL occurred in 2005 when the Legislature required manufacturers to negotiate supplemental rebates for mental health drugs. [33] In addition, the agency applies more stringent standards before allowing physicians to prescribe drugs that are not on the PDL.

Table D-1 shows Florida's average federal and state rebates as a percentage of Medicaid expenditures for last fiscal year. Combined these rebates reduced expenditures by 29.5%.

Table D-1
Drug Manufacturer Rebates to Florida's Medicaid Program Average 29.5% of Fiscal Year 2004-05 Prescription Drug Expenditures

Type of Drugs	Percentage Federal Rebate	Percentage State Rebate	Total Rebate
Single Source Brand Name Drugs	28.22%	5.84%	34.06%
Multiple Source Brand Name Drugs	39.51%	0.18%	39.69%
Generic Drugs	3.18%	0.13%	3.31%
All Drugs	24.56%	4.97%	29.53%

Source: Agency for Health Care Administration, Fiscal Year 2004-05; OPPAGA analysis.

[30] There is no upper limit on the supplemental rebate.

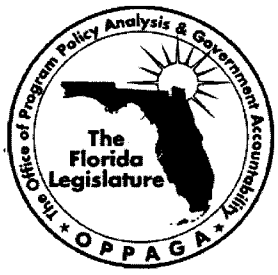
[31] The Pharmaceutical and Therapeutics Committee, composed of doctors and pharmacists, is required by state law to recommend the drugs that AHCA should place on the PDL.

[32] The 2001 legislation allowed drug manufacturers to offer supplemental rebates in the form of Medicaid program benefits that offset a Medicaid expenditure, such as disease management programs, drug product donation programs, and drug utilization control programs. State law was amended in 2004 to limit supplemental rebates to cash rebates.

[33] Prior to 2005, manufacturers were exempted from negotiating prices and paying supplemental state rebates for mental health drugs.

The Florida Legislature

Office of Program Policy Analysis and Government Accountability



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Crohn's Disease & Ulcerative
Colitis Report (DOH)

The Epidemiologic Study on Crohn's Disease and Ulcerative Colitis

HB 869 ER (Section 2)

Bureau of Epidemiology

Florida Department of Health

Background

- Crohn's disease and ulcerative colitis (IBD) are serious chronic disorders of the gastrointestinal tract
- Approximately 1.4 million Americans are afflicted
- No previous research conducted on IBD in Florida
- "Crohn's and Colitis Disease Research Act" (HB869 ER (Section 2)) requires the Florida Department of Health to conduct an epidemiologic study on IBD

Partners

- UF
- AHCA
- CCFA*
- Blue Cross Blue Shield
- Medical providers

* Crohn's and Colitis Foundation of America

Purpose

- Determine:
  - Prevalence of IBD in Florida
  - Demographic characteristics of IBD patients
  - Role of environmental and genetic risk factors

Implementation of the Study

- Literature review
- Consultations from experts
- Advisory Committee
- Epidemiologic study
- Information dissemination

Literature Review

- Rate of IBD
  - Crohn's disease: 162 per 100,000 to 199 per 100,000
  - Ulcerative colitis: 170 per 100,000 to 246 per 100,000

Literature Review

- Characteristics of IBD patient:
  - Females > 50%
  - Mean age at diagnosis: 33.4 - 45 years
  - Non-Hispanic Whites had a higher rate
- Factors Associated with IBD
  - Family history
  - Smoking

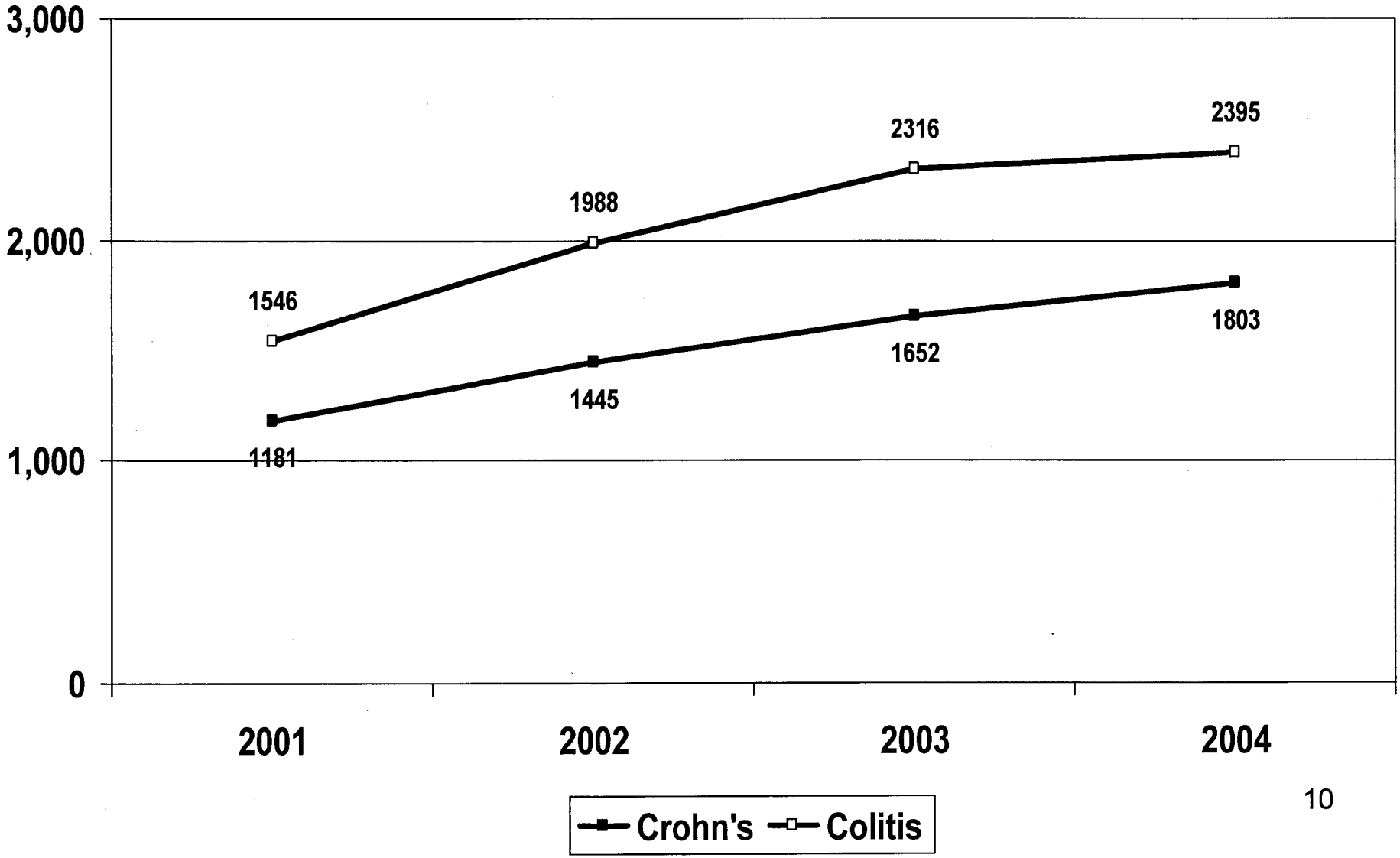
Consultations from Experts

- **CDC**: Sean Cucchi and Siobhán O'Connor
- **CCFA:** Suzanne Rosenthal, Marjorie Merrick and Florida representatives
- **University of Miami:** Amy Trachter
- **Medical College of Wisconsin:** Subra Kugathasan
- **Shafran Gastroenterology Center**: Ira Shafran
- **Kaiser Permanente:** Lisa Herrinton
- **Crohn's and Colitis support group**: David Wolff

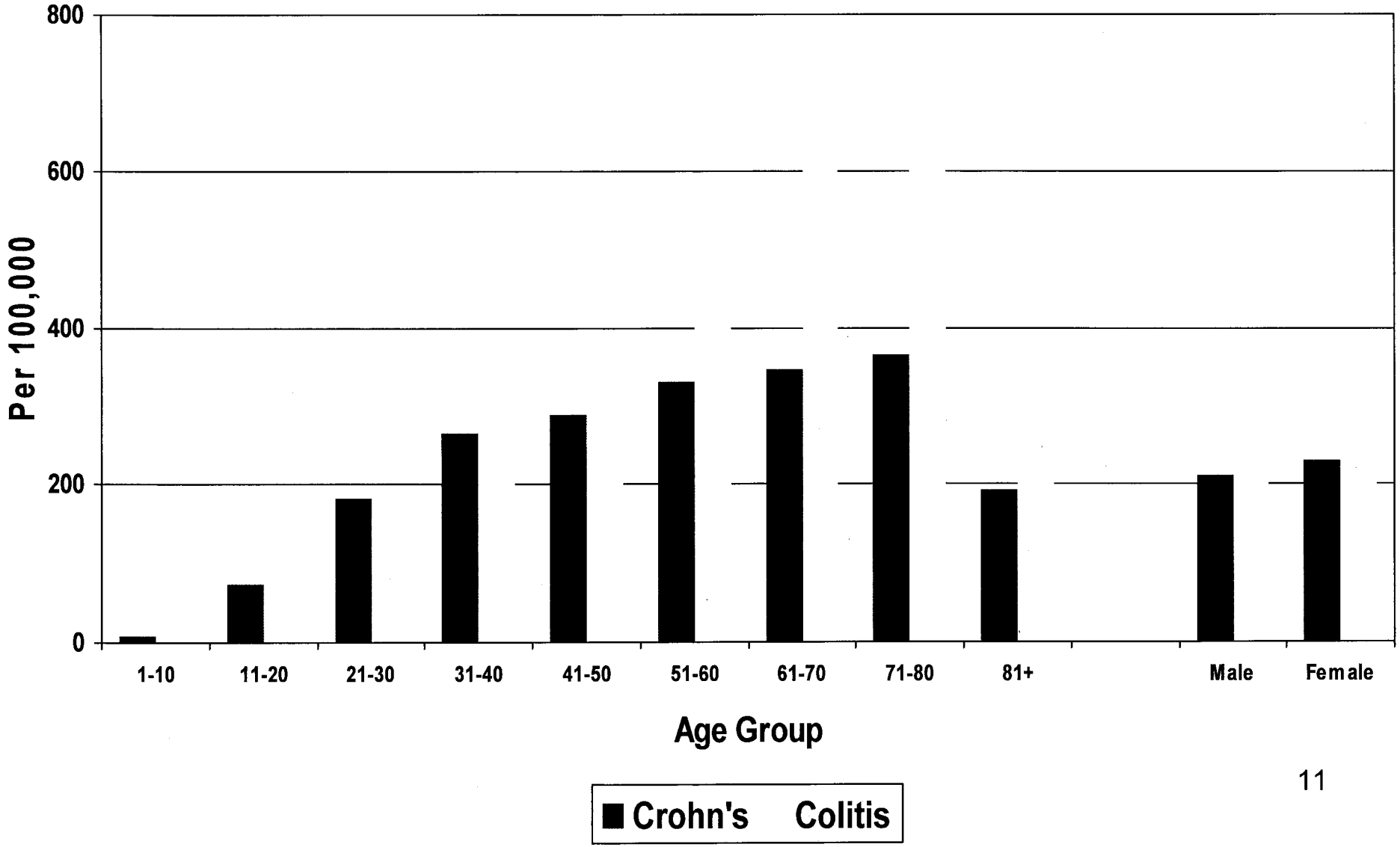
Advisory Committee

- **DOH**: Lisa Fisher, Regan Glover, Youjie Huang, Curt Miller, Heather Murphy, Mike Paredes, and Dian Sharma
- **UF**: Paul Duncan, Chris Jolley, Robert Frank, and John Valentine
- **AHCA**: Gloria Barker, Mel Chang, Susan Chen, Beth Eastman, Adrienne Henderson, Lisa Rawlins, and Cliff Schmidt
- **BCBS**: John Bookstaver, Randy Kammer, John Montgomery, David Pizzi, and John Williams
- **Florida House Representative**: Eleanor Sobel
- **Florida Senate**: Gwen Margolis
- **Physician and Psychologist** : Laurence Adams, Amy Trachter
- **Tidewater Consulting, Inc.**: Frank Mayernick
- **CCFA**: Kiren Annigeri, Marlene Bluestein, Toby Gordon, Marjorie Merrick, Suzanne Rosenthal, Allison Silver, Ellen Shapiro, Kelly Stouten, and Dave Wolff
- **CDC**: Sean Cucchi and Siobhan O'Connor
- **Kaiser Permanente**: Lisa Herrinton

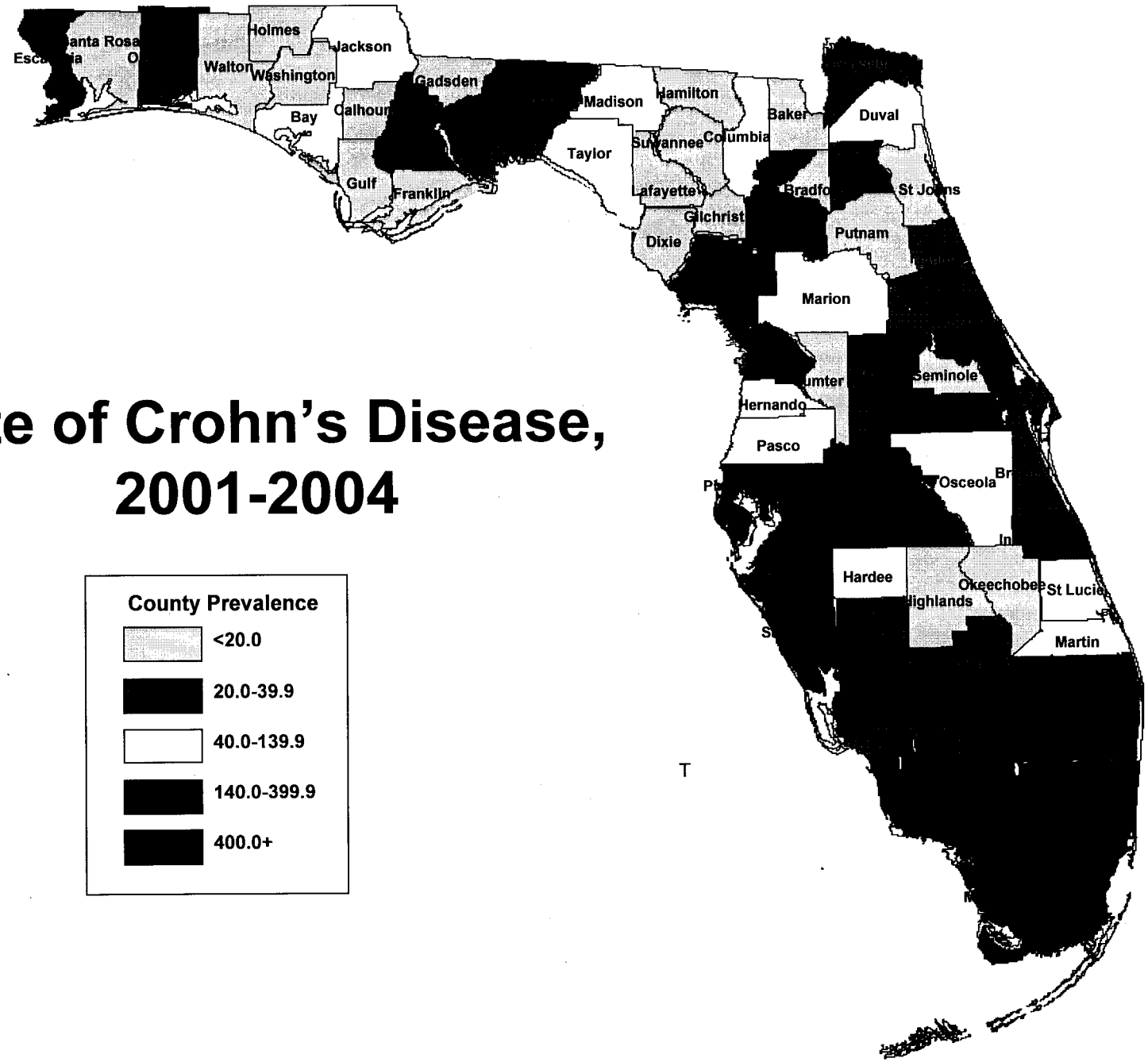
Number of New IBD Patients among BCBS Members, 2001-2004



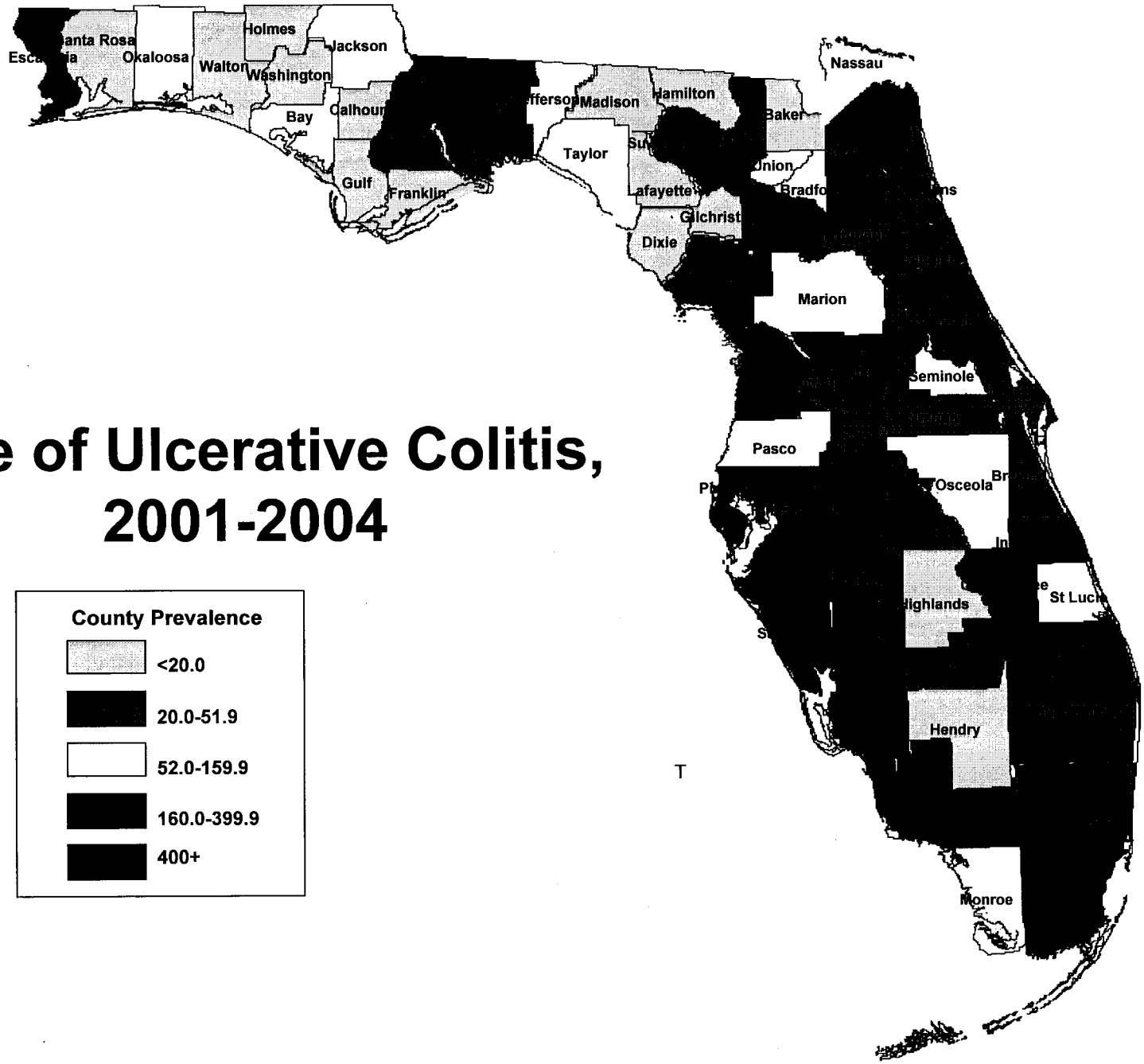
Rate of IBD among BCBS Members 2001-2004



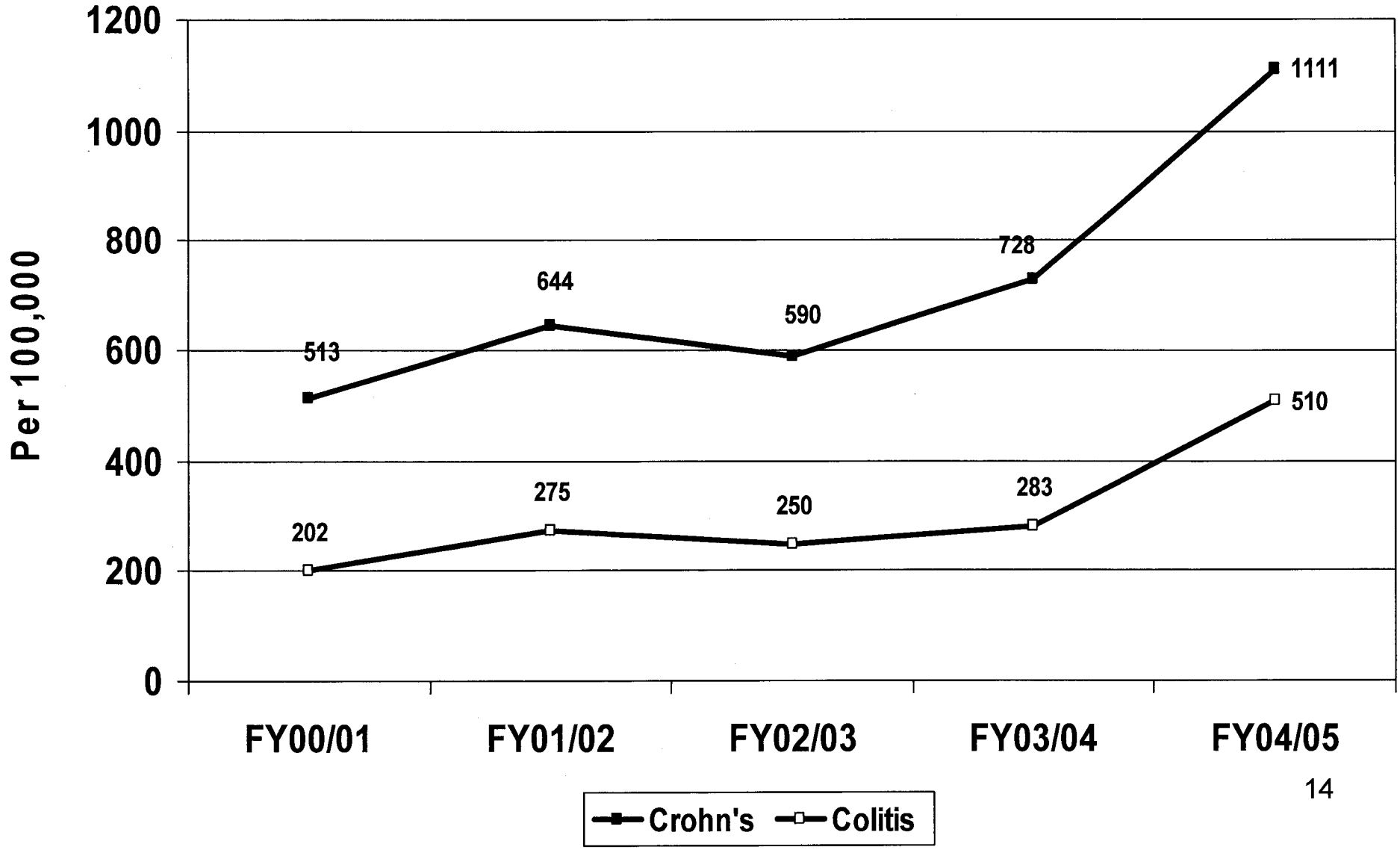
Rate of Crohn's Disease, 2001-2004



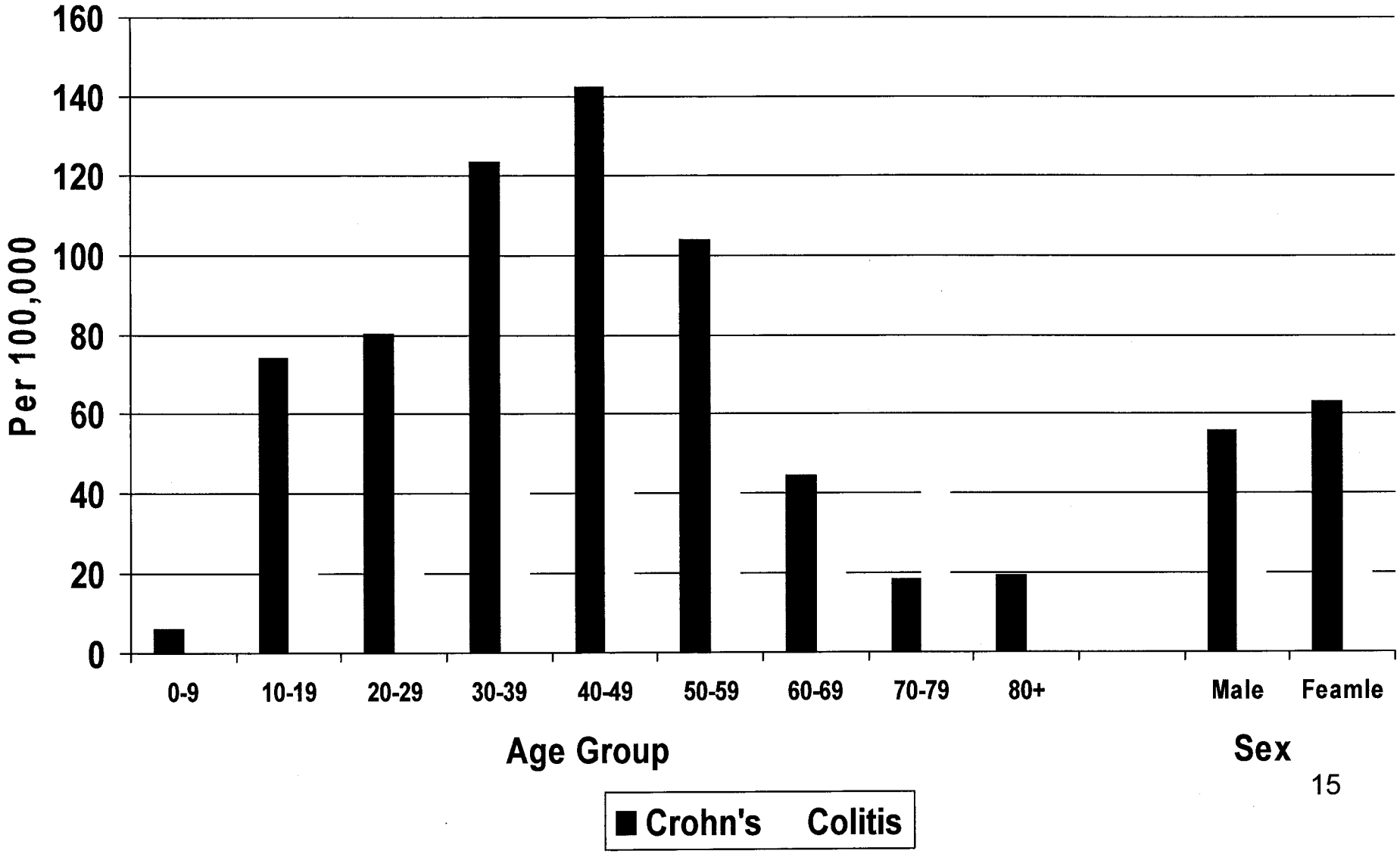
Rate of Ulcerative Colitis, 2001-2004



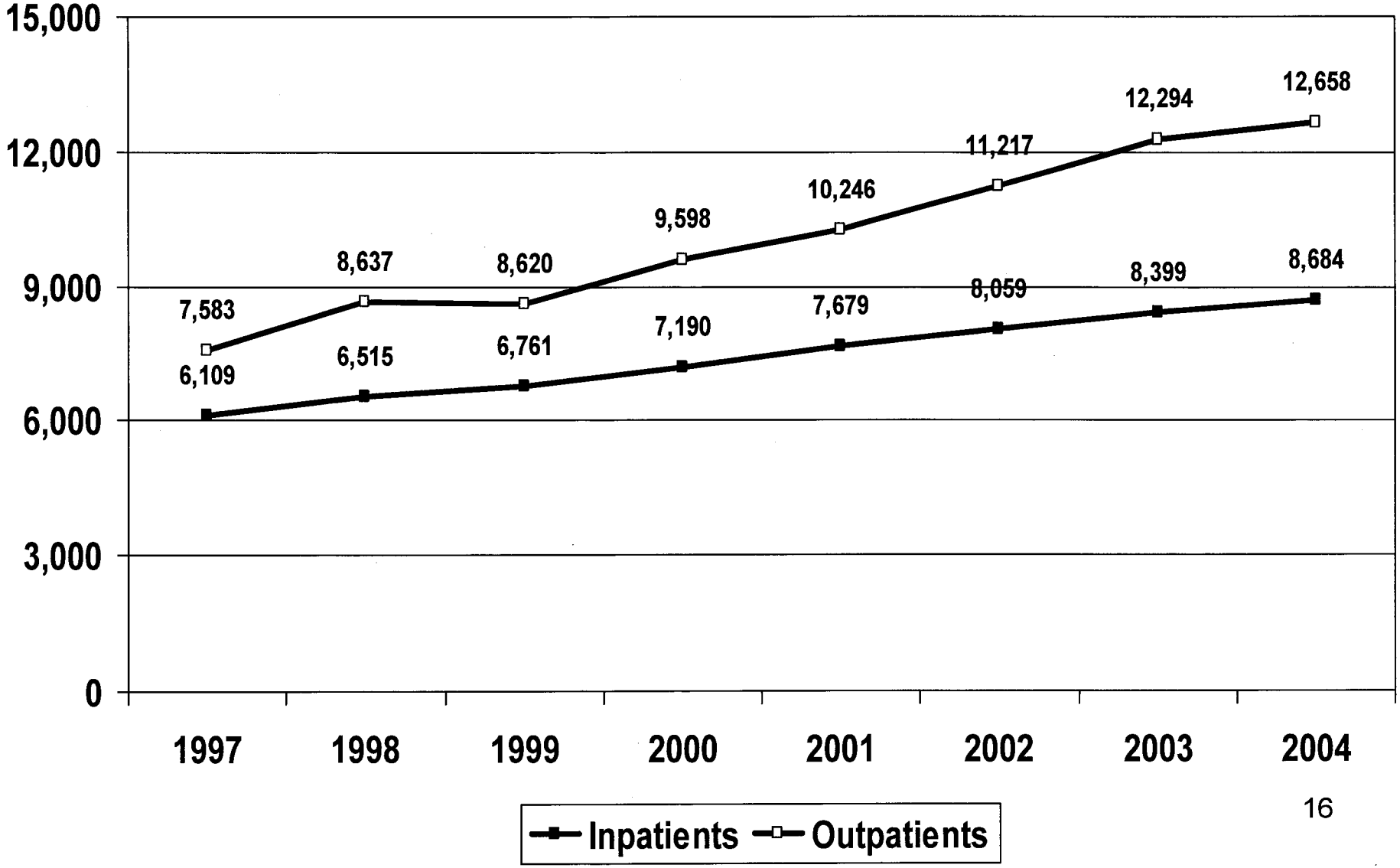
Number of New IBD Cases among Medicaid Recipients, FY00/01 – FY04/05



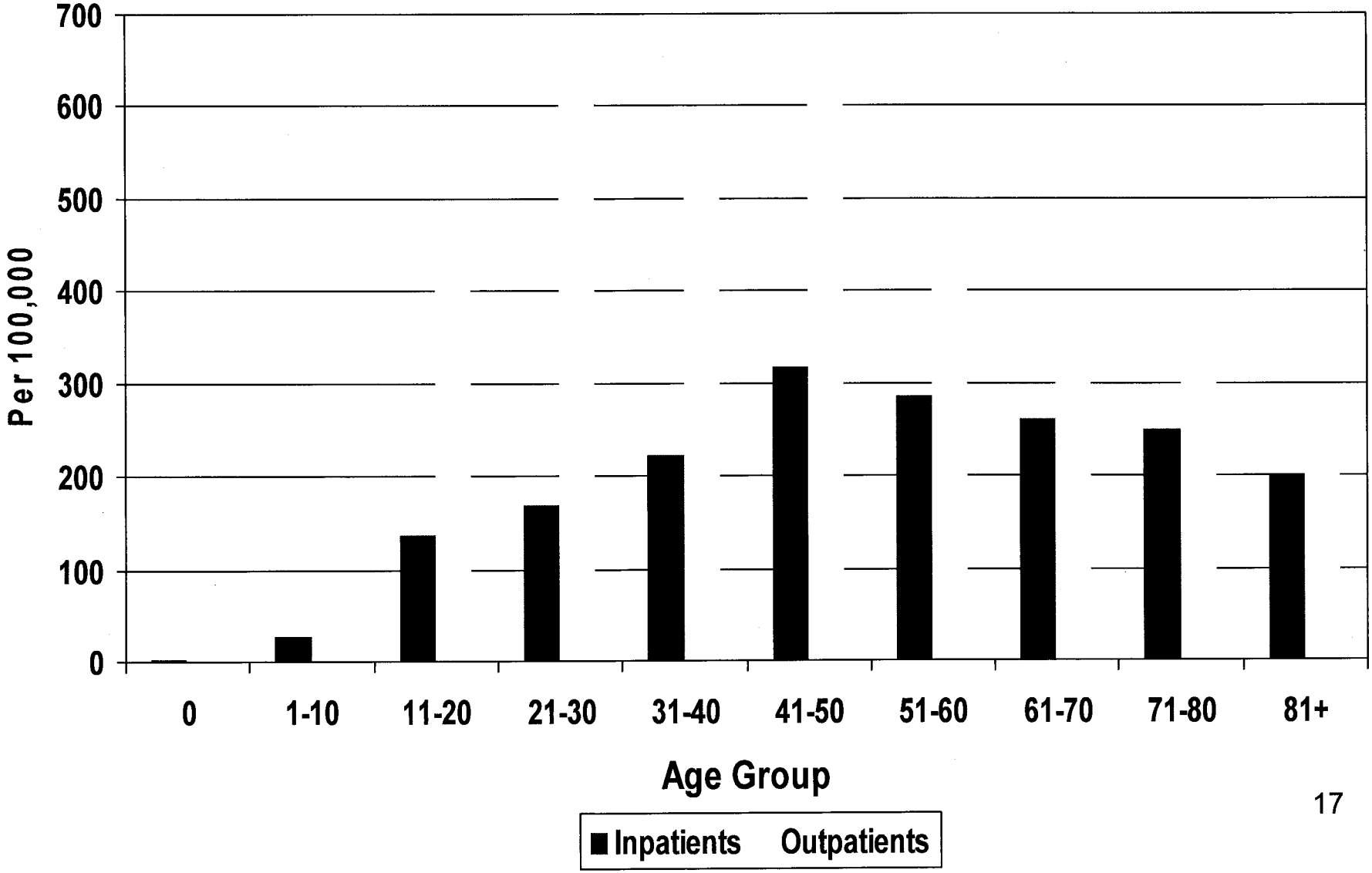
Rate of IBD among Medicaid Recipients, FY00/01- FY04/05



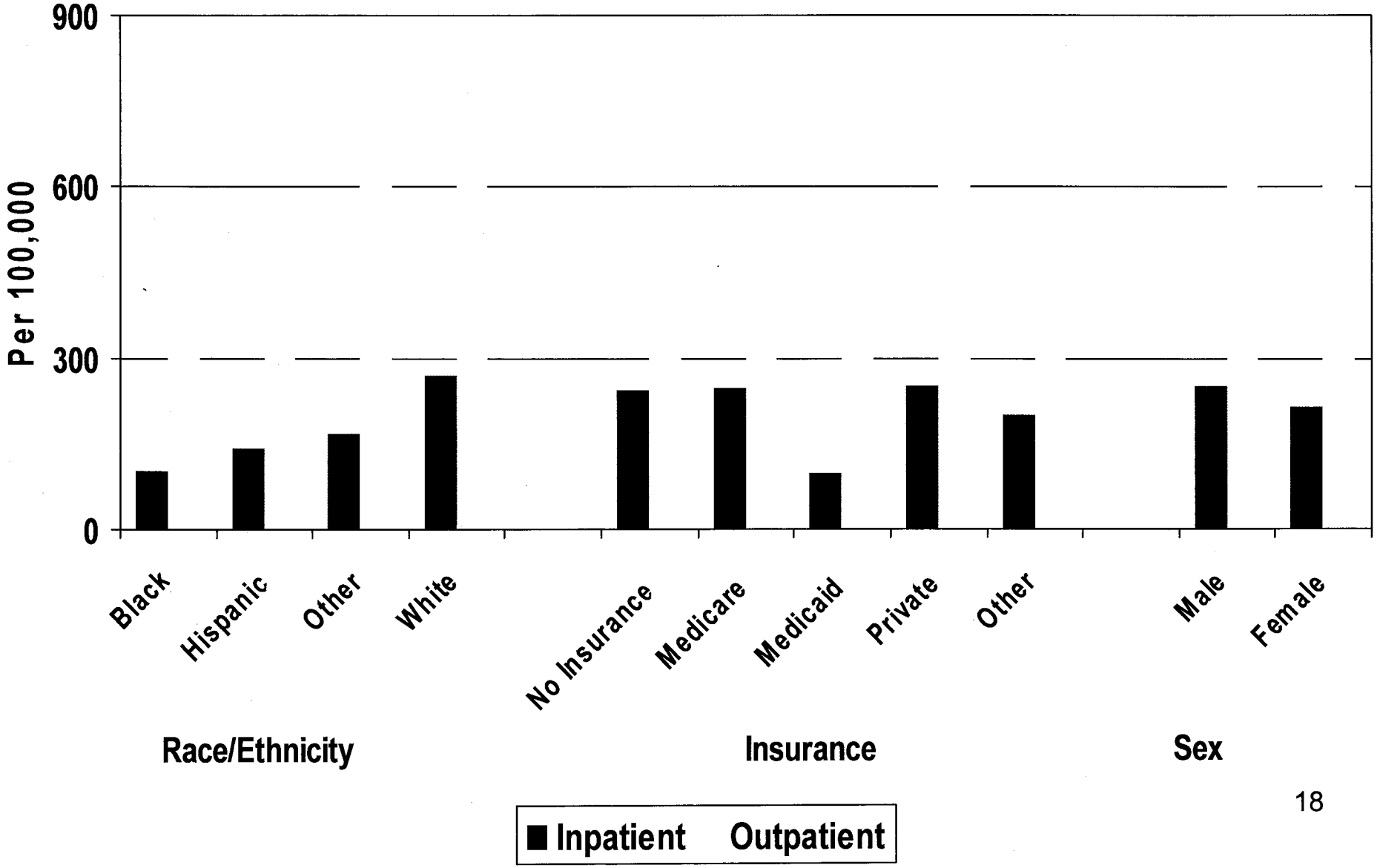
Number of IBD Inpatients and Outpatients, 1997-2004



Rate of IBD Inpatients and Outpatients, 1997-2004



Rate of IBD Inpatients and Outpatients 1997-2004



Surveys: BRFSS

- 3.8% of 1,659 survey respondents reported IBD in their household.
- 4.8% of 63 households had more than one patient
- 18.2% patients were hospitalized in the past year.

Surveys: Physicians and Patients

- 113 physicians
  - 14% diagnosed in the past 12 months;
  - 40% between age 20 and 45 years
  - 93% white and 5% African Americans
  - 22% had a family history
- 27 patients
  - Average time with IBD: 11.1 years
  - 96% whites, 33% Jewish decent
  - 18% with a family history
  - 18% rated their health as poor

Conclusions

- Estimated rate: 529 per 100,000
  - Crohn's disease: 222 per 100,000 persons
  - Ulcerative colitis: 307 per 100,000 persons

- Estimated number of patients: 84,500
  - 35,500 with Crohn's disease
  - 49,000 with ulcerative colitis

Conclusions

- The rate is higher among:
  - Young and middle age adults
  - Non-Hispanic Whites
  - Residents in Sarasota and Palm Beach counties
- Family history suggests genetic factors associated with IBD
- No environmental factors were identified or confirmed in this study

Final Report of The Epidemiologic Study on Crohn's Disease and Ulcerative Colitis

HB 869 ER (Section 2)

Prepared by

Bureau of Epidemiology
Florida Department of Health

February 1, 2006

Jeb Bush
Governor

M. Rony François, M.D., M.S.P.H., Ph.D.
Secretary, Department of Health

EXECUTIVE SUMMARY

Crohn's disease and ulcerative colitis, collectively known as Inflammatory Bowel Disease (IBD), are serious chronic disorders of the gastrointestinal tract. On June 10, 2005, Governor Jeb Bush signed House Bill 869 entitled "Crohn's and Colitis Disease Research Act" that requires the Florida Department of Health (DOH) to conduct an epidemiologic study on IBD. The goal of this epidemiologic study is to determine: (1) the prevalence of Crohn's disease and ulcerative colitis in Florida; (2) the demographic characteristics of patients with Crohn's disease and ulcerative colitis; and (3) the role of environmental and genetic risk factors in the development of Crohn's disease and ulcerative colitis. The act became effective on July 1, 2005, and the final report is due on February 1, 2006.

An advisory committee was developed for the epidemiologic study. The committee members consisted of representatives and researchers at DOH, the University of Florida, Agency for Health Care Administration (AHCA), Blue Cross Blue Shield (BCBS), Crohn's and Colitis Foundation of America (CCFA), members of the House of Representatives and the Senate, physicians, other medical providers, and other interested groups. Monthly conference calls and an in-person conference were held for the committee members to guide the study.

The study was designed based on an extensive literature review of previous epidemiologic studies and recommendations from national experts. This study received support from the Secretary of the Department of Health, medical providers, and IBD patients throughout the state.

BCBS and AHCA provided large healthcare claim datasets, including BCBS data, Medicaid data, hospital discharge data, and ambulatory patient data. The DOH team conducted gastroenterology physician surveys, an IBD patient survey, and a statewide survey of general population through the Behavioral Risk Factor Surveillance System (BRFSS). The definition of IBD was based on a set of International Classification of Disease Version 9 (ICD-9) codes.

The study collected healthcare claim data with more than 42 million unduplicated records in up to 10 years, and surveyed more than 2,000 households, medical providers, and IBD patients statewide during the study period. The data were analyzed by patient's gender, race/ethnicity, age, residential county, household income, and type of health insurance. Statewide prevalence and number of IBD patients were estimated based on the data of this study and make-up of Florida population.

It is estimated that the prevalence of Crohn's disease is 222 per 100,000 persons and the prevalence of ulcerative colitis is 307 per 100,000 persons in Florida. It is also estimated that there are approximately 35,500 Crohn's disease patients and 49,000 ulcerative colitis patients in Florida. Approximately 11 percent of IBD patients are hospitalized and 12 percent of IBD patients are treated as ambulatory patients every year. The prevalence of IBD was higher among people ages 30 to 80 years old than among other age groups, higher among non-Hispanic Whites than among other race/ethnicity groups, and higher among females than among males. Medicaid recipients had the lowest prevalence rates in either inpatients or ambulatory patients. Sarasota and Palm Beach counties were the only two counties that had a high prevalence of Crohn's disease and ulcerative colitis in all hospital discharge data, ambulatory patient data, and BCBS data.

This study surveyed 27 IBD patients and found a high percent of non-Hispanic Whites, a high percent of patients with a family history, and a high percent of Jewish descents, which may

suggest an association between genetic factors and IBD. The survey examined several environmental factors based on literature reviews, including exposures to cigarette smoking, history of living near cattle and history of tonsillectomy or appendectomy. However, no causal relationship could be established between these risk factors and IBD due to the nature of the small survey of a convenient sample.

Future studies are recommended based on this study. These studies include: (1) a BRFSS survey with increased sample size to better estimate the population-based prevalence of IBD; (2) a case-control study to identify risk factors of IBD; and (3) an IBD patient voluntary registry through their providers. This registry will provide data for a longitudinal follow-up study of IBD patients on treatment, outcome, and quality of life.

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BACKGROUND

Crohn's disease and ulcerative colitis, collectively known as Inflammatory Bowel Disease (IBD), are serious chronic disorders of the gastrointestinal tract. Approximately 1.4 million Americans are afflicted with these illnesses, 30 percent of whom are diagnosed during childhood. IBD represents a major cause of morbidity from digestive illness, and ulcerative colitis patients are at high risk for developing colorectal cancer. Although IBD is rarely fatal, it is often devastating.

On November 30, 2004, President George W. Bush signed into law the first piece of legislation focused on Crohn's disease and ulcerative colitis, entitled the "Research Review Act." During the 108th Congress, the Crohn's and Colitis Foundation of America and its National IBD Advocacy Network advanced this legislation with three provisions for advancing research on IBD. Provisions were taken directly from legislation, entitled the "Inflammatory Bowel Disease Research Act." Within 12 months after the date of the enactment, the director of the Centers for Disease Control and Prevention was responsible for submitting a comprehensive plan to address the burden of inflammatory bowel disease, in both adult and pediatric populations, to the Senate Health, Education, Labor and Pensions Committee, the House Energy and Commerce Committee, and the House and Senate Appropriations Committee.

There is a perceived increase of IBD in Florida; however, no previous research has been conducted to reveal the prevalence of these illnesses among Florida residents. Therefore, the Florida State Legislature enacted the "Crohn's and Colitis Disease Research Act."

On June 10, 2005, Florida House Bill 869 was approved by Governor Jeb Bush. House Bill 869 is referred to as the "Crohn's and Colitis Disease Research Act." The act requires the Florida Department of Health (DOH) to conduct an epidemiologic study on inflammatory bowel disease in collaboration with the University of Florida College of Public Health and Health Professions, and requires the establishment of an IBD study group that must consist of representatives from the DOH, the Agency for Health Care Administration (AHCA), Crohn's and Colitis Foundation of America (CCFA), the House of Representatives, the Senate, medical providers, and other interested groups. The effective start date is July 1, 2005, and the final report is due to the Governor and the Florida Legislature by February 1, 2006.

PURPOSE OF THE STUDY

The purpose of this study is to work with the University of Florida and other agencies and organizations to conduct an epidemiologic investigation. The goal of this epidemiologic study is to determine the:

1. Prevalence of Crohn's disease and ulcerative colitis in Florida.
2. Demographic characteristics of patients with Crohn's disease and ulcerative colitis.
3. Role of environmental and genetic risk factors in the development of Crohn's disease and ulcerative colitis.

IMPLEMENTATION OF THE STUDY

Literature Review

As the first step of study design, DOH conducted an extensive literature review for studies on IBD. The project coordinator searched the Internet and journals to identify previous epidemiologic studies on both adult and childhood IBD. Through the literature review, DOH gathered information regarding potential and known IBD risk factors, epidemiologic and clinical characteristics of patients with IBD, and potential environmental exposures for IBD.

Drs. Robert Sandler and Edward Loftus (Sartor RB, Sandborn WJ, eds., Kirsner's *Inflammatory Bowel Diseases*, 6th ed., New York: Saunders, 2004) reviewed risk factors for IBD, including demographic characteristics of patients, diet, breast feeding and perinatal events, marital status, occupation and social class, oral contraceptives, cigarette smoking, non steroidal anti-inflammatory drugs, appendectomy, measles, and other miscellaneous factors. Sandler and Loftus conclude that there is undisputable evidence of heritable factors in the genesis of IBD, and environmental influence may attribute to 85-90 percent in ulcerative colitis and 50-55 percent in Crohn's disease. Smoking is highly associated with Crohn's disease, as is nonsmoking with ulcerative colitis. Truelove (Br Med J 1961:1:61) noted cow's milk might exacerbate symptoms of ulcerative colitis.

Dr. Edward Loftus (Gastroenterology, 2004:126:1504-17) states that previous studies have provided insight into the differences in incidence of IBD across age, time, and geographic region, suggesting that environmental factors can significantly modify the expression of these conditions. They suggest the strongest risk factors to be identified at this time are family history of IBD, cigarette smoking, and appendectomy. Research also suggests variation in the demographics of IBD patients:

- Gender: Females tend to have a predominance of Crohn's disease, whereas men tend to have a higher incidence of ulcerative colitis.
- Age: Both Crohn's disease and ulcerative colitis are most commonly diagnosed in late adolescence and early adulthood, however, the diagnosis may occur at any age.
- Race/Ethnicity: Although Whites have a higher incidence of IBD, the incidence among African Americans is approaching that of Whites. Asian Americans, Hispanic Americans, and aboriginal North Americans are less likely to develop IBD, especially Crohn's disease. Ethnic and racial differences may be more related to lifestyle and environmental influences than genetic differences.

Consultations from Experts

In addition to the literature search, DOH sought national and local experts to provide insights for developing Florida's IBD research plan. The project coordinator and the team consulted with many researchers nationwide for research methodology. The information received from these experts helped the Florida researchers refine the methodology of the IBD study. From August through December of 2005, DOH communicated with the following individuals and organizations for their suggestions and advice:

- Mr. Sean Cucchi and Dr. Siobhán O'Connor, Centers for Disease Control and Prevention (CDC), discussed the "Inflammatory Bowel Disease Research Act," which requires the CDC, in conjunction with CCFA, to conduct a national IBD epidemiology study. DOH requested information regarding CDC's research approach and methodology for data collection at the national level.

- Ms. Suzanne Rosenthal, CCFA Co-Founder, and Chairman of the Board Emeritus, and Marjorie Merrick, CCFA Vice President of Research and Scientific Programs provided contact information for national IBD experts, potential funding sources, and guidance in developing methodology.

- Florida CCFA representatives provided contact information for Florida physicians, IBD support group facilitators, and IBD awareness activities.

- Dr. Robert Sandler, Chief, Division of Gastroenterology and Hepatology at the University of North Carolina, and member of CCFA's National Scientific Committee, provided information on IBD epidemiological literature, former IBD study group activities, survey development, and future research development.

- Dr. Amy Trachter, Assistant Professor of Clinical Medicine, Department of Medicine Division of Gastroenterology, Miller School of Medicine University of Miami, provided revisions to patient survey and disseminated surveys to IBD patients. Dr. Trachter also offered additional support for developing grant proposals and future IBD research.

- Dr. Subra Kugathasan, Associate professor, Pediatrics, Medical College of Wisconsin, discussed resources imperative for the development and maintenance of a pediatric IBD registry.

- Dr. Ira Shafran, Shafran Gastroenterology Center, provided the "Inflammatory Bowel Disease Questionnaire Treatment Evaluation Form," a survey administered to patients at the Gastroenterology Center.

- Dr. Lisa Herrinton (Co-PI of IBD study funded by CCFA) of Kaiser Permanente Division of Research, provided information regarding research approach and methodology of two CCFA-funded epidemiological studies. She also shared with DOH the prevalence of IBD among nine health plans across the United States (U.S.), and incidence and prevalence of IBD at Kaiser Permanente, Northern California.

- Mr. David Wolff, Crohn's and Colitis support group facilitator, provided information about IBD patients and the daily implications of living with these illnesses. Mr. Wolff gave insight for the development of a pilot patient survey and assisted in the distribution of surveys to support group members.

Advisory Committee

The study advisory group (a.k.a. Advisory Committee) consisted of epidemiologists at DOH, analysts at AHCA and Blue Cross Blue Shield, physicians and researchers at the University of Florida, members of the House of Representatives and the Senate, representatives from CCFA, medical providers, and other interested groups. The group welcomed any interested organization or individual to participate in the study group.

The first Advisory Committee conference call was held on June 14, 2005. Representatives from the DOH and the University of Florida (UF) participated in the conference call. The group decided to appoint a coordinator, develop an advisory committee, conduct monthly conference calls, and schedule an in-person meeting for advisory members. The group also approved the data collection methodology proposed by the DOH.

Regan Glover of the DOH was appointed as the project coordinator on July 18, 2005.

A letter of invitation to join the Advisory Committee was sent to medical providers, the legislature, representatives from Blue Cross Blue Shield of Florida, state and national Crohn's and Colitis Foundation of America representatives, and the Agency for Health Care Administration. Those interested in joining the committee and/or following the study were placed in a contact database.

Members of the Advisory Committee, consultants, and analysts for this study are:

- AHCA: Gloria Barker, Mel Chang, Susan Chen, Beth Eastman, Adrienne Henderson, Lisa Rawlins, and Cliff Schmidt
- BCBS: John Bookstaver, Randy Kammer, John Montgomery, David Pizzi, and John Williams
- CDC: Sean Cucchi and Siobhan O'Connor
- CCFA: Kiren Annigeri, Marlene Bluestein, Toby Gordon, Marjorie Merrick, Suzanne Rosenthal, Allison Silver, Ellen Shapiro, Kelly Stouten, and Dave Wolff
- DOH: Lisa Fisher, Regan Glover, Youjie Huang, Curt Miller, Heather Murphy, Mike Paredes, and Dian Sharma
- Florida House Representative: Eleanor Sobel
- Florida Senate: Gwen Margolis
- Kaiser Permanente: Lisa Herrinton
- Tidewater Consulting, Inc.: Frank Mayernick
- Physician: Laurence Adams
- Psychologist: Amy Trachter
- UF: Paul Duncan, Chris Jolley, Robert Frank, and John Valentine

Conference calls were held on August 11, September 1, October 6, November 3, 2005, and January 18, 2006. Representatives from a number of agencies, universities, and organizations, as well as interested individuals, participated in the conference calls. The Advisory Committee provided recommendations for the following issues:

- Requirements of House Bill 869.
- Identification of additional members for the study advisory group.
- Plan of study, including overall approach and timeline.
- Diagnoses and procedure codes (ICD-9) for identifying IBD cases in claim data.
- Methods of conducting a survey of GI physicians and IBD patients.
- Development of the pediatric survey and cover letter.
- Survey questions to be added to statewide Behavioral Risk Factor Surveillance System (BRFSS).
- Progress of the study, including data analyses and survey response.
- Preliminary findings of the study.

On November 15, 2005, the Advisory Committee had an in-person meeting in Gainesville, Florida. The participants reviewed preliminary findings and discussed strengths/limitations of study methods and potential sources of data dissemination.

Information Dissemination

The DOH Bureau of Epidemiology made great efforts to disseminate the information regarding the study, including the purpose, methods, and preliminary results to public health professionals, medical providers, Advisory Committee members, and the general public during the entire study period.

- To public health professionals:
  - The Bureau published an article introducing the new research in *Epi Update* in July 2005. *Epi Update* is a web-based weekly journal published by the Bureau of Epidemiology. A follow-up article to update the progress of the study was published in *Epi Update* in September 2005.
  - The study was introduced to county health departments on a bi-weekly conference call in August 2005.
  - An overview of the IBD study was submitted to The Health Advisor, which is the forum to spotlight Department of Health special events, people, programs, and statistics. The newsletter is sent to county health departments, Department of Health units, legislators, and others involved in health around the state and country. The article will appear in the January/February 2006 issue.

- To Advisory Committee members:
  - Plans, progress of the implementation of the study, and preliminary results were provided to, and reviewed by, the Advisory Committee at monthly conference calls and the in-person meeting in November.

- To Medical providers:
  - The study was introduced to gastroenterologists at the 40th Annual Meeting of the Florida Gastroenterological Society and the American College of Gastroenterology in Naples, Florida, on September 9-11, 2005.

- To interested groups and individuals:
  - The project coordinator presented preliminary findings for Crohn's Disease at the CCFA Fourth Annual Advances in IBD Research in Miami Beach, Florida, in December 2005.
  - Per suggestion from a spokesperson for the national chapter of CCFA, a letter was sent to former first lady, Barbara Bush, introducing the Florida IBD study and inviting her to attend a meeting where the findings from this study will be presented.
  - Frequent conversations were maintained via e-mails and phone calls between the project coordinator and IBD support groups in the state.

METHODS

Sources of Data

When sources of population-based data were identified, the DOH research team found that all databases available were developed for purposes other than IBD epidemiologic study, and not a single database was available that would meet the specific needs for this study. Therefore, the

research team decided to collect a number of large databases that each covers part of the IBD population and then combine the information from these databases for a comprehensive result.

The data included in this study consisted of healthcare claim data (hospital discharge data, ambulatory care data, Blue Cross Blue Shield data, and Medicaid data), and survey data (physician survey, patient survey, and BRFSS survey). Collectively, these data covered a majority of the Florida population and provided a well-represented prevalence of IBD in Florida.

Blue Cross Blue Shield (BCBS) claim data

BCBS of Florida provided claim data for their members from calendar years 2001 to 2005. BCBS is one of the major private health insurance carriers, with approximately 30 percent of Florida's commercial market share. More than 2.5 million BCBS members in Florida receive medical services every year. BCBS members consist of males and females of all ages and races. A majority (more than 80 percent) of members who had a claim record are under the age of 65. Claim data capture information on hospitalizations and clinic visits.

The data were unduplicated to provide the number of patients, instead of the number of medical services. Therefore, if a patient with IBD had more than one visit, he or she was only counted once during the data collection timeframe. Disease diagnoses were grouped into several categories: Crohn's disease (ICD-9 code: 555.9), chronic proctitis (556.2), chronic sigmoiditis (556.3), colitis (556.8, 556.9), enteritis (555.0, 555.1), ileitis (555.2), and other and unspecific colitis (558.9). Data were broken down by patient's age, sex, and residential county.

The DOH included data in four years (2001-2004) in this study, with 10,970,547 person-years. On average, 2,742,637 BCBS members were included in the data each year during 2001-2004.

Medicaid data

Medicaid claim data in fiscal years (FYs) 2000-2004 were provided by AHCA. Medicaid data included all claims, both hospitalizations and clinic visits, for more than one million Medicaid recipients in Florida. Medicaid recipients consist of people of all ages, with more than 50 percent of recipients who are under age 20.

The data were unduplicated to count only the number of patients who received medical care. Disease diagnoses were grouped into several categories: Crohn's disease (ICD-9 code: 555), ulcerative colitis (ICD-9 code: 556), and other IBD (ICD-9 code: 558). Data were broken down by patient's age, sex, and residential county.

Data in all five years (FYs 2000-2004) were included in the study. The data contain 5,922,697 person-years of records, with an average of 1,184,539 recipients each year.

Ambulatory patient data

AHCA provided ambulatory patient data for fiscal years1997-2004. The ambulatory patient data are collected from freestanding ambulatory surgical centers, lithotripsy centers, cardiac catheterization laboratories, and short-term acute care hospitals. Ambulatory patients are those who have a face-to-face encounter with a provider, and who are not formally admitted

as an inpatient in an acute care hospital setting, and not treated in the emergency room. The ambulatory patient data include patients of all ages and races, regardless of the type of a patient's medical insurance.

Disease diagnoses were grouped into several categories based on either primary diagnosis or any of the secondary diagnoses. These categories are Crohn's disease, ulcerative colitis, and other colitis.

Data in all eight years were included in the analysis. There were 12,710,291 patient records analyzed, with an average of approximately 1.6 million patients every year. Patients might have more than one ambulatory visit either in a single year or in different years. The DOH unduplicated multiple visits in two ways: 1) to count each patient only once for the entire 8-year period for number of "new" IBD patients among ambulatory patients; and 2) to count each patient once in a single year for an annual prevalence of IBD patients among ambulatory patients. Data were analyzed by race, age, residential county, and type of medical insurance.

Hospital discharge data

AHCA also provided hospital discharge data for 1995-2004. The hospital discharge data include all inpatients of all ages and types of medical insurance.

Disease diagnoses were grouped into several categories based on either primary or secondary diagnoses. These categories are Crohn's disease, ulcerative colitis, and other colitis.

Data in all 10 years were included in the analysis. There were 12,769,086 inpatient records analyzed, with an average of approximately 1.2 million patients every year. Many patients had more than one hospitalization either in a single year or in different years. The DOH unduplicated multiple hospitalizations in two ways: 1) to count each patient once in the entire 10-year period for number of "new" IBD patients among inpatients; and 2) to count each patient once in a single year for an annual prevalence of IBD patients among inpatients.

IBD inpatients who had ambulatory visit(s) were excluded from the analyses to avoid duplication for patients receiving medical care in hospitals. Data were analyzed by race, age, residential county, and type of medical insurance.

Gastroenterology (GI) Physician survey

DOH Bureau of Epidemiology developed a gastroenterology (GI) physician survey in August 2005. (See attachment 1 for the survey questionnaire.) The survey was designed to estimate:

- Patient demographics
- Number of newly diagnosed IBD cases within past 12 months
- Severity of illness measured by hospitalizations due to IBD
- Role of family history
- Patient's enrollment for colon cancer surveillance

The survey questionnaire was sent to 660 gastroenterologists in Florida by mail. The DOH research team received 132 returned survey questionnaires, among which 113 were completed.

Regan Glover, the project coordinator, distributed the survey questionnaires at the general sessions of the 40th Annual Meeting of the Florida Gastroenterological Society and the American College of Gastroenterology in Naples Florida on September 9-11, 2005. Ten completed surveys were received from the conference attendees.

Pediatric GI physician survey

The Bureau of Epidemiology revised the GI-physician survey questionnaire to address pediatric IBD patients seen by pediatric specialists. Data collected were similar to that collected from the GI physician survey. Survey questionnaires were distributed to 41 Florida members of the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) via mail. A cover letter and pre-paid return envelope were included with the mailed survey. Collection period began September 26, 2005, and ended on October 26, 2005. Eight (20 percent) of 41 physicians returned completed survey questionnaires.

IBD patient survey

The DOH team developed a short anonymous survey of IBD patients. (See attachment 2 for the questionnaire.) Dr. Amy Trachter and GI physicians assisted with the design of questionnaire. The purpose of this survey was to obtain information on risk factors of IBD, particularly environmental factors and genetic factors.

The survey was implemented from December 23, 2005, to January 10, 2006. To keep responses anonymous, the DOH did not disseminate directly surveys to IBD patients. Instead, the survey questionnaire was emailed to facilitators of eight CCFA support groups. The facilitators were asked to distribute the survey questionnaire to their group members though e-mails. The total number of IBD patients who received the questionnaire from their support group facilitator was unknown. IBD patients who were willing to participate in the survey completed survey and returned surveys to DOH either electronically (e-mail/fax), or by U.S. Postal Service. The DOH received 27 completed survey questionnaires from IBD patients with two support groups in Miami and Sarasota.

Behavioral Risk Factor Surveillance System survey

The Behavioral Risk Factor Surveillance System (BRFSS) survey is a statewide random telephone survey of civilian, non-institutionalized adults (age 18 and older). The BRFSS is an ongoing collaborative survey with the CDC to monitor trends in risk behaviors related to preventable chronic diseases and conditions in Florida. Respondents are asked about health status, health behaviors, use of screening services, and access to health insurance and health care.

Three questions were designed by the Bureau of Epidemiology to survey the general population. These questions are:

- (Q1) Has anyone, including yourself, in your household, ever been told by a doctor or other health professional that you have Crohn's disease or ulcerative colitis?

- (Q2) How many people in your household have been told that they have Crohn's disease or ulcerative colitis?
- (Q3) How many of these people have been admitted to a hospital in the past 12 months because of Crohn's disease or ulcerative colitis?

The purpose of these questions is to assess the prevalence of IBD (Q1), familial aggregation of IBD cases (Q2), and severity of IBD (Q3) among general population. These questions were included in the BRFSS survey from September 1, 2005, through December 15, 2005. There were 1,847 individuals surveyed, among whom 1,678 responded to these three questions.

Medicare data were requested in October 2005; however, approval to use those records was not received as of the date of this report.

Definition of IBD

The following are the International Classification of Disease Version 9 (ICD-9) codes that were used to define Crohn's disease, ulcerative colitis, and other IBD in healthcare claim data:

Crohn's disease:

555.0: Ileitis (regional, segmental) and Regional enteritis or Crohn's disease of duodenum, ileum, or jejunum
555.1: Colitis (granulmatous, regional, or transmural) and regional enteritis or Crohn's disease of colon, large bowel, or rectum
555.2: Ileitis
555.9: Crohn's disease NOS

Ulcerative Colitis:

556.0: Ulcerative (chronic) enterocolitis
556.1: Ulcerative (chronic) ilecocolitis
556.2: Ulcerative (chronic) proctitis
556.3: Ulcerative (chronic) proctosigmoiditis
556.5: Left-sided ulcerative (chronic) colitis
556.6: Universal ulcerative (chronic) colitis
556.8: Other ulcerative colitis
556.9: Ulcerative colitis, unspecified.

Other IBD:

558.9: Other and unspecified (noninfectious gastroenteritis and colitis)

Procedure code:

45.23: Colonoscopy

Analysis

The primary purpose of analysis was to identify prevalence of IBD, patients' characteristics, and IBD related risk factors. The DOH team did not attempt to make comparisons of prevalence among subpopulations. Therefore, the team did not conduct any statistical tests for difference

in prevalence among subpopulations, nor to adjust prevalence by age-distribution of the population. The methods that the DOH used for this study were:

1. Claim data
   a. Numbers of patients with IBD were tabulated.
   b. Prevalence of IBD was estimated in various populations. Prevalence is the proportion of the population with IBD in a specific year. The prevalence was calculated as follows:
      i. BCBS data and Medicaid data: by sex and age
      ii. Hospital discharge data and ambulatory patient data: by sex, age, race, and ethnicity, and type of insurance
   c. Incidence of IBD was estimated for BCBS IBD patients. Incidence is the number of new cases diagnosed per 100,000 persons in a year. Although BCBS data counted only new patients to the BCBS system in the four-year period, some of "new" patients might have been diagnosed before the study period.
   d. Proportion of IBD patients with a colonoscopy was calculated.

2. BRFSS survey data
   Prevalence of IBD was estimated by race and household income. The prevalence was not weighted by the probability of respondents being selected for the survey because the weight variable was not available during preparation of this report. Responses of "don't know" or "unsure" were excluded from analyses.
3. Physician survey
   Percents of responses were tabulated for estimates of:
   a. Newly diagnosed cases (within past 12 months)
   b. Patient demographics
   c. Severity of illness (hospitalizations)
   d. Role of family history
   e. Colon cancer surveillance

4. Patient survey
   Percents of responses were tabulated for estimates of:
   a. Patient demographics (sex, race/ethnicity and region)
   b. Age of diagnosis/time lived with IBD
   c. Type of IBD (Crohn's disease and ulcerative colitis)
   d. Severity of symptoms (mild, moderate, severe)
   e. Presence of family history
   f. Risk behaviors (active or passive inhalation of cigarette smoke)
   g. General assessment of health

There was a close collaboration among BCBS, AHCA, and DOH representatives and data analysts for this study. John Montgomery, John Williams, and John Bookstaver provided information on BCBS and conducted analyses of BCBS claim data. AHCA representatives Mel Chang, Beth Eastman, Susan Chen, Gloria Barker, Adrienne Henderson, and Cliff Schmidt provided support and conducted analyses on Medicaid data, hospital discharge data, and ambulatory patient data. DOH epidemiologist Youjie Huang and health data analyst Curt Miller analyzed the survey data and conducted part of the analyses of hospital discharge data and ambulatory patient data.

RESULTS

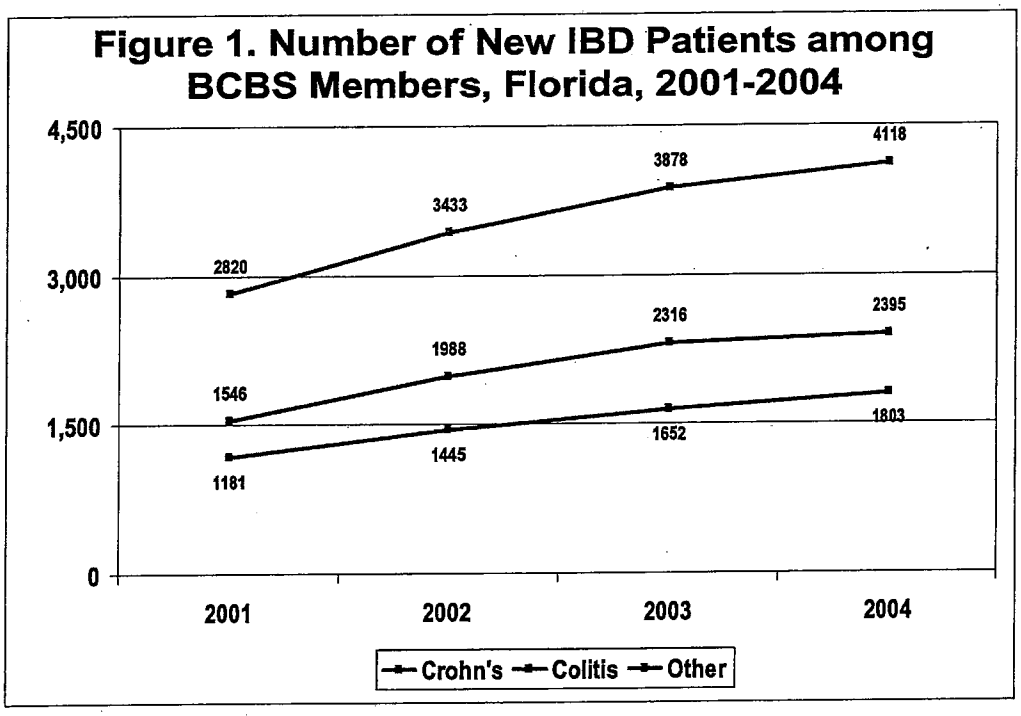
BCBS data

During 2001-2004, 6,373 BCBS members were diagnosed with Crohn's disease and 8,658 were diagnosed with ulcerative colitis. In the BCBS claim data, an average of 2,742,637 BCBS members per year received medical services. Among those members, 1,520 members, on average, were diagnosed with Crohn's disease and 2,061 were diagnosed with ulcerative colitis per year. (Table 1)

Table 1. Average Number of BCBS Members with IBD per Year, Florida, 2001-2004

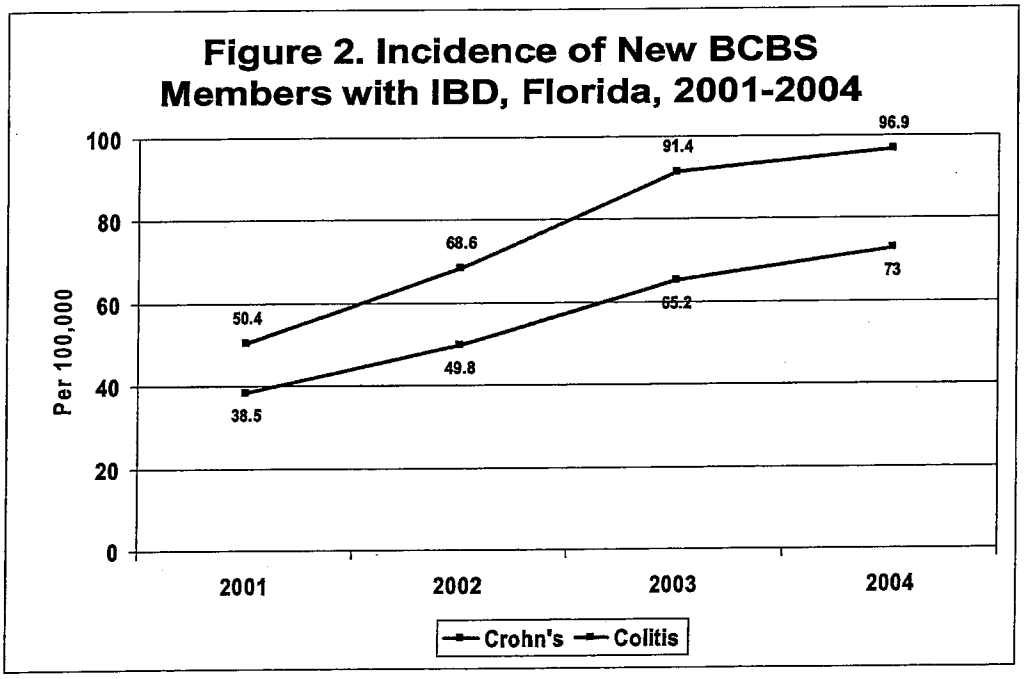
	All IBD	Crohn's	Colitis	Other	# of Members
Total	7,144	1,520	2,061	3,563	2,742,637
By Age Group					
1-10	25	7	9	10	289,104
11-20	196	81	48	68	431,765
21-30	472	150	131	180	350,594
31-40	841	234	258	349	352,003
41-50	1,231	287	381	563	398,637
51-60	1,464	305	420	738	370,815
61-70	1,294	222	388	684	256,748
71-80	1,144	156	311	677	170,573
81+	430	59	102	269	122,395
By Sex					
Male	3,006	684	956	1,365	1,296,831
Female	4,091	826	1,092	2,173	1,445,806

Number of members who were first time diagnosed with Crohn's disease increased by 55 percent from 1,546 in 2001, to 2,395 in 2004. Similarly, the number of members diagnosed with ulcerative colitis increased by 53 percent from 1,181 in 2001, to 1,803 in 2004, and the number of patients diagnosed with other colitis increased by 45 percent from 2,820 in 2001, to 4,118 in 2004 (Figure 1).



The overall four-year prevalence was 222 per 100,000 persons for Crohn's disease, 301 per 100,000 persons for ulcerative colitis, and 520 per 100,000 persons for other IBD.

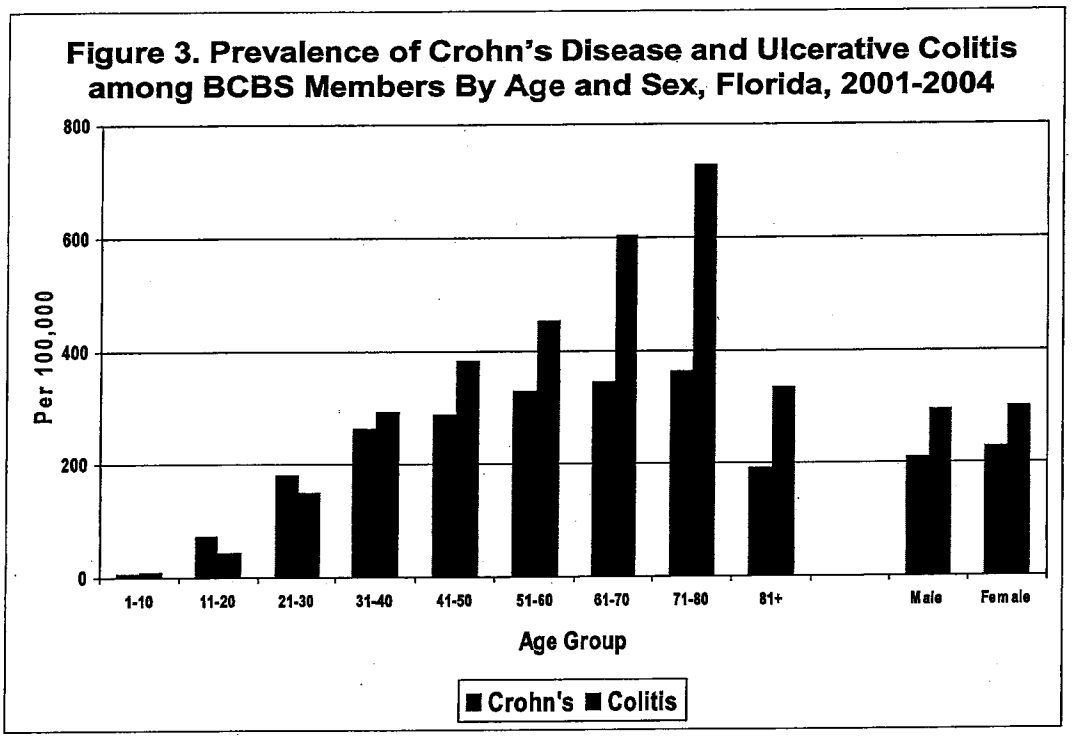
The incidence (number of new patients among 100,000 people at risk in a year) increased during the four-year period. For Crohn's disease, the rate increased by 92 percent from 50.4 per 100,000 to 96.9 per 100,000 person. The prevalence of ulcerative colitis increased by 90 percent. (Figure 2)



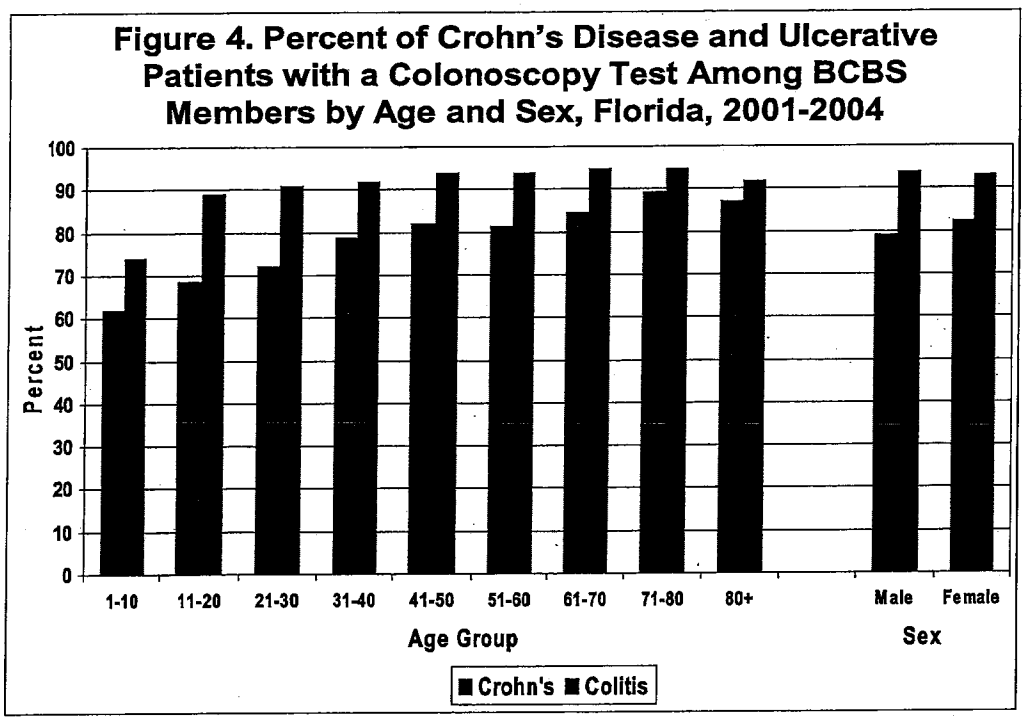
During the four-year period, the number of patients diagnosed with Crohn's disease and ulcerative colitis increased by age, and reached a peak in the 51-to-60–year-old age group (Table 1).

The four-year prevalence was the highest among people between the ages of 71 and 80 years. The prevalence increased by age, except among people age 81 years and older. (Figure 3)

The prevalence was slightly higher among females than among males for Crohn's disease (229 per 100,000 people versus 211 per 100,000 people), and ulcerative colitis (302 per 100,000 people versus 295 per 100,000 people). (Figure 3)



A colonoscopy is a medical procedure that is required to confirm the diagnosis of Crohn's disease and ulcerative colitis. Among BCBS members, a majority of new patients with Crohn's disease and ulcerative colitis had a colonoscopy. The percent of Crohn's disease patients who had a colonoscopy increased by age, from 61 percent among patients under age 11, to 87 percent among patients aged 80 years and older. The percent of patients with a colonoscopy was higher among ulcerative colitis patients than among Crohn's disease patients. Ninety percent of patients with ulcerative colitis had a colonoscopy with the exception of patients under age 11. (Figure 4)



Among Crohn's disease patients, more females (82 percent) had a colonoscopy than did males (79 percent). Among ulcerative colitis patients, 93 percent of both males and females had a colonoscopy.

Among BCBS members, the prevalence of Crohn's disease was greater than 400 per 100,000 in Liberty, Wakulla, Jefferson, Brevard, Glades, and Lee counties. (Figure 5) Liberty, Wakulla, Leon, Columbia, Brevard, Glades, Orange, Hillsborough, Polk, Sarasota, Palm Beach, and Broward counties had a prevalence of ulcerative colitis greater than 400 per 100,000 people. (Figure 6) Liberty, Wakulla, Brevard, and Glades counties had a high prevalence for both Crohn's disease and ulcerative colitis.

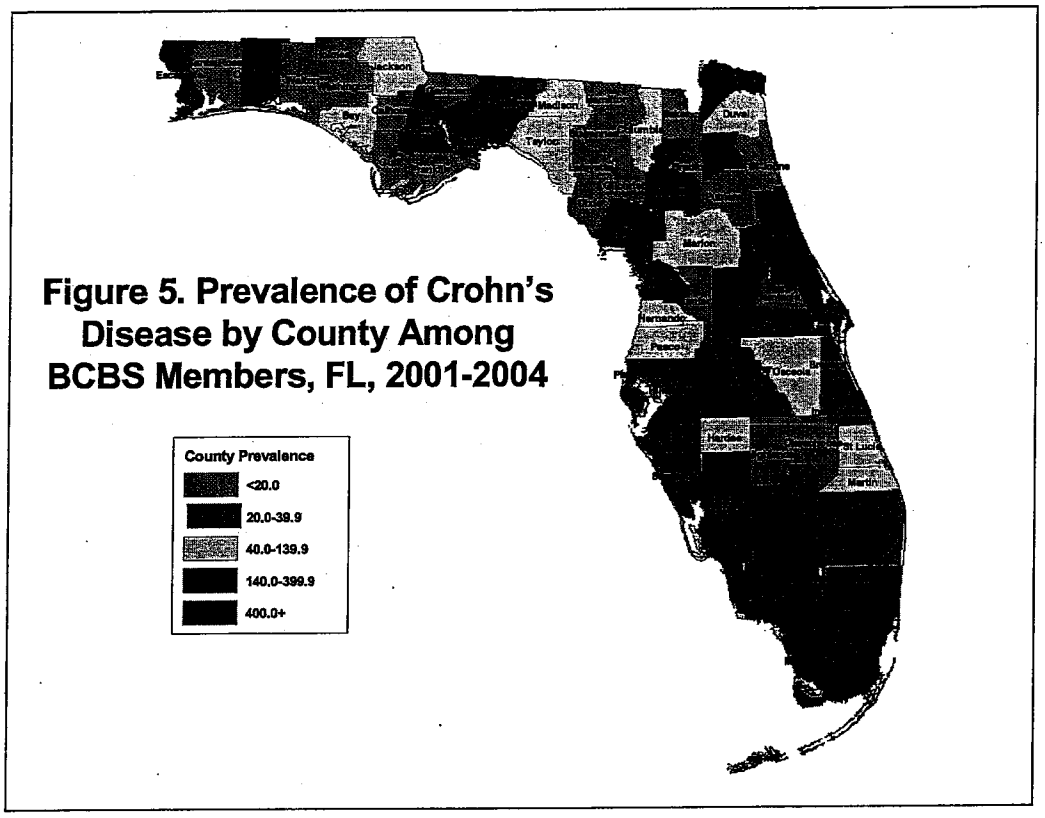


Figure 5. Prevalence of Crohn's Disease by County Among BCBS Members, FL, 2001-2004

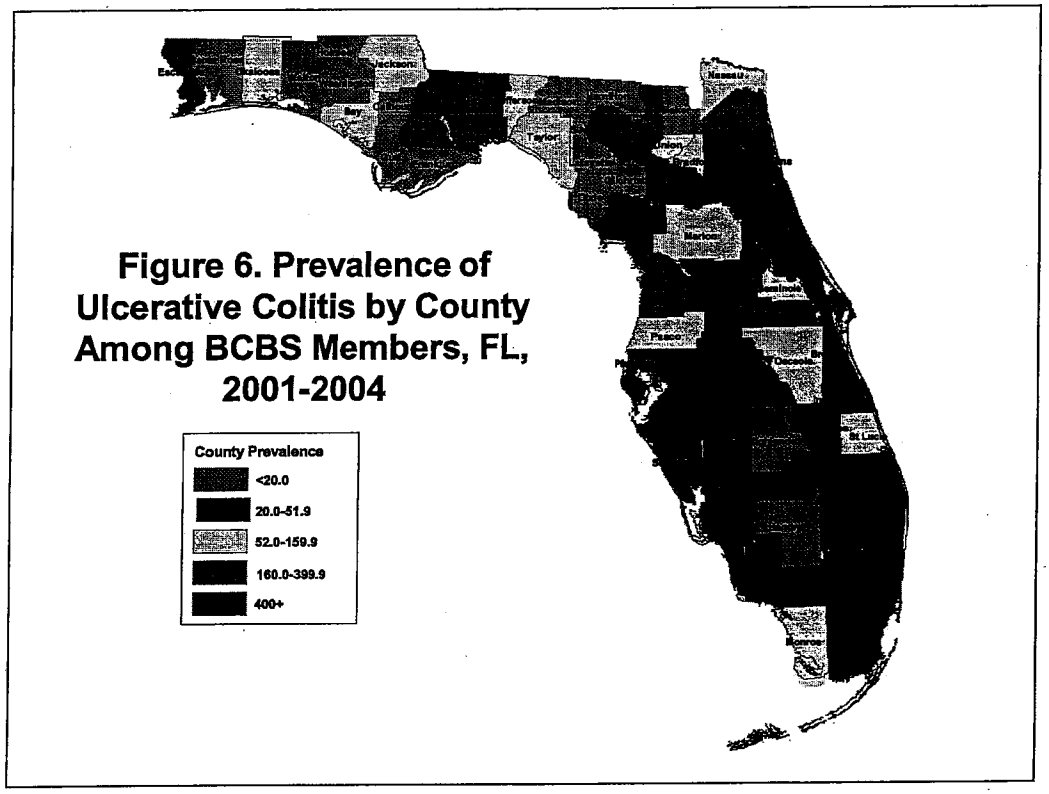


Figure 6. Prevalence of Ulcerative Colitis by County Among BCBS Members, FL, 2001-2004

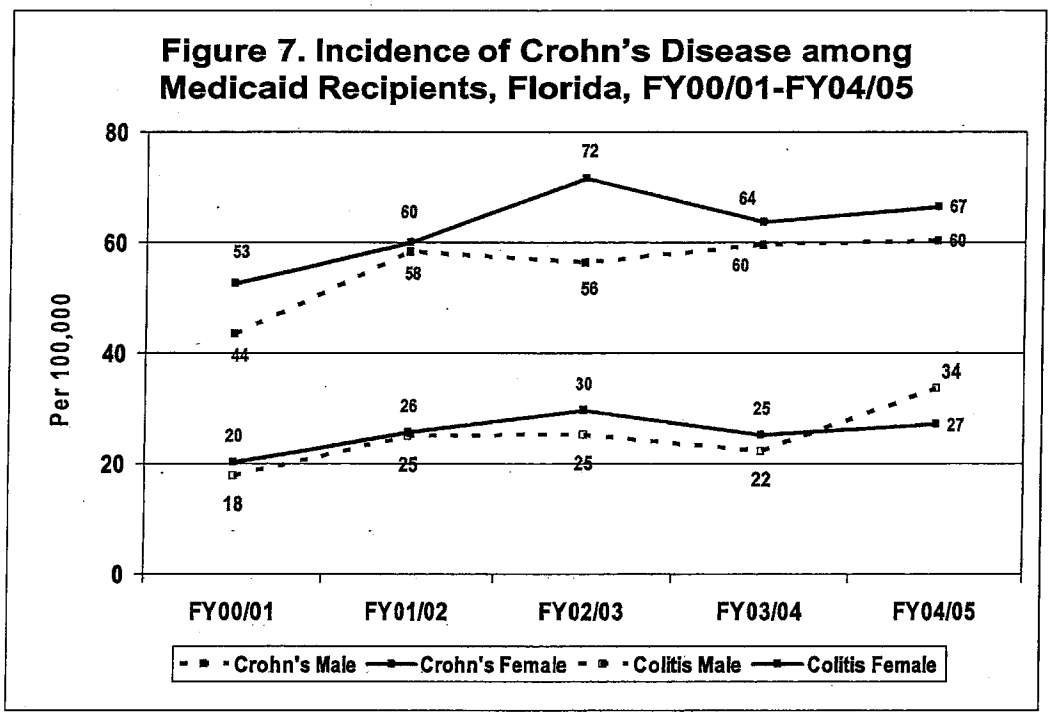
Medicaid data

The number of Medicaid recipients receiving medical service varied greatly during FY 2000-2001 through FY 2004-2005. The average number of recipients with at least one claim for medical service was 1,184,535 per year. The average number of Medicaid recipients diagnosed with Crohn's disease per year was 717 patients, with a prevalence of 61 per 100,000 people. On average, 304 recipients per year were diagnosed with ulcerative colitis, with a prevalence of 26 per 100,000 people. The number of recipients diagnosed with other colitis was 26,055 per year with a prevalence of 2,200 per 100,000 people. (Table 2)

Tables 2. Number of Patients with IBD among Medicaid Recipients, Florida, FY00/01-FY04/05

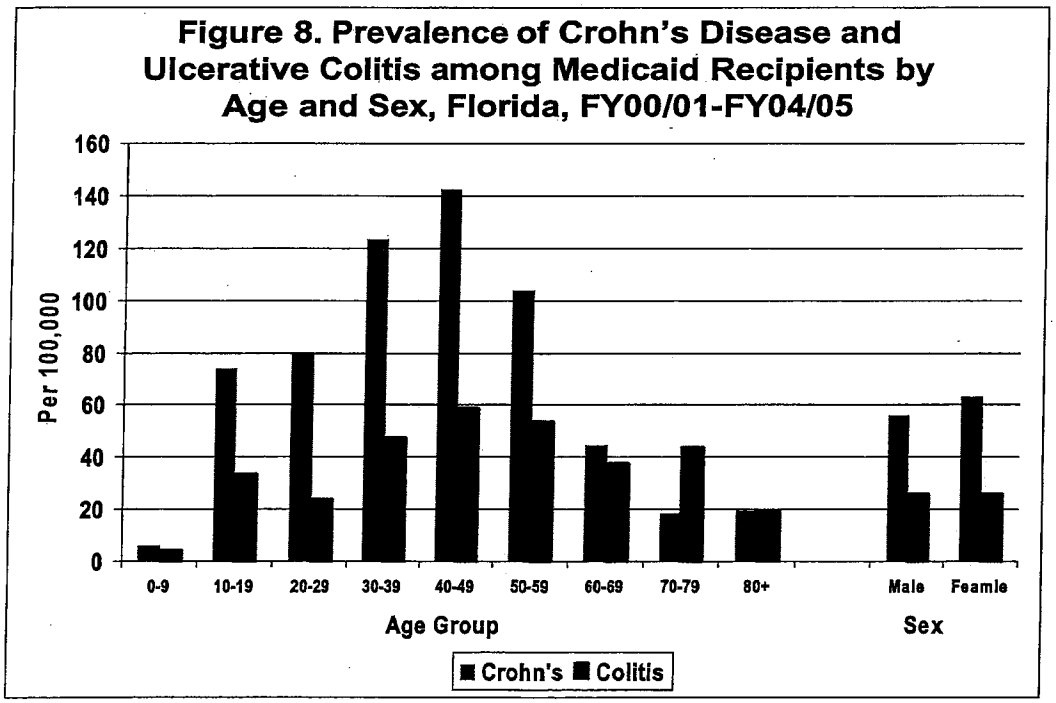
	FY00/01	FY01/2	FY02/3	FY03/4	FY04/5
# of Recipients	**1,042,369**	**1,084,413**	**895,044**	**1,170,599**	**1,730,249**
Crohn's Disease					
Total	**513**	**644**	**590**	**728**	**1,111**
Female	**348**	**416**	**406**	**474**	**733**
Male	**165**	**228**	**184**	**254**	**378**
Ulcerative Colitis					
Total	**202**	**275**	**250**	**283**	**510**
Female	**134**	**177**	**168**	**188**	**300**
Male	**68**	**98**	**82**	**95**	**210**
Other					
Total	**25,966**	**20,785**	**18,755**	**27,360**	**37,411**
Female	**13,863**	**10,990**	**9,928**	**14,317**	**20,076**
Male	**12,101**	**9,793**	**8,824**	**13,038**	**17,333**

The prevalence of both Crohn's disease and ulcerative colitis increased during FY2000-2001 through FY2004-2005. The prevalence of Crohn's disease increased by 30 percent (38 percent for males and 27 percent for females), and the prevalence of ulcerative colitis increased by 52 percent (87 for males and 35 percent for females). (Figure 7)



The age-specific prevalence was the highest among people between ages 40 and 49 for both Crohn's disease (142 per 100,000 persons) and ulcerative colitis (58 per 100,000 persons).

Females had a higher prevalence of Crohn's disease (63 per 100,000 persons) than males (56 per 100,000 persons). However, the prevalence of ulcerative colitis was the same (26 per 100,000 persons) among both males and females. (Figure 8)



Hospital discharge data

There were 12,769,086 patients discharged from hospitals during 1995-2004. During this period, 187,700 patients were diagnosed with IBD, among whom 15,340 had Crohn's disease and 13,820 had ulcerative colitis.

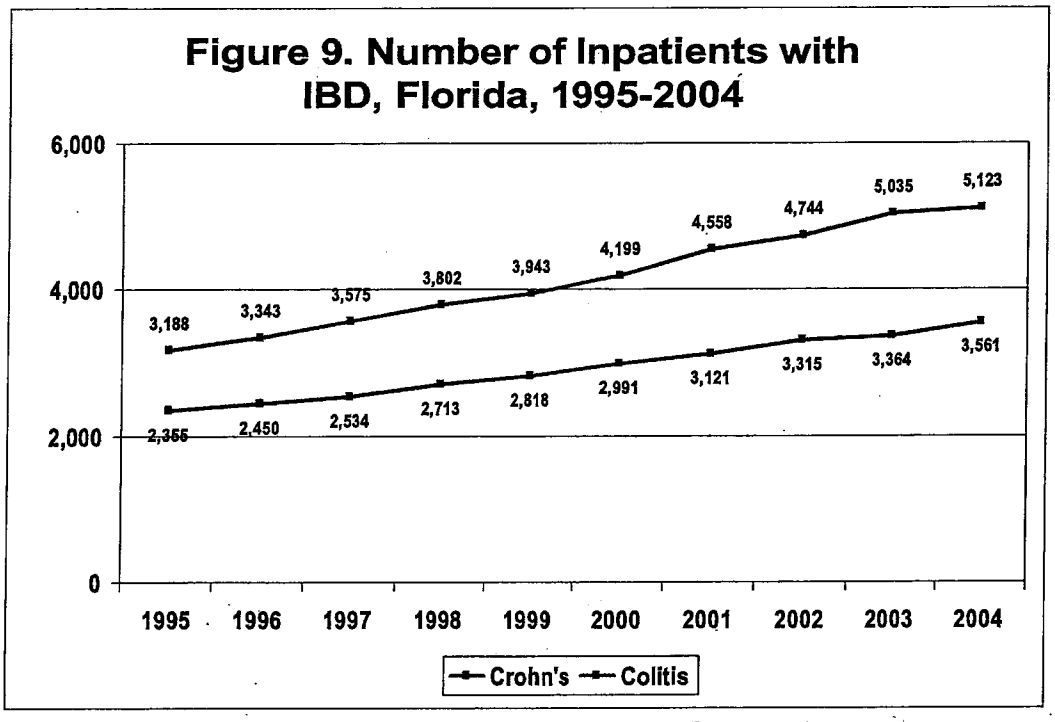
Among patients with Crohn's disease and ulcerative colitis, there were more female patients, than there were male patients. Although most Crohn's disease and ulcerative colitis patients were Whites, many patients of other races/ethnicities were diagnosed with IBD as well. (Table 3)

Table 3. Average Number of New Patients Hospitalized with IBD per Year, Florida, 1995-2004

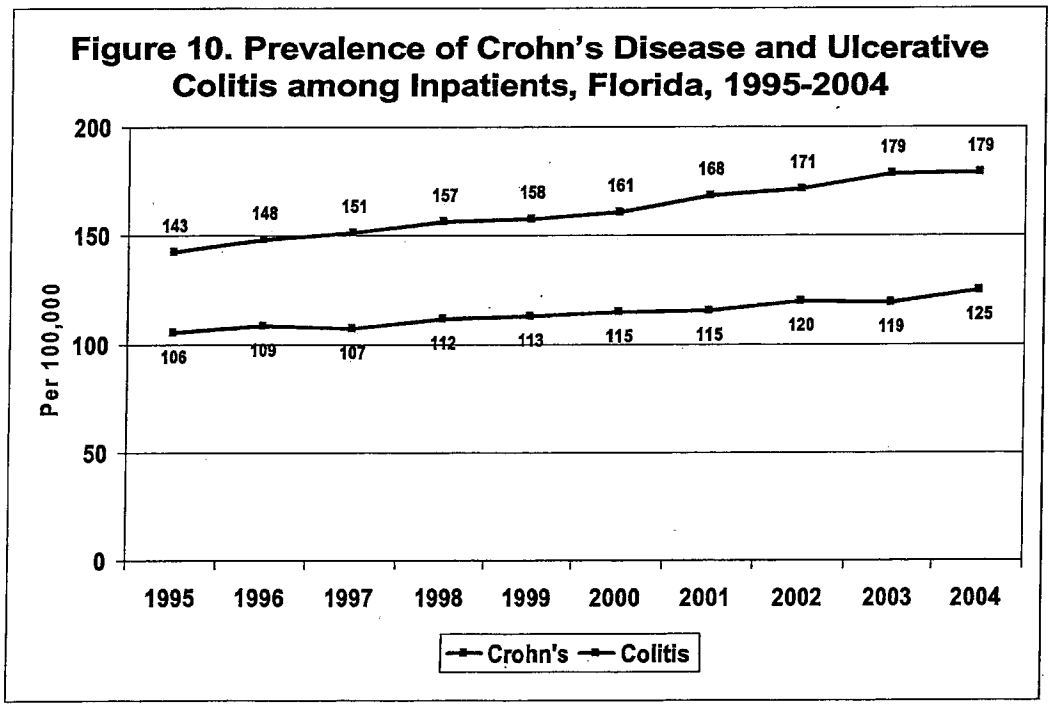
	All IBD	Crohn's	Colitis	Other		All IBD	Crohn's	Colitis	Other
Total	18770	1534	1382	16314					
By Age					By Race				
0-	246	0	0	246	Black	2,186	92	90	2,039
1-10	1,129	5	3	1,123	Hispanic	2,424	90	117	2,256
11-20	534	60	30	456	Other	442	35	34	383
21-30	1,193	158	83	987	White	13,718	1,318	1,140	11,635
31-40	1,946	227	141	1,638	By Insurance				
41-50	2,207	237	152	1,882	No Insurance	1,265	141	72	1,083
51-60	2,156	217	177	1,821	Medicare	8,899	602	741	7,788
61-70	2,708	231	232	2,309	Medicaid	2,120	95	71	1,993
71-80	3,673	260	331	3,172	Private	6,052	646	463	5,090
81+	2,980	139	231	2,681	Other	433	50	35	361
By Sex									
Male	7,134	662	600	6,049					
Female	116,356	872	782	10,265					

New patients, excluding patients who were diagnosed as outpatients

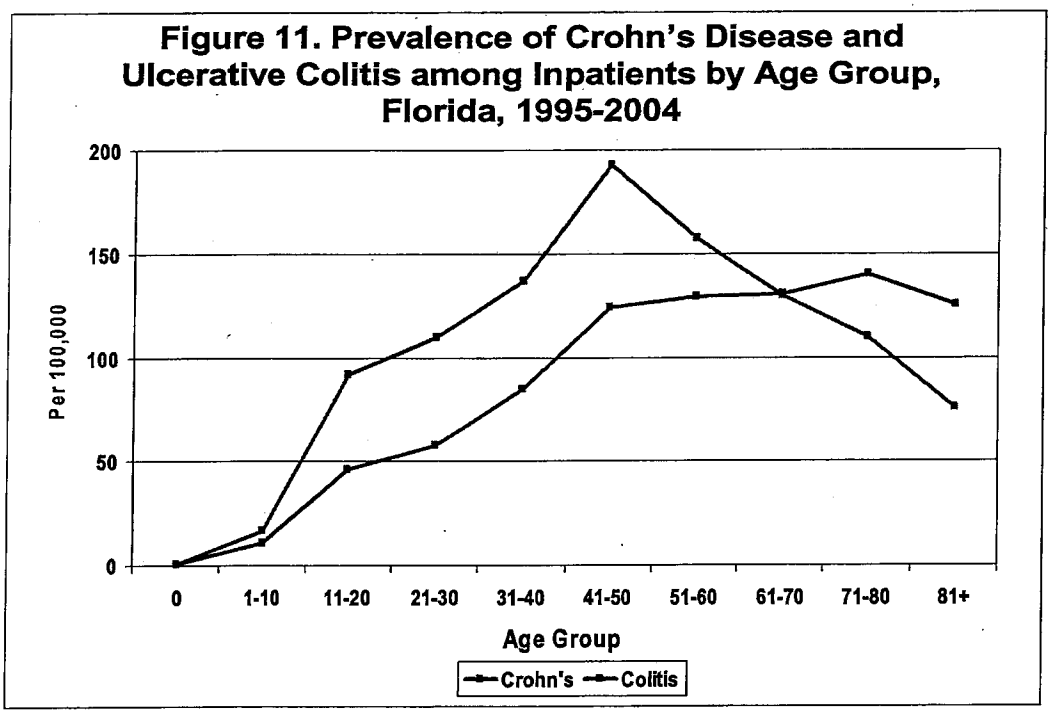
The number of patients with Crohn's disease and ulcerative colitis that were hospitalized increased by 61 percent and 51 percent, respectively, from 1995 to 2004. In 2004, 5,123 Crohn's disease and 3,561 ulcerative colitis patients were hospitalized. (Figure 9)
The 10-year overall prevalence was 120.1 per 100,000 people for Crohn's disease and 108.2 per 100,000 people for ulcerative colitis during the 10-year period. For calculating overall prevalence, a patient with an IBD diagnosis was counted once, regardless of how many times the patient was hospitalized in the 10-year period. Some patients were diagnosed with both Crohn's disease and ulcerative colitis. The average prevalence of patients with either Crohn's disease and/or ulcerative colitis was 221.0 per 100,000 people among inpatients.



The annual prevalence of Crohn's disease increased by 26 percent, from 143 per 100,000 people in 1995 to 179 per 100,000 people in 2004. The annual prevalence of ulcerative colitis increased by 18 percent, from 106 per 100,000 persons in 1995 to 125 per 100,000 persons in 2004. (Figure 10)



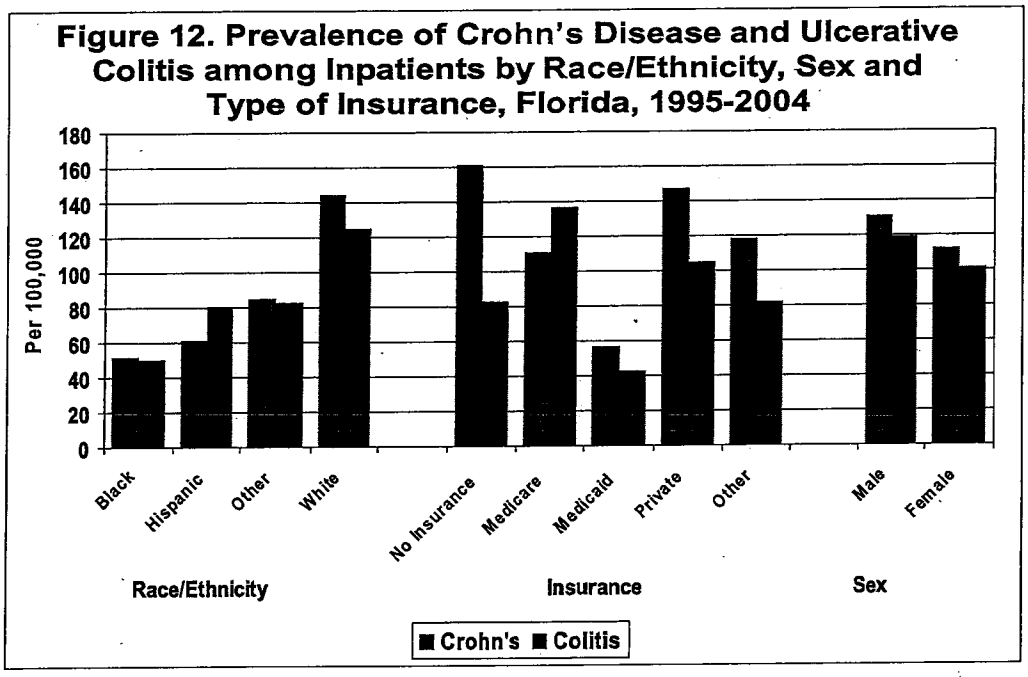
The age-specific prevalence of Crohn's disease increased by age, reached a peak of 193 per 100,000 people among the 41-to-50-year age group, then it decreased to 76 per 100,000 people among people aged 81 years and older. The prevalence of ulcerative colitis also increased by age, reached a peak of 140 per 100,000 people among 41-to-50 year age group, and decreased to 125 per 100,000 people among people aged 81 years and older. (Figure 11)



Whites had the highest prevalence of Crohn's disease (145 per 100,000 people) and ulcerative colitis (125 per 100,000 people) among four race/ethnicity groups. Blacks had the lowest prevalence for both Crohn's disease (61 per 100,000 people) and ulcerative colitis (51 per 100,000 people).

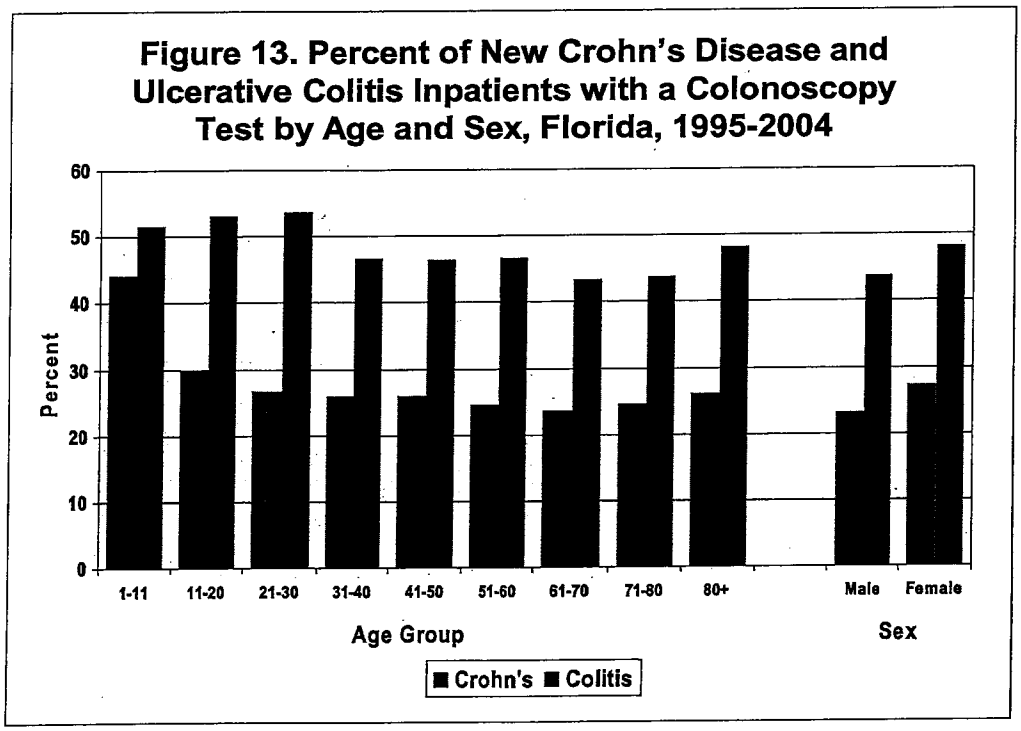
Patients who had a private medical insurance (147 per 100,000 people) and patients without any insurance (162 per 100,000 people) had a higher prevalence for Crohn's disease than their counterparts did. Medicare beneficiaries had the highest prevalence (137 per 100,000 people) of ulcerative colitis. Medicaid recipients had the lowest prevalence of both Crohn's disease (57 per 100,000 people) and ulcerative colitis (43 per 100,000 people).

Males had a higher prevalence of both Crohn's disease (131 per 100,000 people versus 113 per 100,000 people) and ulcerative colitis (119 per 100,000 people versus 101 per 100,000 people) than females. (Figure 12)

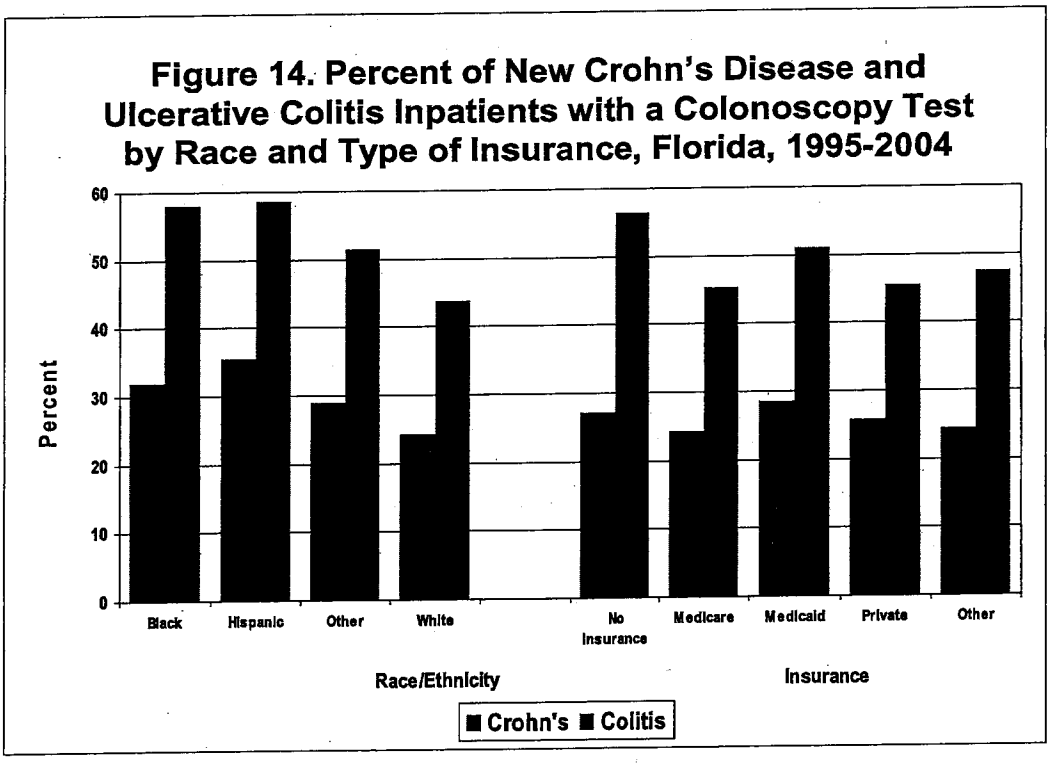


Approximately one quarter (25.5 percent) of new Crohn's disease patients had a colonoscopy. The percent of patients with a colonoscopy was higher among younger patients (under age 20) than among older patients, and higher among females than among males.

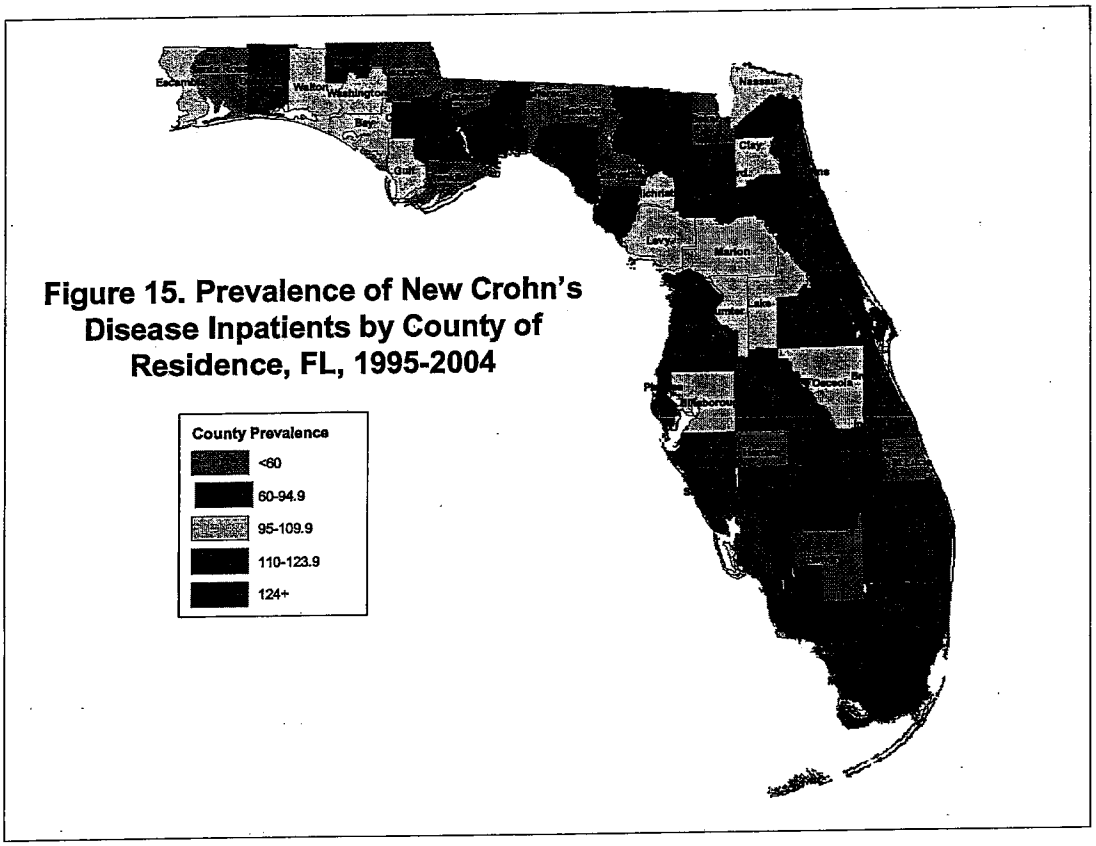
Among new patients with ulcerative colitis, 42.3 percent had a colonoscopy. The percent of patients with a colonoscopy was also higher among patients under age 30 and among females than among their counterparts. (Figure 13)



The percent of new Crohn's disease patients with a colonoscopy was the highest among Hispanics. Both Medicaid recipients and patients without any medical insurance had a higher percent than their counterparts did. The percent of new ulcerative colitis patients with a colonoscopy was higher among Hispanics and Blacks than Whites and people of other races. The percent of ulcerative colitis patients with a colonoscopy was also higher among people without medical insurance and Medicaid recipients than for people with a private insurance and Medicare beneficiaries. (Figure 14)

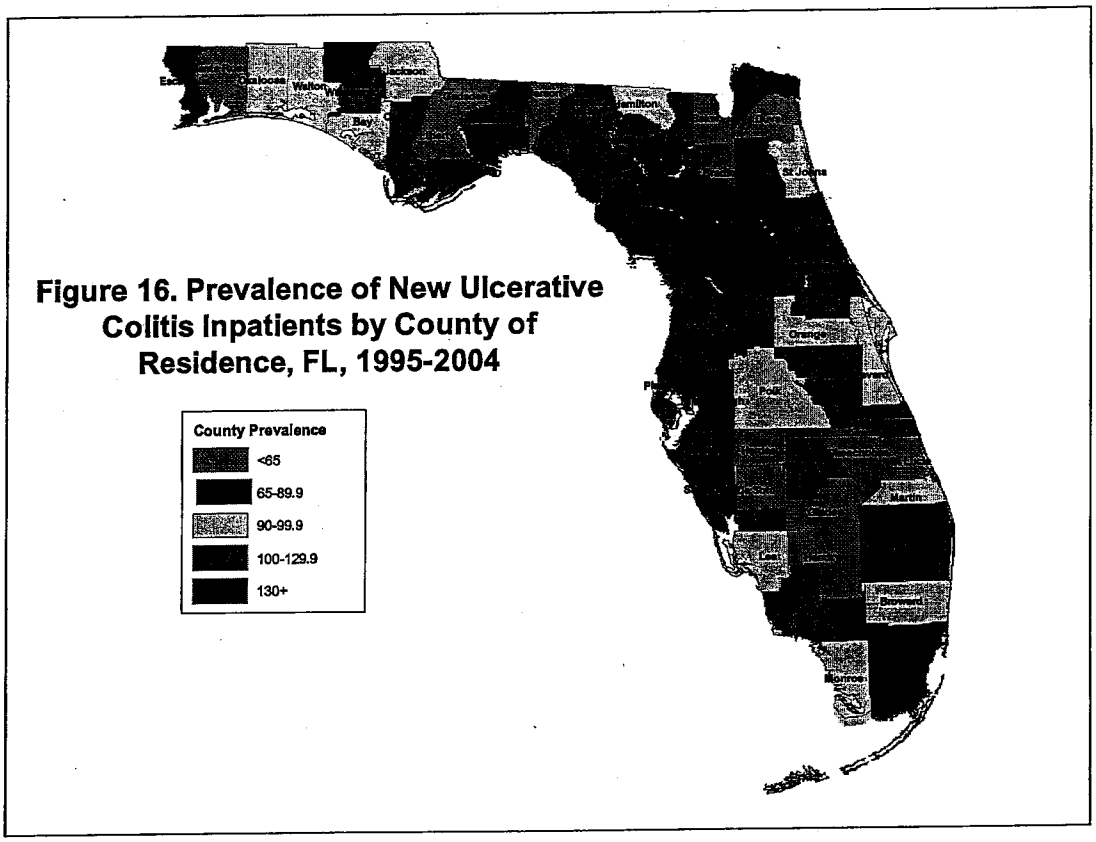


Twelve counties had a 10-year overall prevalence of Crohn's disease of 124 per 100,000 people or greater in Florida. These counties are Holmes, Union, Seminole, Hernando, Pasco, Pinellas, Indian River, Okeechobee, Sarasota, Charlotte, Collier, and Monroe. (Figure 15)



Twelve counties had a prevalence of ulcerative colitis of 130 per 100,000 or greater in Florida. These counties are Gulf, Suwannee, Columbia, Union, Citrus, Sumter, Lake, Hernando, Osceola, Sarasota, Charlotte, and Collier. (Figure 16)

Union, Hernando, Sarasota, Charlotte, and Collier had higher prevalence rates for both Crohn's disease and ulcerative colitis than other counties in Florida during 1995-2004.



Ambulatory patient data

There were 12,710,291 patients who received at least one ambulatory care service during 1997-2004. Among these patients, 22,005 were diagnosed with Crohn's disease, 32,541 were diagnosed with ulcerative colitis, and 120,138 were diagnosed with other colitis.

There were more females than males among patients with Crohn's disease and ulcerative colitis. Approximately 80 percent of Crohn's disease and ulcerative colitis patients were White, and 60 percent of patients had a private health insurance. (Table 4)

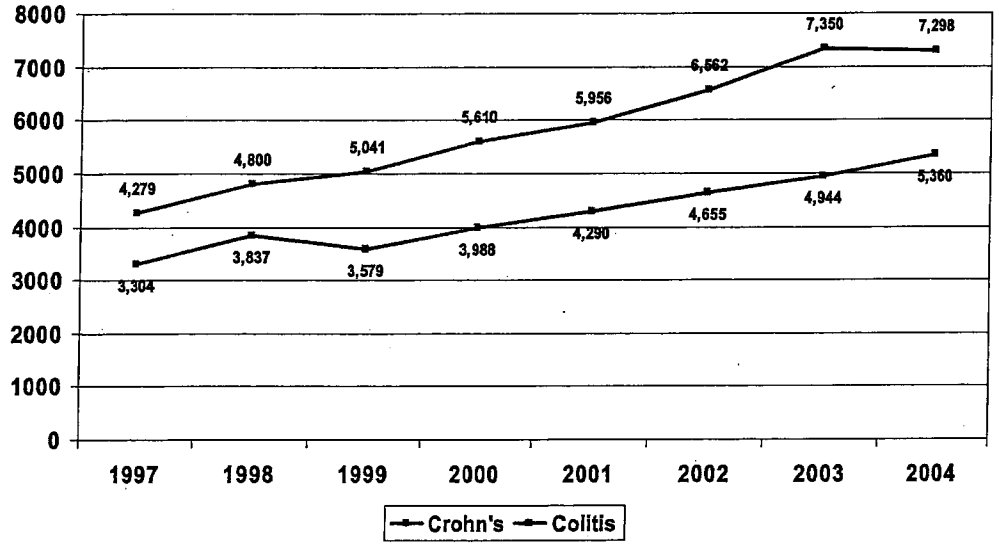
Table 4. Average Number of New Outpatients with IBD per Year, Florida, 1997-2004

	All IBD	Crohn's	Colitis	Other		All IBD	Crohn's	Colitis	Other
Total	20,143	2,751	4,068	15,017					
By Age					By Race				
0-	28	1	3	27	Black	950	111	186	729
1-10	123	11	11	105	Hispanic	1,492	142	268	1,196
11-20	503	135	115	314	Other	1,583	292	382	1,007
21-30	1,323	300	327	837	Whites	16,117	2,207	3,232	12,085
31-40	2,374	439	595	1,588	By Insurance				
41-50	3,185	498	707	2,284	No Insurance	509	77	100	366
51-60	3,697	494	706	2,803	Medicare	7,337	756	1,291	5,815
61-70	3,836	423	710	2,992	Medicaid	629	91	88	490
71-80	3,768	348	679	3,004	Private	11,100	1,726	2,446	7982
81+	1,306	105	218	1,064	Other	568	101	142	363
By Sex									
Male	8,151	1,180	1,915	5,829					
Female	11,993	1,571	2,153	9,189					

New patients, including patients who were also hospitalized

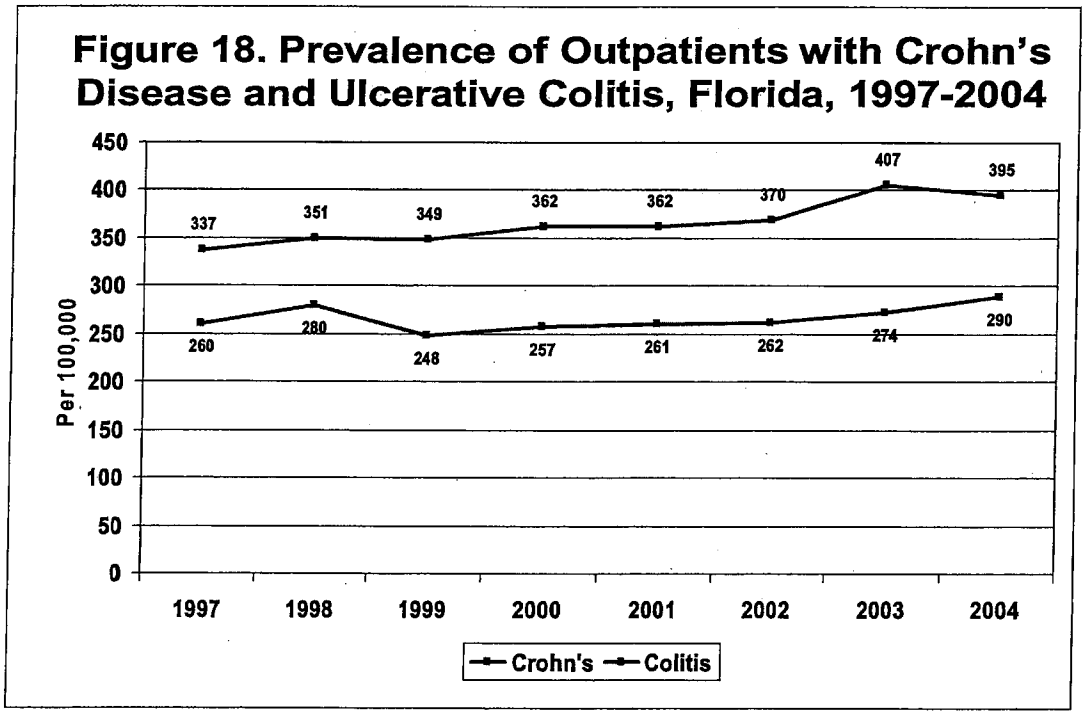
The number of Crohn's disease patients that were treated as ambulatory patients was 3,304 in 1997 and increased by 62 percent to 5,360 in 2004. The number of ulcerative colitis patients increased by 71 percent, from 4,279 in 1997 to 7,298 in 2004. (Figure 17)

Figure 17. Number of Outpatients with Crohn's Disease and Ulcerative Colitis, Florida, 1997-2004



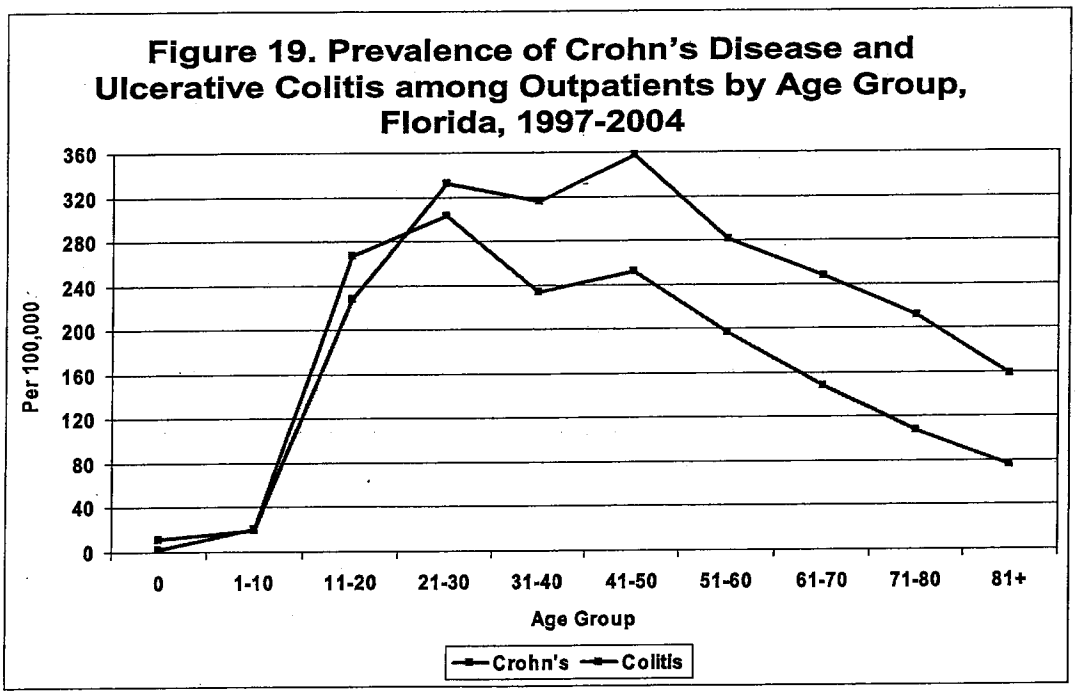
The 8-year overall prevalence (each patient was counted only once) was 173.1 per 100,000 people for Crohn's disease and 256 per 100,000 people for ulcerative colitis during 1997-2004. Some patients were diagnosed with both Crohn's disease and ulcerative colitis. The average prevalence of patients with Crohn's disease and/or ulcerative colitis was 412.4 per 100,000 people.

The annual prevalence of ambulatory patients increased for both Crohn's disease and ulcerative colitis in the 8-year period. The prevalence of Crohn's disease increased by 11 percent, from 260 per 100,000 persons in 1997 to 289 per 100,000 persons in 2004. The prevalence of ulcerative colitis increased by 17 percent, from 337 per 100,000 persons in 1997 to 395 per 100,000 persons in 2004. (Figure 18)

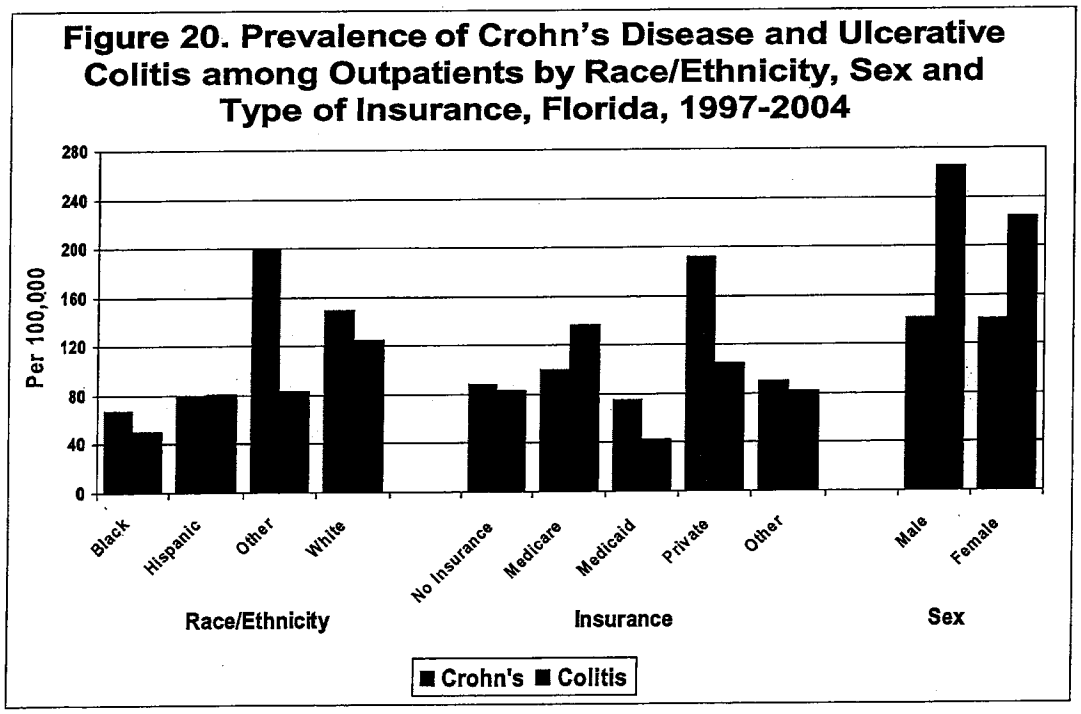


The age-specific prevalence of Crohn's disease increased dramatically in teenagers and peaked in the 21- to 30-year-old age group. Age-specific prevalence decreased among patients aged 30 years and older, with an exception of an increase in the 41- to 50-year-old age group.

The age-specific prevalence of ulcerative colitis increased among patients between ages 11 and 30 years, and then reached a peak of 358 per 100,000 persons among the 41- to 50-year–old age group. The prevalence then decreased by age among people aged 50 years and older. (Figure 19)



Patients of other races had the highest prevalence of Crohn's disease at 200 per 100,000 people. The prevalence of Crohn's disease among Whites was the second highest at 150 per 100,000 people. The prevalence of Crohn's disease was the highest among patients with a private health insurance (193 per 100,000 people). The prevalence was the lowest among Medicaid recipients (75 per 100,000 people). The prevalence of Crohn's disease was slightly higher among males (143 per 100,000 people) than among females (141 per 100,000 people). (Figure 20)

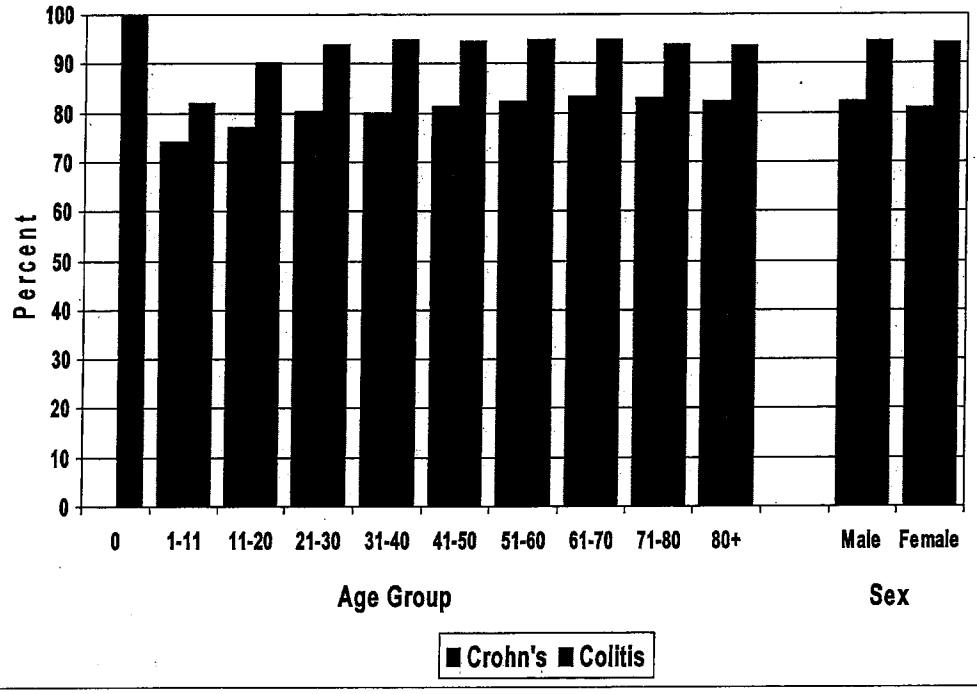


The prevalence of ulcerative colitis was the highest among Whites (125 per 100,000 people), and among Medicare beneficiaries (137 per 100,000 people). The prevalence was the lowest among Medicaid recipients (43 per 100,000 people). Males had a higher prevalence of ulcerative colitis (265 per 100,000 people) than females (224 per 100,000 people). (Figure 22)

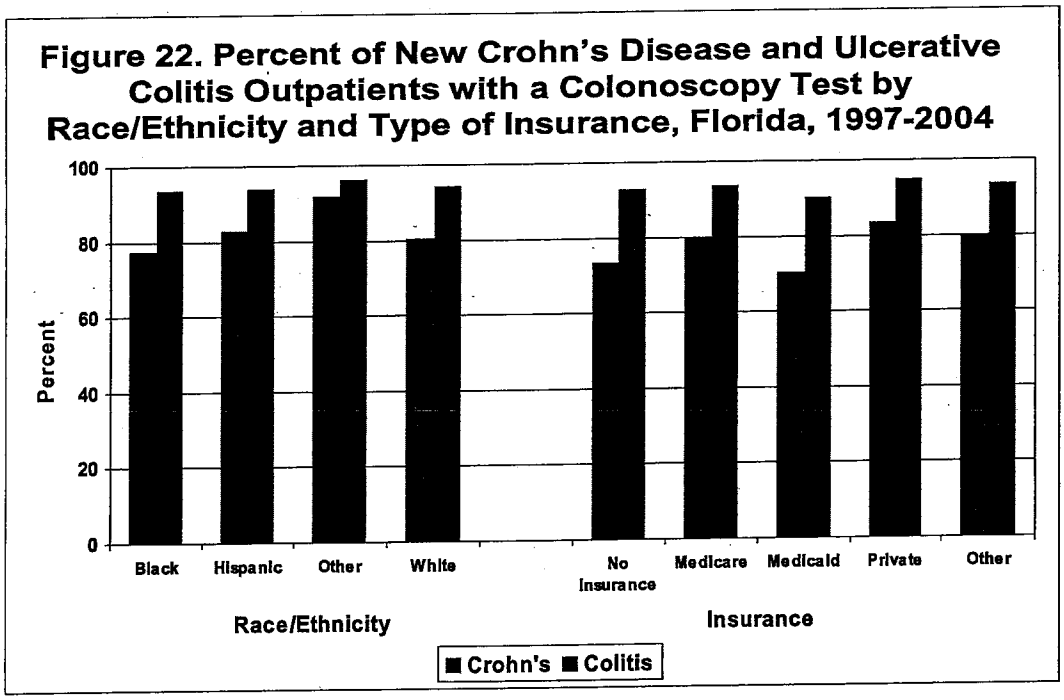
Approximately 82 percent of Crohn's disease patients had a colonoscopy. The percent of Crohn's disease patients with a colonoscopy was lower among patients under age 20 than among older patients. The percent was the same among both males and females.

A majority (94 percent) of ulcerative colitis patients had a colonoscopy. The percent of ulcerative colitis patients with a colonoscopy was higher among patients aged 20 years and older. There was no difference in the percentage between males and females. (Figure 21)

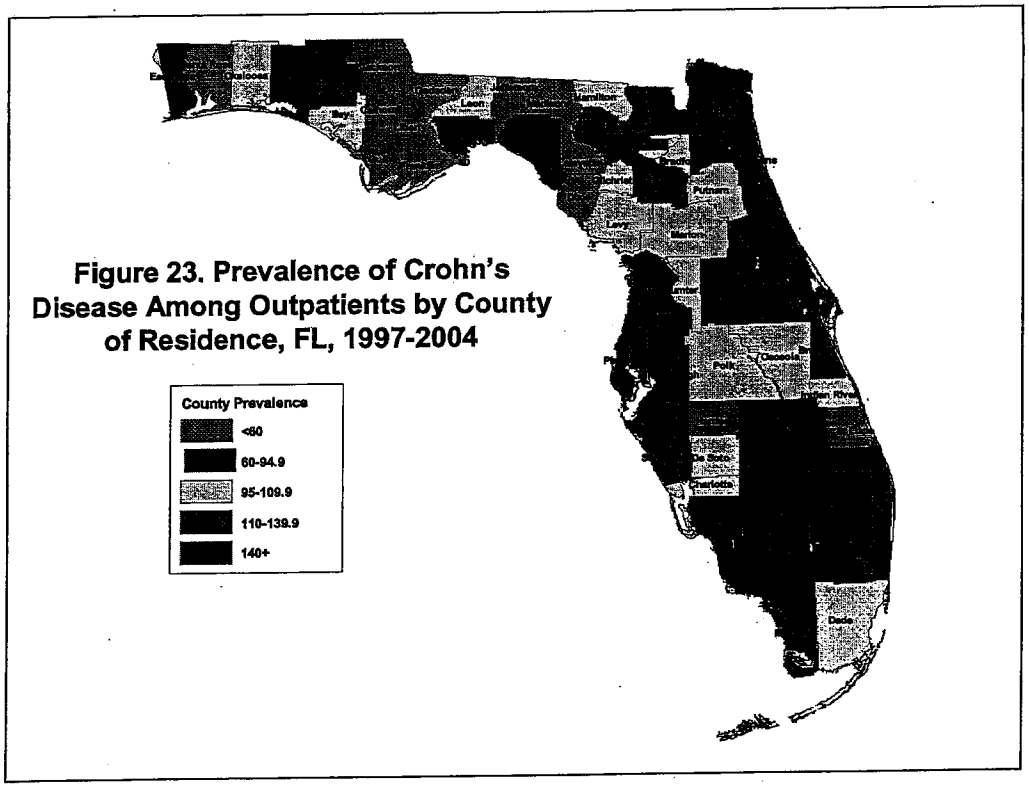
Figure 21. Percent of New Crohn's Disease and Ulcerative Colitis Outpatients with a Colonoscopy Test by Age and Sex, Florida, 1997-2004



The percent of Crohn's disease patients with a colonoscopy was the highest among patients of other races (96 percent), and among patients with a private health insurance (95 percent). The percent of ulcerative colitis patients who had a colonoscopy was the lowest among Medicaid recipients (90 percent). (Figure 22)



Twelve counties had an eight-year overall prevalence of Crohn's disease of 140 per 100,000 persons or greater in Florida. These counties are Columbia, Union, Clay, Alachua, Flagler, Seminole, Pinellas, Manatee, Sarasota, Lee, Hendry, and Broward. (Figure 23) It is noteworthy that Union, Seminole, Pinellas, and Sarasota also had a high prevalence of Crohn's disease among inpatients. (Figure 15)



Thirteen counties had an overall prevalence of ulcerative colitis of 300 per 100,000 people or greater in Florida. These counties are Gulf, Leon, Jefferson, Citrus, Lake, Hernando, Seminole, Pinellas, Sarasota, Collier, Palm Beach, Broward, and Monroe. (Figure 24) Among these counties, Gulf, Citrus, Lake, Hernando, Sarasota, and Collier also had a high prevalence of hospitalization for ulcerative colitis.

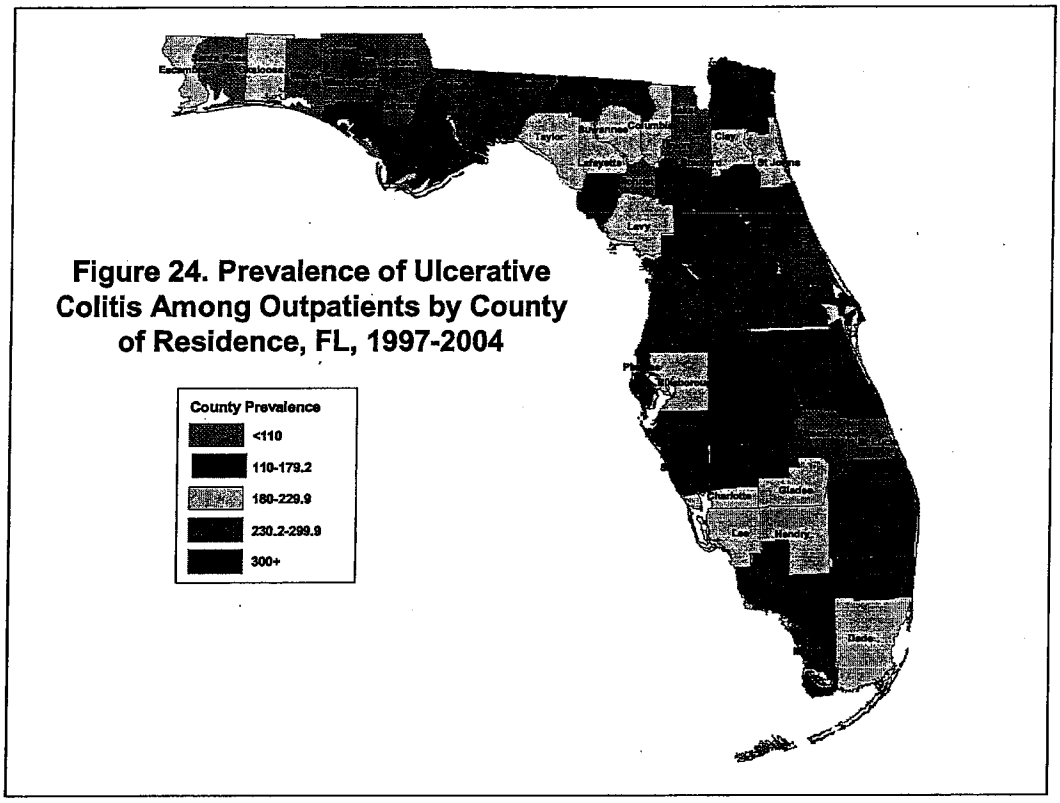


Figure 24. Prevalence of Ulcerative Colitis Among Outpatients by County of Residence, FL, 1997-2004

Seminole, Pinellas, Sarasota, and Broward counties had high prevalence rates for both Crohn's disease and ulcerative colitis among ambulatory patients.

Sarasota was the only county that had a high prevalence for both Crohn's disease and ulcerative colitis among both inpatients and ambulatory patients.

BRFSS Survey

A total of 1,678 respondents answered the survey questions in the IBD module. Excluded from the analysis were 19 respondents who answered "don't know" or "not sure." Among the 1,659 respondents included in the final analysis, 63 reported that someone in their household was diagnosed with IBD. Three (4.8 percent) of 63 households had more than one person diagnosed with IBD.

BRFSS data suggested that 3.2 percent of all households have IBD patient(s), with 4.2 percent of households among Whites, 3.4 percent of households among Hispanics, 1.6 percent of households among Blacks, and 1.7 percent of households among other races.

There was no difference in the percent of having somebody with IBD between households with annual income less than $50,000 and household with annual income of $50,000 or more.

Among the 3,066 adults and 916 children within the 1,659 households, 66 persons were reported being diagnosed with IBD. Because the BRFSS survey did not ask for the age of individuals with IBD, the DOH team estimated that two of the people with IBD were children (under age 20), based on the age distribution of hospital discharge, and ambulatory care, data. The prevalence of IBD was estimated as 2.1 percent for adults and 0.22 percent for children. These estimates were not weighted prevalence, which did not take into account of probability of survey respondents being included in the survey. A weighted prevalence will be available after CDC has completed the data weighting process.

Among survey respondents, 12 (18.2 percent) persons with IBD in 10 households were hospitalized in the past year. There was no difference in the percent of households with an IBD patient being hospitalized by race or by household income.

GI Physician Survey

The DOH received 113 completed survey questionnaires from GI physicians. The GI physicians who responded to the survey reported that 9,005 (7.3 percent) IBD patients were seen in the past 12 months among their 123,480 patients within that timeframe. Among IBD patients, approximately 14.2 percent were diagnosed in the past 12 months.

It was estimated that 40 percent of IBD patients were between the ages 20 and 45 years, and 30 percent were between the ages 45 and 65 years. IBD patients under age 20 years only accounted for approximately 10 percent.

Whites accounted for 93 percent of IBD patients; Blacks accounted for approximately 5 percent. Very few IBD patients were either Asian or other races.

Among IBD patients, females accounted for 51 percent and males for 49 percent. Approximately one quarter (22.4 percent) of patients had a family history of IBD, and one-eighth (12.2 percent) were hospitalized in the past 12 months.

The majority (94 percent) of IBD patients under the care of the responding physicians were enrolled in colon cancer surveillance.

IBD Patient Survey

The DOH received 27 completed survey questionnaires from IBD patients who voluntarily participated in the survey. The following are the results of the survey:

Age range of participants: 9 to 79 years

Age of diagnosis:

Age	<10	11-19	20-39	40-64	65 +
Percent	7.5	11	48	26	7.5

Average time living with IBD: 11.1 years

Gender: 78 percent Female 22 percent Male

Race/ethnicity: 96 percent Caucasian 4 percent Other

Jewish Decent: 33 percent yes, 63 percent no, and 4 percent unsure

Region of birth (within the US):
93 percent of respondents were born in the United States, of those:

Region	Southeast	Midwest	Northeast
Percent	28	4	68

Type of IBD:

Disease	Crohn's	Colitis	Crohn's & Colitis
Percent	56	40	4

Severity of symptoms:
78 percent of respondents reported their illness as active, of those:

Severity	Mild	Moderate	Severe
Percent	33	62	5

Family History:- 18 percent had a family history; 78 percent reported no family history of IBD; and 4 percent unsure

Proximity to cattle:
- 19 percent lived near cattle prior to diagnosis.

Smoking status:
- 30 percent of respondents were current smokers, and 67 percent lived with a smoker prior to diagnosis. The percent of current smoking among IBD patients was higher than the 2004 state average prevalence (20.2 percent).

Colonoscopy:
- 56 percent had first colonoscopy due to IBD symptoms

Other medical conditions prior to diagnosis of IBD:
- 27 percent had serious medical illnesses
- 11 percent had psychological illnesses
- 37 percent were hospitalized
- 59 percent reported having surgeries

Of those reporting surgeries:
- 25.0 percent had appendectomies; 62.5 percent had tonsillectomies; 12.5 percent had other surgeries
- Other surgeries listed: liver transplant and c-section

Assessment of overall health:

- 18 percent said their health was poor

CONCLUSIONS

The Crohn's disease and ulcerative colitis epidemiologic study was conducted by the DOH in conjunction with the University of Florida, AHCA, and BCBS, under the guidance of the Advisory Committee. This study is a large population-based study that combined multiple sources of data that covers a majority of Florida's population. The data used in this study included 42,372,600 patient claim records in up to 10 years and survey data of approximately 2,000 households, providers, and patients.

This study was the first to provide state-specific data on IBD for Florida, in terms of estimating the prevalence of Crohn's disease and ulcerative colitis, the demographic characteristics of IBD patients, and major risk factors of the IBD.

Estimated prevalence of Crohn's disease and ulcerative colitis

The Prevalence

The population-based prevalence of Crohn's disease is estimated at 222 per 100,000 people, and the prevalence of ulcerative colitis at 307 per 100,000 people. These estimates were calculated based on age distribution of Florida's population and age-specific prevalence of Crohn's disease and ulcerative colitis of BCBS members.

The BCBS data showed that the prevalence of IBD among BCBS members, including inpatients and outpatients was for:

- Crohn's disease: 220 per 100,000 persons
- Ulcerative colitis: 300 per 100,000 persons
- Other colitis: 520 per 100,000 persons

BCBS data captured information on both hospitalizations (severe disease) and clinic visits (less severe disease). BCBS data were a good source in determining the prevalence of IBD because there is less disparity in access to health care among BCBS members. However, BCBS members are not a representative sample for overall Florida population, among which approximately 17 percent of people without a health insurance.

The estimates based on BCBS data were consistent with findings from previous epidemiologic studies in North America, which suggested population-based prevalence varied from 162 per 100,000 people to 199 per 100,000 people for Crohn's disease and from 170 per 100,000 people to 246 per 100,000 people.

The combined hospital discharge data and ambulatory patient data showed that, among patients treated in hospitals, the prevalence of:

- Any IBD: 2,737.8 per 100,000 people (or 2.74 percent)
- Crohn's disease and/or ulcerative colitis: 633.4 per 100,000 people
- Crohn's disease: 293.3 per 100,000 people
- Ulcerative colitis: 364.2 per 100,000 people

The prevalence of Crohn's disease and ulcerative colitis among inpatients and ambulatory patients was 32 percent and 19 percent, respectively, higher than the prevalence among BCBS members. The difference in prevalence might reflect a compositional difference of populations between hospital patients and BCBS members.

The prevalence of IBD among Medicaid recipients was lower than that among BCBS members the prevalence of patients with:

- Crohn's disease: 61 per 100,000 people.
- Ulcerative colitis: 26 per 100,000 people.
- Other colitis: 2,200 per 100,000 people.

The causes of low prevalence of IBD among Medicaid recipients were unknown based on the data of this study. More studies are needed to examine further the contribution factors of low prevalence of IBD, including access to health care and composition of the Medicaid population.

The BRFSS survey was unable to distinguish type of IBD due to the nature of a telephone survey of the general public. An overall prevalence of IBD was estimated as 2.1 percent for adults and 0.22 percent for children. The BRFSS data represented population-based estimates, although the estimate was un-weighted and might carry large sample errors due to small sample size. The estimate was in line with other data in this study.

Number of Patients

It is estimated that approximately 35,500 Floridians have Crohn's disease and 49,000 have ulcerative colitis based on the estimated prevalence.

Hospitals in Florida served approximately 4,285 Crohn's disease patients and 5,450 ulcerative colitis patients either as inpatients or as ambulatory patients every year, accounting for approximately 12 percent and 11 percent of Crohn's disease and ulcerative colitis patients, respectively.

Demographic Characteristics

Age

The prevalence of Crohn's disease was relatively low among children and the elderly (age 70 years and older). The majority of IBD patients were diagnosed between the ages 11 and 40. The prevalence increased with age until age 50, then decreased with age.

The age-distribution might vary by population depending on the source of data. For example, the age-specific prevalence of ulcerative colitis among Medicaid recipients began to decrease among people age 50 years and older, which might reflect the fact that most Medicaid recipients were under age 50. On the other hand, the age-specific prevalence did not decrease until age 80 and older among hospital inpatients, among whom there were more elderly.

Sex:

The overall prevalence was very close between males and females, with a slightly higher prevalence among females than among males.

Both BCBS and Medicaid are population-based data that show a slightly higher prevalence of IBD among females than among males. However, the prevalence was slightly higher among males than among females for patients seen in hospitals, which might be due to the sex-distribution of hospital patients (more male patients than female patients are seen in hospitals).

Race/ethnicity:

Non-Hispanic Whites had a higher prevalence than non-Hispanic Blacks, Hispanics, and people of other races. Crohn's disease and ulcerative colitis occurred in all racial/ethnic groups.

Household Income:
No difference in prevalence by household income was found according to data from the BRFSS survey.

Type of Health Insurance:
Patients who were Medicare beneficiaries or who had private insurance had a higher prevalence rate of Crohn's disease or ulcerative colitis. Medicaid recipients had the lowest prevalence for both Crohn's disease and ulcerative colitis.

Type of medical insurance was the only variable available in the claim data and might be a surrogate indicator of socioeconomic status. The difference in prevalence might be attributable to the disparity in access to health care and the difference in race and age composition of the populations.

Residential County:
Based on hospital discharge data and ambulatory patient data, the following counties had high prevalence rates:

- Pinellas, Sarasota, and Seminole had a high prevalence of Crohn's disease.
- Citrus, Collier, Gulf, Hernando, Lake, and Sarasota had a high prevalence of ulcerative colitis.

Among BCBS members, those who resided in Glades and Wakulla counties had a high prevalence of Crohn's disease, and those who resided in Wakulla and Liberty counties had a high prevalence of ulcerative colitis.

Sarasota and Palm Beach counties were the only two counties that had a high prevalence of Crohn's disease and ulcerative colitis in all hospital discharge data, ambulatory patient data, and BCBS data.

Risk factors

Previous epidemiologic studies on risk factors of Crohn's disease and ulcerative colitis suggested that although genetic factors might be strongly associated with IBD, environmental factors would explain most variations in the prevalence of IBD. The data in this study supported the findings from previous studies.

Genetic factors

A family history was found among approximately 20 percent of patients from the patient survey, physician survey, and BRFSS survey. Both claim data and survey data indicated that the majority of patients were non-Hispanic White. The patient survey data showed that nearly two thirds of IBD patients were born in the Northeast region of the U.S. and many of IBD patients were of Jewish descent.

The consistency of the finding of family history across surveys and aggregation of IBD in a population indicated a strong association between genetic factors and occurrence of IBD.

Environmental factors

Previous studies suggested several environmental risk factors, including cigarette smoking, consumption of milk, contact with cattle, and receiving certain types of surgery, might be associated with IBD. However, none of these environmental risk factors has been confirmed.

In this study, the DOH surveyed a small group of IBD patients for these potential risk factors. The survey found that the prevalence of cigarette smoking was higher than the state's average prevalence. Many patients were exposed to second-hand smoke, and had surgical procedures, such as tonsillectomy and appendectomy. However, because of the nature of the survey (a self-reported survey without a control group) and small sample size of the survey, no causal relationship could be established between these risk factors and IBD.

Recommendations for Future Studies

This study collected a great deal of data about IBD, and laid a foundation for future studies about IBD in Florida. To better assess IBD and to serve IBD patients in Florida, more studies are needed to:

- Increase sample size for the BRFSS survey to obtain a more accurate estimate of the population-based prevalence of IBD.
- Conduct a case-control study to identify risk factors of IBD.
- Develop an IBD patient voluntary registry through healthcare providers. This registry will provide data for a longitudinal follow-up study of IBD patients and many other studies on treatment, outcome, and patient's quality of life.

ATTACHMENTS

Attachment 1: GI PHYSICIAN SURVEY

A Survey about Inflammatory Bowel Disease Patients

The purpose of this survey is to collect data on inflammatory bowel disease patients, particularly for those who may not have been hospitalized. **All data collected from this survey will be kept strictly confidential.** Please give your best approximation for the following questions.

1. How many patients have you seen in the past 12 months? (please check one)
   □ <100 □ 100-499 □ 500-999 □ 1000-1499 □ 1500 and more

How many of your patients are diagnosed with an Inflammatory Bowel Disease, such as Crohn's disease or ulcerative colitis? ____ ____

2. Please **estimate** the number of IBD patients from question 2 for the following:

Age	<20 yrs	20-44 yrs	45-64 yrs	65 yrs and older
# Patients				

Race	White	Black	Asian	Other
# Patients				

Sex	Male	Female
# Patients		

Ethnicity	Hispanic	Non-Hispanic
# Patients		

3. Among those IBD patients, how many have been hospitalized for IBD in the past 12 months?
   ____ ____

4. How many of your patients with IBD report a family history of the illness?
   ____ ____

5. Among all IBD patients, about how many were diagnosed within the past 12 months?
   ____ ____

6. Do you enter your IBD patients into the colon cancer surveillance program?
   ____yes____no

7. Please provide any additional information or comments about your IBD patients:

_____

_____

_____

Thank you very much for completing the survey. Your information will greatly assist our study. In case we need to contact you for further information, please provide the following information:

Your name: _____

Your office phone number: ( ) _____-_____

Attachment 2: IBD PATIENT SURVEY

Inflammatory Bowel Disease Patient Questionnaire

Dear Respondent: As you may be aware, the Florida Department of Health is conducting a study to uncover the potential role of genetic and environmental risk factors associated with Inflammatory Bowel Disease (as mandated by House Bill 869, also known as the "Crohn's & Colitis Disease Research Act"). This is a short survey designed to evaluate potential genetic and environmental exposures for patients with IBD. If you have been diagnosed with IBD, please answer the following questions to the best of your ability. You are not obligated to answer every question, though we kindly ask that you answer as many questions as you feel comfortable in giving a response. **All information provided will remain confidential**. We are not asking for any personal identifiers (such as name, date of birth, or social security number), to ensure that your information is also anonymous. You are an invaluable resource in the development of this area of research. Your time, effort, and comments are greatly appreciated. If you have any questions or comments about this study, please contact the Crohn's & Colitis Research Coordinator at the Florida Department of Health, (850) 245-4444 extension 2424.

1. Current age:

2a. Age at Diagnosis of Inflammatory Bowel Disease:
1) 10 or under 2) 11-19 3) 20-39 4) 40-64 5) 65 or older

2b. Time you have lived with the disease in years (or months if less than 1 year):

3. Gender: 1) Male 2) Female

4. Ethnicity: 1) Caucasian 2) African American 3) Asian 4) Hispanic 5) Other:

5. Are you of Jewish descent? 1) Yes 2) No 3) Partly 4) Don't know/unsure

6a. Do you have:
1) Ulcerative Colitis 2) Crohn's Disease 3) Both CROHN'S DISEASE & ULCERATIVE COLITIS 4) Unsure

6b. Where is your disease located?
1) small intestine 2) large intestine 3) both small and large intestines
4) other 5) unsure

6c. Currently, is your disease active? 1) No 2) Yes
If yes, would you say your symptoms are: 1) mild 2) moderate 3) severe

7a. Do you have a family member who is also diagnosed with an IBD?
1) No 2) Yes

7b. If yes, please select all who have been diagnosed:
1) Mother 2) Father 3) Brother 4) Sister 5) Your child/children 6) Other:

8a. Were you born in the United States? 1) Yes 2) No

8b. If yes, what area of the United States were you born?
1) NorthEast 2) SouthEast 3) Midwest 4) NorthWest 5) SouthWest

9. Before you were diagnosed with an IBD, did you live near cattle? 1) Yes 2) No

10. Before you were diagnosed with an IBD, did you smoke cigarettes regularly, meaning on most or all days?
1) Yes-# of years: 2) No

11a. Before you were diagnosed with an IBD, did the other people living in your residence smoke cigarettes? 1) No 2) Yes

11b. If yes, please list the number of years you lived in this residence prior to your diagnosis:

12a. Did you receive a colonoscopy before you were diagnosed with an IBD?
1) Yes 2) No 3) Unsure

12b. If yes, was your first colonoscopy a result of your IBD symptoms?
1) Yes 2) No 3) Unsure

13a. Before you were diagnosed with an IBD, did you have any of the following:

Medical illnesses	1) Yes 2) No 3) Don't know/unsure
Psychological illnesses	1) Yes 2) No 3) Don't know/unsure
Medical hospitalizations	1) Yes 2) No 3) Don't know/unsure
Surgeries	1) Yes 2) No 3) Don't know/unsure

13b. Before you were diagnosed with an IBD, did you have any of these procedures:

Appendectomy	1) Yes 2) No 3)Don't know/unsure
Tonsillectomy	1) Yes 2) No 3) Don't know/unsure
Other (please list):	

14. In general, would you say your health is: 1) Excellent 2) Good 3) Average 4) Poor

Emergency Psychiatric Care
A Community Crisis

House Health Care Committee

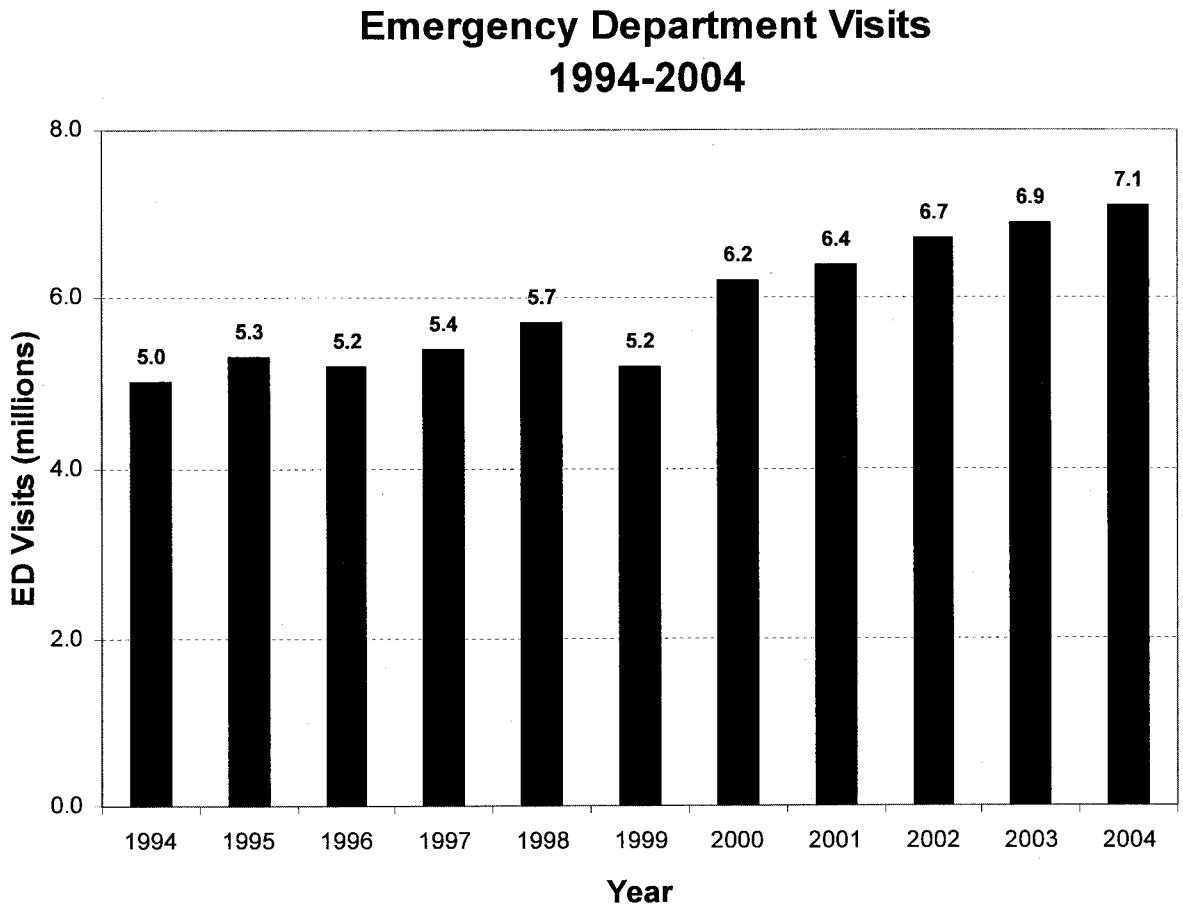
March 8, 2006

Florida Council

Emergency Department (ED) Use The Facts

- In 2004, there were 7.1 million ED visits in Florida; 1.3 million resulted in hospital admissions (AHCA, 2006).
- From 1994 to 2003, visits increased by 26.2% in the U.S. (AHCA, 2006).
- Between 1994-2004, the number of ED visits in Florida increased by 40.9%, while there was a 5.3% decrease in the number of EDs (AHCA, 2006).
- Accounting for increases in population, the visit rate per 1,000 persons increased by 12.9% over the same period (AHCA, 2006).

Florida Emergency Department Visits



Source AHCA Hospital Financial Database

Emergency Department (ED) Use The Facts

- In 2004, total ED charges in Florida were $4.4 billion, a 457.0% increase from 1994 [$791 million]; the average charge per visit was $619 (AHCA, 2006).
- The average ED wait time in Florida is 3 hours (AHCA, 2006); half of ED patients nationally spend 2-6 hours in the ED (CDC, 2005).
- The number of EDs per 1 million people in Florida: 7.82 – 47th in the nation (ACEP, 2006).
- Florida's rank on access to emergency care: C- [41st in nation] (ACEP, 2006); overall Florida ED Rank: C- (ACEP, 2006).
- Nationally, 62% of emergency departments are at or over capacity; one-half of urban EDs are at over capacity (AHCA, 2002).

Emergency Department (ED) Use Psychiatric Disorders

- ED use by those with psychiatric/substance abuse disorders constitutes a significant and growing burden on hospital EDs.
- Two million people visited EDs for psychiatric care in the U.S. in 2002 (NCHS, 2003).
- Many hospital EDs are ill equipped to meet the needs of patients with psychiatric disorders because of inadequate numbers of psychiatric practitioners and beds in many EDs.
- Nationally, from 1992 to 2001, mental health-related ED visits increased from 4.95 to 6.3% of total ED visits and increased from 17.1 to 23.6 visits per 1,000 population (Larkin et al, 2005).

Emergency Department (ED) Use Psychiatric Disorders

- In a 2004 survey conducted by the American College of Emergency Physicians, 60% of physicians reported that the increase in psychiatric ED patients is:
  - negatively affecting access to emergency medical care for all patients;
  - causing longer wait times;
  - fueling patient frustration;
  - limiting the availability of hospital staff; and
  - decreasing the overall availability of ED beds (ACEP, 2006).
- Two-thirds of emergency physicians attribute the recent escalation of psychiatric patients to budget cutbacks and the decreasing number of psychiatric beds (ACEP, 2006).

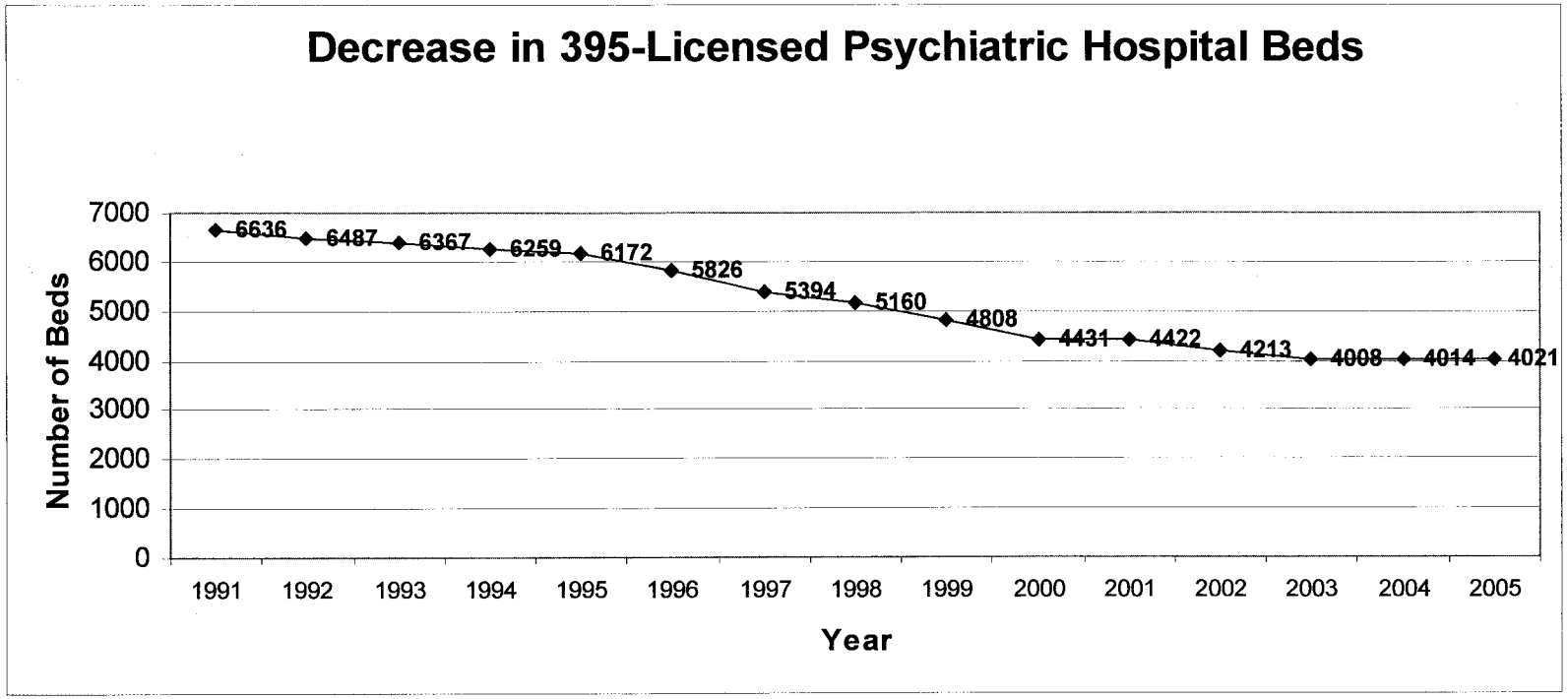
Emergency Department (ED) Use Psychiatric Disorders

- Significant predictors of high ED utilization: prior number of ED visits, prior number of hospitalizations, and history of depression, psychoses, alcohol abuse, and homelessness.
- At a 6.4% prevalence rate, Florida's EDs treat an estimated 1,245 patients with psychiatric disorders every day or more than 454,000 visits/year.
- Homeless individuals account for 30 percent of ED use for psychiatric emergency care; 33% of homeless individuals have one or more ED encounters annually.
- Homeless individuals are more likely than other emergency service patients to have multiple episodes of service and to be hospitalized after the emergency department visit.

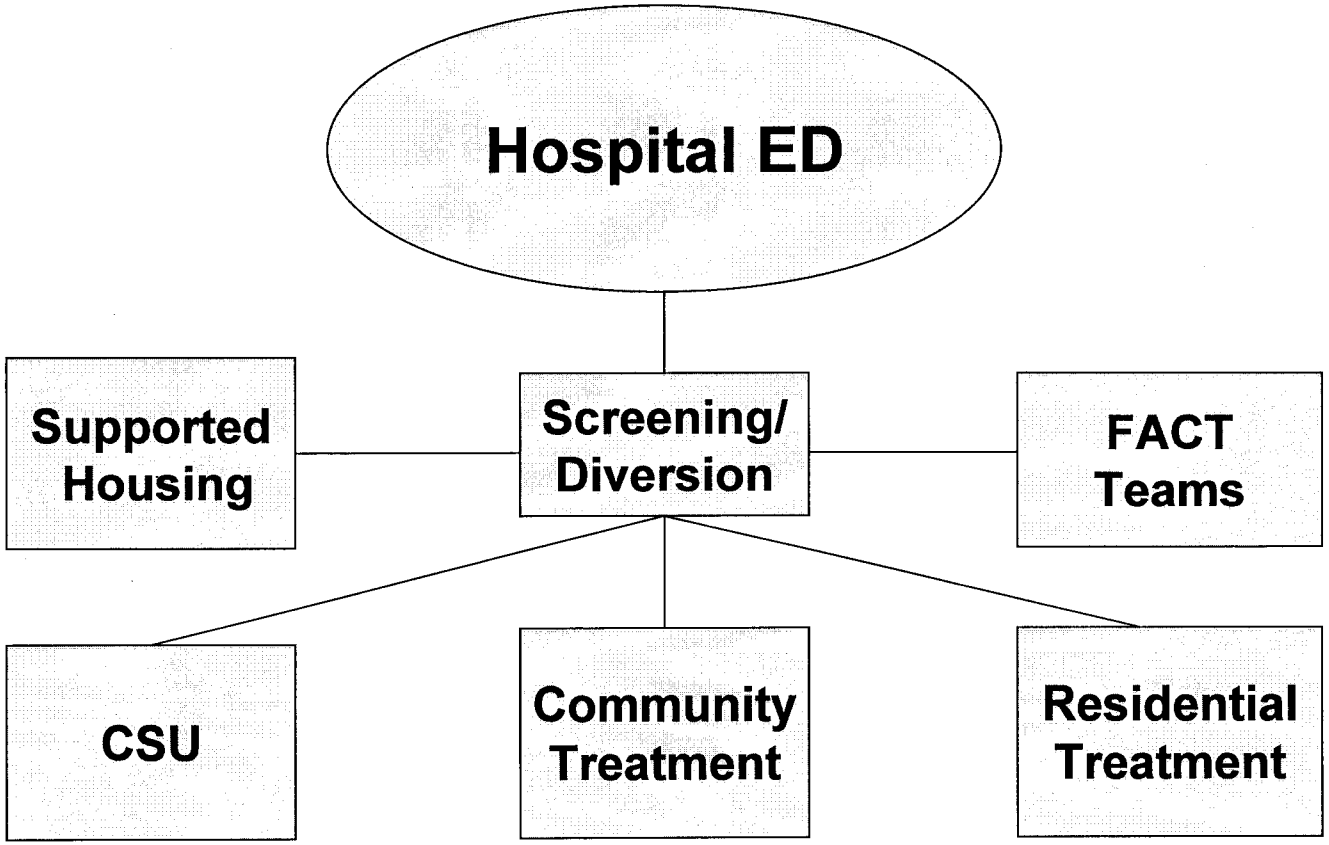
Acute and Emergency Care Issues

- Psychiatric and substance abuse patients represent the 'frequent flyers' and a disproportionate share of total ED visits.
- Increases in ED boarding.
- Reduction in overall psychiatric acute care bed supply and an underfunded publicly financed acute and emergency care system.
- Shortage of CSU and short-term residential beds.
- ED "revolving door" because of lack of post-discharge services.
- Shortage of low-income housing; unstable housing.
- Lack of Medicaid and DCF financed community treatment (crisis and recovery-based services).

Acute and Emergency Care Issues



A New Cost-Effective Approach to Acute and Emergency Psychiatric Care



Crisis Stabilization Units

- Crisis Stabilization Units (CSUs) provide brief psychiatric intervention for low-income individuals with acute psychiatric conditions who are a danger to themselves or others.
- CSU stays average 3 days; 90% of admissions are involuntary and a result of law enforcement intervention.
- CSUs may screen, assess, and admit for stabilization persons who are voluntarily or involuntarily placed pursuant to Chapter 394, F.S.
- Clients may be provided 24-hour observation, medication, and other appropriate services.
- CSUs must provide services regardless of the client's ability to pay and shall be limited in size to a maximum of 30 beds.

Crisis Stabilization Units

- Florida has 45 public receiving facilities with 923 DCF-purchased CSU beds (765 adult beds and 158 children beds); there are 477 Medicaid reimbursable hospital psychiatric beds (306 adults and 171 children's beds).
- DCF estimates that Florida needs 10 CSU beds per 100,000 population.
- Adult Bed Need: 1,395
- Unmet Need: 324 Beds (1,395-[765+306])
- CSU Rates: $292 – no rate increase since 1999 (Recommended rate: $358).
- Additional Funding: $30.6 Million for Beds/$16.1 Million for Rates (75% State-25% Local).

Short-Term Residential Treatment Facilities (SRTs)

- SRTs provide residential care for up to 90 days for individuals experiencing an acute mental health crisis.
- SRT Beds in Florida: 269
- SRT Facilities in Florida: 11
- No SRTs Located in Districts 1, 2, 4, 8, 9, and 13.
- Need: Additional SRTs/SRT Beds

Community Treatment – Unmet Needs

- Prevalence of SPMI Adults: 5.4% (13.9M x .054 = 753,068 x. 33 (SPMI and Seek Treatment – Currently Served [130,702]).
- Unmet Adult Need: 120,070
- Prevalence of SED Children: 7.9% (4.1M x. .079 x .286 (uninsured) x .36 require public coverage.
- Unmet Child Need: 161,654 (207,205- 45,551 [currently served])
- $ Needed: Adults - $136.9M; Children - $97.0M
- Florida ranks 47th in per capita state spending on mental health care.
- ED use drops by 50+% with community treatment.

Assertive Community Treatment

- Florida has 32 FACT Teams.
- The annual cost of a FACT Team is $1,254,394; total appropriation is $40.1 million.
- Each team serves 100 individuals; 60% are Medicaid eligible.
- Total FACT Team capacity statewide – 3,200 individuals; average monthly caseload in 9/05 was 2,844 – 94% of statewide capacity.
- ACT Findings: ED use down 32-50%, hospitalization down 58-78%; ACT highly successful in engaging individuals in treatment, increasing housing stability and improving symptoms.
- Needs: Additional FACTs (Adult, Children, Forensic) and Rate Increases.

Model Programs

- San Francisco General Hospital Frequent User Program/ED Case Management Program/Crisis Resolution Team
- Boston Health Care for the Homeless Project
- Comprehensive Psychiatric Emergency Programs (Maryland, New York)
- Psychiatric Emergency Response Team/Services (Multiple Sites)
- Orlando Community Receiving Center
- Mobile Crisis Teams (Multiple Sites)
- Crisis Family Care (Multiple Sites)
- Crisis Care Center (San Antonio)
- Assertive Community Treatment (Multiple Sites)
- Jail Diversion Programs (Multiple Sites)

Recommendations

- Assess Acute and Emergency Psychiatric Care Needs in Florida; Determine Effect of Psychiatric Emergency Care on ED Overcrowding
- Expand CSU Capacity – Increase Beds/Increase Rates
- Expand Short-Term Residential Capacity
- Expand FACT Teams
- Close the Treatment Gap/Achieve Funding Equity
- Increase Permanent and Supported Housing
- Create Integrated Systems of Care

Health Care General Committee

Wednesday, March 8, 2006
10:00 AM – 12:00 PM
306 HOB

COMMITTEE MEETING PACKET

Revised

ADDENDUM "A" (03/07/2006; 6:00 PM)

Allan G. Bense
Speaker

Gayle B. Harrell
Chair

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 645 Nursing Home Facilities
SPONSOR(S): Gelber
TIED BILLS: **IDEN./SIM. BILLS:** SB 298

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care General Committee		Brown-Barrios	Brown-Barrios
2) Domestic Security Committee			
3) Health Care Appropriations Committee			
4) Health & Families Council			
5)			

SUMMARY ANALYSIS

HB 645 requires the Agency for Health Care Administration (AHCA) to reimburse an eligible nursing home facility for the costs of building or modifying its emergency electrical power system capacity to fully operate the facility during and after an emergency when power is interrupted. To be eligible for reimbursement, a nursing home facility must:

- Not have been cited for a class I deficiency as defined in s. 400.23(8)(a), F.S., within the last 30 months preceding the application for reimbursement,
- Not be in the hurricane evacuation zone in its county,
- Have the capacity, as determined by AHCA, to receive transferred residents that are evacuated, and
- Agree to receive those transferred residents.

The AHCA estimates the fiscal impact of the bill to be $57 million (general revenue).

If enacted, the bill takes effect upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government – HB 645 requires AHCA to reimburse certain nursing homes for the installation cost of an emergency generator to fully operate the facility during and after an emergency when power is interrupted.

B. EFFECT OF PROPOSED CHANGES:

The bill creates s. 400.0627, F.S., to require the AHCA to reimburse nursing homes, meeting certain eligibility criteria, for the installation cost of an emergency generator to fully operate the facility due to a utility interruption during and after an emergency in order to remain fully operational and to provide care of residents evacuated from other nursing facilities. This installation would be additional to the existing installation and would not require the nursing home to modify the existing electrical system.

BACKGROUND

Hurricane Evacuation Zones

Hurricane evacuation zones are predetermined geographic areas that are likely to experience destruction or severe damage, from storm surge, waves, erosion, or flooding.[1] Depending on the track of the storm, the greater the intensity of a storm (Tropical to Category 5) the greater the geographic area that will experience these conditions and therefore need to be evacuated. The closer the nursing home is to the coast, the more likely that a nursing home will be located in an evacuation zone.

According to AHCA, there are 677 licensed nursing homes in Florida. During the 2005 hurricane season there were five recorded hurricanes which caused Florida evacuations. There were 21 nursing home facilities that were completely evacuated and four that were partially evacuated with a total of 1,795 patients being displaced. Only one nursing home facility was actually closed or became inactive during the entire 2005 season. There were 51 nursing home facilities that sustained some type of damage from the hurricanes. A total of 239 nursing home facilities lost power and switched to generators during the hurricane season with one additional nursing home facility losing power without the availability of a generator.[2]

AHCA estimates approximately 466 nursing facilities are not located in county hurricane evacuation zones. This represents approximately 57,000 nursing home beds or about 70% of capacity.

Requirements for Nursing Home Licensure - Essential Electrical System

Since July 1982, all nursing home facilities licensed under part II of ch. 400, F.S., have been required by rule to have an onsite Essential Electrical System (EES) with an onsite fuel supply of up to 64 hours.[3] The design, installation, operation, and maintenance of this EES is reviewed by AHCA.

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[1] According to NOAA, storm surge maps reflect the worst case hurricane storm surge inundation (including astronomical high tide), regardless of the point of where the center of the hurricane (or tropical storm) makes landfall. No single hurricane will necessarily cause all of the flooding represented on evacuation maps. The data reflect only still-water saltwater flooding and do not take into account the effects of pounding waves that ride on top of the storm surge in locations exposed to wave action. Evacuation maps do not show areas that may be flooded by excessive rainfall-they only depict flooding that would occur as a result of the ocean level rising as well as estuaries and rivers that can be affected by hurricane storm surge.

[2] Senate Staff Analysis and Economic Impact Statement SB 298, revised January 23, 2006

[3] FAC 59A-4.133. Of the 669 existing licensed nursing home facilities, there are 30 facilities constructed prior to 1982 that do not have an existing generator system. These facilities house only residents, who do not require any life support systems, and as such, these facilities are in compliance with all state and federal codes and standards through the use of a battery supplied emergency electrical system that supplies emergency power to the life safety components of the facility as required by NFPA 99 for 1-½ hours duration. These components include the fire alarm, nurse call, emergency egress lighting, exit lighting, and locking systems.

The EES supplies electrical service to the three main electrical branches, including the Life Safety branch, the Critical Branch, and the Equipment Branch within 10 seconds of normal service interruption. As required by the NFPA standards, these emergency electrical branches provide emergency electrical service to specified electrical components of the facility such as the fire alarm system, the nurse call system, the emergency egress lighting system, the exit lighting system, the magnetic door locking system, and selected critical convenience receptacles and equipment in the facility. In addition, since 1996, all new nursing home facilities and new additions to these facilities have been required to have an EES that supplies electrical power to all ventilating fans, ice making equipment, refrigeration equipment, and selected heating, ventilation, and air conditioning equipment as determined by the facility, for a period up to 72 hours of continuous service at actual load capacity of the generator.

The EES is not required to provide electrical service to the heating, ventilation, and air conditioning (HVAC) equipment of the facility nor to the general lighting or other electrical items not specifically required by the National Fire Protection Association codes and standards.

Class I Deficiency

Section 400.23, F.S., requires AHCA to evaluate all nursing home facilities and against standards and make a determination as to the degree of compliance by each licensee with the established standards adopted in rules. The agency bases its evaluation on the most recent inspection report, taking into consideration findings from other official reports, surveys, interviews, investigations, and inspections. Findings of deficient practice are classified according to the nature and the scope of the deficiency.

There are four classes of deficiencies:

- A class I deficiency is a deficiency in which immediate corrective action is necessary because the facility's noncompliance has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident receiving care in a facility.
- A class II deficiency is a deficiency that has compromised a resident's ability to maintain or accomplish his or her highest practicable physical, mental, and psychosocial well-being, as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services.
- A class III deficiency is a deficiency that will result in no more than minimal physical, mental, or psychosocial discomfort to the resident or has the potential to compromise the resident's ability to maintain or accomplish his or her highest practical physical, mental, or psychosocial well-being, as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services.
- A class IV deficiency is a deficiency that will result in no more than a minor negative impact on the resident.

According to AHCA, data from the most recent 30-month period indicates that 47 facilities have received a Class I deficiency. The classification of a deficiency affects the licensure status of the facility. A conditional license is issued if a facility has one or more class I or class II deficiencies, or class III deficiencies not corrected within the time established by the Agency. In addition, a facility that is cited for a class I deficiency, two or more class II deficiencies arising from separate surveys or investigations within a 60-day period, or has had three or more substantiated complaints within a 6-month period, each resulting in at least one class I or class II deficiency, is placed on a 6-month survey cycle for the next 2-year period.

Evacuation and Transfer of Nursing Home Residents

Section 400.23(2)(g), F.S., requires AHCA to develop rules after consultation with the Department of Community Affairs that requires each nursing home to develop a comprehensive emergency management plan (CEMP). At a minimum, the rules must provide for plan components that address emergency evacuation transportation; adequate sheltering arrangements; postdisaster activities, including emergency power, food, and water; postdisaster transportation; supplies; staffing; emergency equipment; individual identification of residents and transfer of records; and responding to family inquiries. The comprehensive emergency management plan is subject to review and approval by the

local emergency management agency. During its review, the local emergency management agency must ensure that the following agencies, at a minimum, are given the opportunity to review the plan: the Department of Elder Affairs, the Department of Health, AHCA and the Department of Community Affairs. The local emergency management agency must complete its review within 60 days and either approves the plan or advices the facility of necessary revisions.

Rule 59A-4.126, F.A.C., incorporates by reference a publication (AHCA 3110-6006, March 1994) which lists the minimum criteria for a nursing home's CEMP. The CEMP must state the procedures to ensure that emergency power, whether natural gas or diesel, is supplied to the nursing home. If the fuel supply is natural gas, the plan must identify alternate means should loss of power occur that would affect the natural gas system. The plan must state the capacity of the emergency fuel system.

C. SECTION DIRECTORY:

Section 1. Creates s. 400.0627, F.S., to provide state financial assistance to eligible nursing homes to upgrade their emergency electrical power system capacity.

Section 2. This bill provides that an unspecified sum of money shall be appropriated during the 2006-07 fiscal year from the General Revenue Fund to AHCA for the purpose of reimbursing eligible nursing homes for building or modifying their emergency electrical power system capacity to fully operate during and after an emergency.

Section 3. Provides that the bill takes effect upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None

2. Expenditures:

   The bill appropriates an, as yet, unspecified sum from the General Revenue Fund to implement the provisions of this bill. According to AHCA, the average nursing home with 120 beds is about 50,000 square feet or about 400 square feet per bed. AHCA assumes that 47,700 nursing home beds out of a total of 84,000 beds will be eligible for this grant and if each bed requires approximately 400 square feet of building to house the bed and its support functions, there could be as much as 19 million square feet of building to supply with emergency electrical power if all eligible nursing homes took advantage of the program. Based on current estimates from the industry, AHCA estimates that the total cost to equip all of these facilities with a supplemental emergency electrical power system would cost an average of $3.00 per square foot or approximately $57 million.

   Using these assumptions an electrical generator and modifications for a 120 bed nursing home with 50,000 square feet of space would cost $150,000.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None

2. Expenditures:

   None

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

If implemented the bill should have a positive economic effect on the business sector the sells, installs and provides maintenance for large electrical generators. Depending on the size of the facility, and decisions regarding how much of the facility's normal electric needs should be met by emergency electric generators, costs can vary widely. The cost for a large facility to purchase large fixed diesel generators that will automatically detect loss of grid power and immediately start up to provide uninterrupted emergency supplemental power to all of the facility's regular electrical needs can range from $10,000 to $100,000+. Maintenance costs for generators can also vary widely. Most generator manufacturers advise that generators be tested and run at least once monthly to ensure they will be operational when needed. Depending on the size of the generator, fuel costs can also vary widely.[4]

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or to take any action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

   None

B. RULE-MAKING AUTHORITY:

The bill does not provide specific rule authority however, s. 400.23(2), F.S., gives AHCA the authority to adopt and enforce rules to implement part II (related to nursing homes) of chapter 400, F.S.

C. DRAFTING ISSUES OR OTHER COMMENTS:

A key feature of the bill is to provide electrical generators to a nursing home so that the facility "can fully operate" during and after an emergency However, the bill does not define "fully operate".

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

[4] U.S. Department of Homeland Security, U. S. Coast Guard http://www.uscg.mil/hq/g-/mp/pdf/Best%20Practice%20Backup%20Generators.pdf:

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1027 Biomedical Research
SPONSOR(S): Hasner, Coley and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1826

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care General Committee		Ciccone	Brown-Barrios
2) Health Care Appropriations Committee			
3) Health & Families Council			
4)			
5)			

SUMMARY ANALYSIS

This bill provides legislative intent to provide funding to support grants for biomedical research in Florida with particular emphasis on cancer research and Alzheimer's disease research. The bill amends several statues that govern state funding for biomedical research.

The bill requires that the Florida Center for Universal Research to Eradicate Disease (CURED) provide grants for cancer research to further the search for cures of cancer and authorizes the center to give preference to grant proposals that foster collaborations between institutions, researchers, and community practitioners. The bill requires that state-funded biomedical research grants be awarded on a competitive basis subject to a peer review process.

The bill establishes the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program in the Department of Health and expands the purpose of the CURED center to include providing grants through the newly established research program. The bill revises the composition of the CURED center's advisory council and establishes 4-year terms for advisory board members and requirements for the election of a chair and for periodic board meetings.

The bill discontinues the automatic annual distribution of alcoholic beverage tax collections from the State Treasure for the Center for Universal Research to Eradicate Disease, the James and Esther King Biomedical Research Program, and the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute and provides for an annual appropriation for these programs. The bill requires the Department of Health to submit an annual report on the William G. "Bill" Bankhead, Jr. and David Coley Cancer Research Program. Further the bill requires the annual operating budget for the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute be submitted to the Governor and Cabinet, Senate President, House Speaker and State Board of Education chair and requires additional information regarding the center's expenditure of funds and research.

The bill includes appropriations as follows:

- $6 million to the James and Esther King Biomedical Research Program,
- $9 million to the CURED center; and
- $15 million to the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute,

The bill provides for an effective date of July 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Limited Government - Adds a new grant program and expands the administrative and oversight responsibility of the Department of Health.

Empower families - Florida families should benefit from greater access to information and health care services derived from cancer and Alzheimer's disease clinical trials and resultant new therapies.

B. EFFECT OF PROPOSED CHANGES:

The Florida Center for Universal Research to Eradicate Disease is located within the Department of Health. The purpose of the center is to coordinate, improve, expand, and monitor all biomedical research programs within the state, facilitate funding opportunities, and foster improved technology transfer of research findings into clinical trials and widespread public use. The goal of the center is to find cures for cancer and other diseases including Alzheimer's disease. The bill creates the William G. "Bill" Bankhead and David Coley Cancer Research Program within the Department of Health thereby expanding the purpose of the CURED center to provide grants through this newly established Bankhead-Coley Cancer Research Program. The bill replaces the automatic annual appropriation with a $9 million non-recurring appropriation.

The bill revises the composition of the center's advisory council to provide for an 18-member board instead of the current 54-member board by requiring one member from the Florida Research Consortium rather than all 37 members of the consortium board of directors.

Florida Cancer Council is located within the Department of Health. The purpose of the Council is to establish the state as a center of excellence for cancer research by expanding cancer research capacity, improving research and treatment through greater clinical trial participation, and reducing the impact of cancer in disparate groups. The council must work in concert with the Florida Center for Universal Research to Eradicate Disease (CURED) to ensure that the goals of the center are advanced. The bill provides that the council will identify ways to attract new research talent and national grant-producing researchers to cancer research facilities "in this state" rather than "Florida-based" facilities. The effect of this change is to expand the types of facilities that may be awarded grants. Grant funding decisions would be based on a peer-review system according to specific criteria.

The Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute is located within the Department of Health. The purpose of the Center is to encourage research, education, treatment, prevention and the early detection of Alzheimer's disease. The bill revises the information contained within the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute's annual report to include a description of the expenditure of all funds, information concerning research conducted or funded by the center, and the expected or actual result of such research. Further, the center's chief executive officer is required to submit an annual operating budget to the Governor, Cabinet, Senate President, House Speaker and State Board of Education chair. The bill replaces the automatic $15 million distribution from alcoholic beverage tax collection with a $15 million non-recurring appropriation.

The bill reduces the Governor's appointments to the Biomedical Research Advisory Council from six to four and requires one appointment by the Senate President and one by the House Speaker. The bill replaces the automatic $6 million distribution from alcoholic beverage tax collection with a $6 million non-recurring appropriation.

Background:

Cancer Research:

The emphasis that Florida places on cancer research is evidenced in the high-profile cancer related programs and funding strategies that have been established over the years. In addition, Florida recognizes the importance of a coordinated and collaborative approach to biomedical research. The scientific, humanitarian and economic value that is derived from a coordinated state, federal, and academic and private effort can not be overstated. Ultimately, biomedical research contributes to a healthier population and biomedical discoveries and the resultant products or treatments contribute to the economy of the area in which they are produced. For both health and economic reasons, governments are interested in furthering the work of biomedical researchers and in helping researchers collaborate and share resources.

Efforts in Florida relating to the coordination and development of medical research and disease prevention include:

The James and Ester King Biomedical Research Program

The 1999 Legislature established the Lawton Chiles Endowment Fund [1] funded as a result of its settlements with the tobacco industry to enhance or support expansions in children's health care programs, child welfare programs, community-based health and human service initiatives, and biomedical research. Section 215.5602, F.S., establishes the James and Ester King Biomedical Research Program funded from earnings of the endowment fund and provided that funds appropriated to the program are to be devoted to competitive grants and fellowships in research relating to prevention, diagnosis, and treatment of tobacco-related illnesses, including cancer, cardiovascular disease, stroke and pulmonary disease. The Biomedical Research Advisory Council in the Department of Health assists the Secretary in establishing criteria and guidelines for the competitive grant programs. Grants and fellowships are awarded on the basis of scientific merit, as determined by an open, objective peer-review process.

The Florida Center for Universal Research to Eradicate Disease

Section 381.855, F.S., creates the Florida Center for Universal Research to Eradicate Disease within the Department of Health. The purpose of the center is to coordinate, improve, expand, and monitor all biomedical research programs within the state, facilitate funding opportunities, and foster improved technology transfer of research findings into clinical trials and widespread public use. The goal of the center is to find cures for diseases such as cancer, heart disease, lung disease, diabetes, autoimmune disorders, and neurological disorders, including Alzheimer's disease, epilepsy and Parkinson 's disease.

The center must hold an annual biomedical technology summit in Florida to which biomedical researchers, biomedical technology companies, business incubators, pharmaceutical manufacturers, and others around the nation and world are invited to share biomedical research findings in order to expedite the discovery of cures for diseases. Summit attendees are required to cover, or obtain sponsorship for, the costs of their attendance.

An advisory council, established within the center, must meet at least annually. The council consists of the members of the board of directors of the Florida Research Consortium and at least one representative from each of the following:

- The Emerging Technology Commission;
- Enterprise Florida, Inc;
- BioFlorida;
- The Biomedical Research Advisory Council;

[1] Section 215.5601, F.S., ch. 99-167, Laws of Florida

- The Florida Medical Foundation;
- Pharmaceutical Research and Manufacturers of America;
- The Florida Tri-Agency Coalition on Smoking and Health;
- The Florida Cancer Research Council;
- The American Cancer Society, Florida Division, Inc;
- The American Heart Association;
- The American Lung Association of Florida;
- The American Diabetes Association, South Coastal Region;
- The Alzheimer's Association;
- The Epilepsy Foundation;
- The National Parkinson's Foundation;
- The Florida Public Health Foundation, Inc; and
- Scripps Florida, or the entity formed by the Scripps Research Institute in Florida.

  Members of the council will serve without compensation and each organization represented must cover all expenses of its representative.

The Florida Cancer Council

In 2004, the Legislature created the Florida Cancer Council within the Department of Health for the purpose of making Florida a center of excellence for cancer research. [2] Section 381.921, F.S., provides the overall mission of the Florida Cancer Council and stipulates that the council must work in concert with the Florida Center for Universal Research to Eradicate Disease to ensure that the goals of the center are advanced, and must work toward dramatically improve cancer research and treatment in Florida through a number of specific efforts including expanding cancer research capacity in Florida, improving research and treatment through greater participation in clinical trials networks, and reducing the impact of cancer on disparate groups of persons.

The Florida Cancer Council membership is representative of Florida cancer centers, hospitals, and patient groups. The council is authorized to create not-for-profit corporate subsidiaries to fulfill its mission and those subsidiaries could receive, hold, invest and administer property and any monies acquired from private, local, state and federal sources and technical and professional income from the mission-related activities of the council.

The council membership is as follows:

- The Chairman of the Florida Dialogue on Cancer, who serves as the council chairman;
- The Secretary of the Department of Health, or his or her designee;
- The Chief Executive Officer of the H. Lee Moffitt Cancer Center, or his or her designee;
- The President of the University of Florida Shands Cancer Center, or his or her designee;
- The Chief Executive Officer of the University of Miami Sylvester Comprehensive Cancer Center, or his or her designee;
- The Chief Executive Officer of the Mayo Clinic, Jacksonville, or his or her designee;
- The Chief Executive Officer of the American Cancer Society, Florida Division, or his or her designee;
- The President of the American Cancer Society, Florida Division Board of Directors, or his or her designee;
- The President of the Florida Society of Clinical Oncology, or his or her designee;
- The President of the American College of Surgeons, Florida Chapter, or his or her designee;
- The Chief Executive Officer of Enterprise Florida, Inc., or his or her designee;
- Five representatives from cancer programs approved by the American College of Surgeons. Three of whom shall be appointed by the Governor, one by the Speaker of the House of Representatives and one by the President of the Senate;

[2] Section 381.92, Florida Statutes, s.10, ch. 2004-2 Laws of Florida

- One member of the House of Representatives, to be appointed by the Speaker of the House of Representatives; and
- One member of the Senate, to be appointed by the President of the Senate.

Appointments made by the Speaker of the House of Representatives and the President of the Senate are two-year terms concurrent with the terms of the presiding officers who make the appointments. Appointments made by the Governor are two-year terms, and the Governor may reappoint directors. Members of the council or any subsidiaries serve without compensation and each organization represented covers the expenses of its representatives.

The council issues an annual report to the Center for Universal Research to Eradicate Disease, the Governor, the Speaker of the House of Representatives, and the President of the Senate by December 15th of each year. The report contains policy and funding recommendations regarding cancer research capacity in Florida and related issues.

The Florida Dialogue on Cancer

The Florida Dialogue on Cancer is a collaboration of Florida leaders of hospitals, research centers, universities, professional medical groups, community-based organizations, and private business groups, and government officials, FDOC is an initiative designed to expand the state's capacity to reduce the incidence and mortality rates of cancer. The goals of FDOC are to:

- Create a coalition that speaks with one voice on major statewide cancer issues for Florida;
- Enhance and promote Florida's capacity to conduct cancer research, professional education, clinical trials and treatment programs; and
- Identify and promote the replication of best practices in providing access to cancer prevention, education, and screening, diagnosis, and treatment programs for all Floridians to reduce the disparities that exist.

The Florida Division of the American Cancer Society sponsors FDOC, which is based on the work of the National Dialogue on Cancer.

Alzheimer's Disease:

Alzheimer's disease is a progressive, irreversible brain disorder with no known cause or cure. Symptoms of the disease include memory loss, confusion, impaired judgment, personality changes, disorientation, and loss of language skills. Alzheimer's disease is the most common form of irreversible dementia—symptom escalation varies from person to person and includes confusion, personality and behavior changes and impaired judgment. Most people with Alzheimer's disease become unable to care for themselves.

There is no known cure for Alzheimer's disease; however certain medications can help relieve symptoms or slow the progression of the disease. Approximately 100,000 victims die and 360,900 new cases of Alzheimer's disease are diagnosed each year in the United States. According to the Alzheimer's Association, the number of Americans with the disease has doubled since 1980 and current estimates reflect 4.5 million Americans have Alzheimer's disease. By 2050, it is estimated that 14 million Americas will have this disease. There are currently 396,000 people with Alzheimer's disease in Florida.

Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute:

Section 1004.43, F.S., establishes the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute at the University of South Florida. The institute is governed by a not-for-profit corporation in accordance with an agreement with the State Board of Education. The corporation is managed by a board of directors consisting of the President of the University of South Florida and the chair of the

State Board of Education, or his or her designee, five representatives of the state university system, and between 9-14 additional directors who are not medical doctors or state employees. The institute is administered by a chief executive officer, who serves at the pleasure of the board of directors.

The mission of the Byrd Alzheimer's Research Center is to collaborate with researchers throughout the State of Florida and the wider global research community to develop treatment to cure and prevent this disease.

The Byrd Alzheimer's Research Center will conduct state of the art research in addition to serving as the site for coordinating and facilitating the state's various efforts to diagnose, treat and prevent the disease. Funding for the institute is generated through state and federal grants and other fundraising efforts.

C. SECTION DIRECTORY:

Section 1. Provides legislative intent.

Section 2. Amends s. 215.5602, F.S., relating to the membership of the Biomedical Research Advisory Council and to create a new subsection (11) authorizing an annual appropriation to the James and Esther King Biomedical Research Program.

Section 3. Provides language regarding the expiration of certain appointments to the Biomedical Research Advisory Council.

Section 4. Amends ss. 381.855 (3) (5), F.S., relating to Center for Universal Research to Eradicate Disease (CURED). Provides new language regarding the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program and creates new subsections (6) (7) and (8), F.S, to revise advisory council membership, term and grant peer review process.

Section 5. Provides language regarding the expiration of certain appointments to the advisory council for the Center for Universal Research to Eradicate Disease (CURED).

Section 6. Amends ss 381.921 (1), F.S., relating to the mission and duties of the Florida Cancer Council.

Section 7. Creates s. 381.922, F.S., to establish the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program.

Section 8. Amends s. 561.121 (1), F.S., and deletes language relating to certain automatic annual distributions of alcoholic beverage tax collections from the State Treasury.

Section 9. Amends s. 1004.445 (2) (6), F.S., relating to the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute and creates new subsections (8) and 12) relating to research funding and authorizes an annual appropriation to the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute.

Section 10. Provides language regarding the expiration of certain appointments to the board of directors of the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute.

Section 11. Provides for a $6 million non-recurring appropriation from the General Revenue Fund to be deposited into the Biomedical Research Trust Fund; provides for a $9 million non-recurring appropriation from the General Revenue Fund to be deposited into the Florida Center for Universal Research to Eradicate Disease; provides for a $15 million non-recurring appropriation from the General Revenue fund to be deposited into the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute; provides for specific use of such funds.

Section 12. Provides for an effective date of July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None

2. Expenditures:

   The Department of Health estimates the following expenditures:

Estimated Expenditures	1st Year	2nd Year (Annualized/Recur)
Salaries:		
1.5 Senior Attorney @54,795	$70,138	$72,242
1 Administrative Secretary @$27,397	35,068	36,120
1 Program Administrator @$57,000	72,960	75,149
1 Administrative Assistant @$32,000	32,000	32,960
(FTE computed w/28% fringe; 3% annual increase In 2nd year		
Expenses:		
1 Std DOH professional pkg. w/maximum travel (1 FTE)	$19,097	$15,867
2 Std DOH profession package w/limited travel (1.5 FTE)	27,640	21,000
2 Std DOH support pkg. (2 FTE)	16,300	10,728
Sub-contracting of grant management And major grant cycle processes	610,000	350,000
Council Travel	30,000	30,000
General Office Expenses	10,250	10,250
Staff Development	5,250	5,250
Operating Capital Outlay		
3 Std DOH professional pkg. (2 FTE)	5,400	- 0 –
2 Std DOH support Pkg. (2 FTE)	4,200	- 0 –
Human Resources Services 5 FTEs	1,965	I,965
Total Estimated Expenditures	$940,268	$661,531

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None

2. Expenditures:

None

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

By referring to research facilities as those which are "in this state", non-state universities, not-for-profit entities, researchers, biotechnology and pharmaceutical companies and others will benefit from this bill by receiving grants from which they may develop patented or licensed intellectual property. Further, new research talent and national grant-producing researchers should be attracted to cancer research facilities in this state change.

Florida citizens should benefit from greater access to information and health care services derived from cancer clinical trials and resultant new therapies.

D. FISCAL COMMENTS:

The bill discontinues the annual distribution of alcoholic beverage tax collections from the State Treasury for the Center for Universal Research to Eradicate Disease (CURED), the James and Esther King Biomedical Research Program, and the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute and provides instead for an annual appropriation by the Legislature.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill has no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

2. Other:

This bill has no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

B. RULE-MAKING AUTHORITY:

No additional rule making is required for the Department of Health to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES