Health Care General Committee

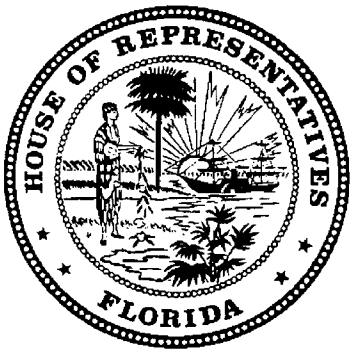
Wednesday, February 22, 2006
10:30 AM – 12:00 PM
306 HOB

COMMITTEE MEETING PACKET

REVISED

Allan G. Bense
Speaker

Gayle B. Harrell
Chair



AGENDA
Health Care General Committee
February 22, 2006
10:30 a.m. – 12:00 p.m.
306 HOB

I. Call to order/Roll Call

II. Opening Remarks

III. Consideration of the following bills:

- HB 241 - - Florida KidCare Program by Vana
- HB 311 - - Vaccine Production Facilities by Cretul

IV. Consideration of the following proposed committee bill:

- PCB HCG 06-01 - - Emergency Management

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

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 241 Florida KidCare Program
SPONSOR(S): Vana and others
TIED BILLS: **IDEN./SIM. BILLS:**

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

SUMMARY ANALYSIS

Florida KidCare was created in 1998 to provide health benefits to uninsured children through the State Children's Health Insurance Program (SCHIP) or Medicaid. KidCare has four program components. These components include Medicaid, MediKids, Healthy Kids, and the Children's Medical Services (CMS) Network. Participation by children in these programs is contingent on age, family income, and special health care needs.

HB 241 amends s. 409.814, F.S., to allow a family with a child who is not eligible for the KidCare program because the family income is above 200 percent of the Federal Poverty Level (FPL) to apply for health insurance coverage from KidCare programs and requires the KidCare program to allow their participation in the program. Current law allows these families to apply for MediKids and Healthy Kids but does not require these programs to allow their participation. In practice, only Healthy Kids has enrolled children from families with income above 200 percent of the FPL. Thus, the impact of this bill will be realized more by the MediKids program which has not enrolled children from families with income above 200 percent of the FPL. A family with income above 200 percent of the FPL must pay the full premium without any premium assistance to receive health insurance coverage under KidCare.

Current law excludes a child from a family whose income is above 200 percent of the FPL from participating in the Medicaid component of KidCare. HB 241 does not change this.

The bill has no fiscal impact.

If enacted, the bill takes effect July 1, 2006.

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Empower families - The bill creates an opportunity for certain families to secure health insurance coverage for their children.

B. EFFECT OF PROPOSED CHANGES:

Although this bill affects the KidCare program, the most significant impact is on MediKids. Unlike Healthy Kids that has allowed the enrollment of children from families with income above 200 percent of the FPL, MediKids has not enrolled children from families with income above 200 percent of the FPL. This bill would allow families to apply for health insurance coverage from the MediKids program and requires the MediKids program to allow their participation in the program.

BACKGROUND

The Florida KidCare Program

The State Children's Health Insurance Program (SCHIP) under Title XXI of the Social Security Act is a Federal/State partnership which provides insurance to uninsured children under age 19 whose family income is above Medicaid limits but below 200 percent of the FPL. Under SCHIP, the Federal government provides a capped amount of funds to States on a matching basis[1]. SCHIP expands insurance coverage for low-income children who do not qualify for Medicaid. Florida's SCHIP eligible children are served in the Florida KidCare Program.

Medicaid under Title XIX of the Social Security Act is a Federal/State entitlement program that pays for medical assistance for certain individuals and families with low incomes and resources.

Florida KidCare was created in 1998 to provide health benefits to uninsured children through either SCHIP or Medicaid. The statutory framework for KidCare is delineated in sections 409.810 through 409.821, F.S. KidCare has four components:

- Medicaid:
  - Birth to age 1, with family incomes up to 200 percent of the FPL.
  - Ages 1 through 5, with family incomes up to 133 percent of the FPL.
  - Ages 6 through 18, with family incomes up to 100 percent of the FPL.
  - Ages 19 through 20, with family incomes up to 24 percent of the FPL.
- MediKids:
  - Children ages 1 through 4 with family incomes above 133 percent to 200 percent of the FPL.
- Healthy Kids:
  - Children age 5, with family incomes above 133 percent to 200 percent of the FPL.
  - Children age 6 through 18, with family incomes above 100 percent to 200 percent of the FPL.
  - A limited number of children who have family incomes over 200 percent of the FPL are enrolled in the unsubsidized full-pay option in which the family pays the entire cost of the premium, including administrative costs.
- Children's Medical Services (CMS) Network:
  - Children ages birth through age 18 who have serious health care problems. For Title XXI-funded eligible children with special health care needs, the CMS Network receives a

[1] The federal allocation for FY 05/06 is $249,329,871 and the federal matching rate is 71.22%.

capitation payment from the Agency for Health Care Administration to provide services for them. For children who do not qualify for Title XIX or Title XXI-funded coverage, services are limited and subject to the availability of funds

2006 Federal Poverty Level

Persons in Family or Household	100%	200%
1	$ 9,800	19,600
2	13,200	26,400
3	16,600	33,200
4	20,000	40,000
5	23,400	46,800

The Agency for Health Care Administration (AHCA) administers Medicaid and MediKids. AHCA is also the lead State agency for the federally funded portion of the KidCare program. The Florida Healthy Kids Corporation (FHKC), under contract with AHCA, administers the Healthy Kids component. FHKC responsibilities include eligibility determination, collection of premiums, contracting with authorized insurers, and the development of benefit packages. CMS is under the Department of Health and administers the CMS Network. For Title XXI-funded children with special health care needs, the CMS Network receives a capitation payment from the Agency for Health Care Administration of approximately $518.00 per child, per month. Children's Medical Services also administers a state-funded "Safety Net" program for children who do not qualify for Title XIX- or Title XXI-funded coverage, but services are limited and subject to the availability of funds.

Section 409.814(5), F.S., allows a child whose family income is above 200 percent of the FPL to participate in MediKids and Healthy Kids if the family pays the full premium without any premium assistance. In practice, only Healthy Kids has enrolled children from families with income above 200 percent of the FPL. The Healthy Kids full pay premium is $110 per child per month. MediKids has not enrolled children from families with income above 200 percent of the FPL. Current law limits the participation of families with income above 200 percent of the FPL in MediKids and Healthy Kids to no more than 10 percent of total enrollees in the programs in order to avoid adverse selection[2]. Section 409.814(5), F.S., excludes a child whose family income is above 200 percent of the FPL from participating in the Medicaid component of KidCare. It is unclear whether current law allows families with income above 200 percent of the FPL to participate in the CMS Network (see DRAFTING ISSUES OR OTHER COMMENTS)

The differences in the eligibility and ability to offer a full pay premium option for families with incomes above 200 percent of FPL, has created the potential for confusion. Families may find that they can insure one child but not the other.

Summary of KidCare Full Pay Option

Florida KidCare	**Children from families with incomes above 200% of FPL allowed to participate.**	**Children from families above 200% of FPL actually participating in program.**
Medicaid	No	N/A
MediKids	Yes	No
Healthy Kids	Yes	Yes
CMS Network	Unclear	No

[2] Adverse selection occurs when too many children who are likely to incur high medical cost join the same health insurance plan. Adverse selection can cause what insurers refer to as a "death spiral". As more sick children join, the health insurance plan must raise premiums to cover cost. As premiums increase, families with healthier children leave to join less costly plans. The plan is left with only sick children and has difficulty spreading risk to cover their cost and ultimately may fail.

C. SECTION DIRECTORY:

Section 1. Amends subsection (2) and (5) of section 409.814, F.S.

Section 2. Establishes an effective date for the act of July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None

2. Expenditures:

   None

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None

2. Expenditures:

   None

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Health care providers, including health maintenance organizations, which arrange most of the health services for children enrolled in MediKids and the Children's Medical Services Network, should realized an increase in revenue as a result of increased enrollment in KidCare by families that are willing to pay the full premium.

Children with families above 200 percent of the FPL must pay the full pay premium without any premium assistance to participate in MediKids or Healthy Kids.

D. FISCAL COMMENTS:

AHCA for MediKids and DOH for the CMS Network (if included) would need to obtain actuarial services to calculate an appropriate premium for the full pay option that would support the cost of services, reinsurance, and other administrative costs. DOH estimates the cost to determine the actuarial based premium at $9,000.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Sufficient rulemaking authority exists to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

It is unclear whether the provisions of this bill apply to the CMS Network program. This is not a problem with the bill but with current law.

Section 409.814(3), F.S., states that a child who is eligible for the Florida KidCare program who is a child with special health care needs, as determined through a medical or behavioral screening instrument, is eligible for health benefits coverage from and shall be referred to the Children's Medical Services Network. Unlike Medicaid, subsection (5) of s. 409.814 (see line 34 of the bill) does not specifically exclude the CMS Network from the full-pay option for those children from families above 200 percent of the FPL.

However, paragraphs (a) – (d) of this subsection (see lines 36 -56 of the bill) does not contain any language limiting the number of children who can participate in the CMS Network whose family income exceeds 200 percent of the FPL. This could imply that the full pay option is not available for the CMS Network or imply that there is no limitation to the number of the full pays the CMS Network can accept which is highly unlikely. Committee staff suggests one of two amendments to correct this ambiguity.

To exclude the CMS Network from the full pay provision:
On line 34 after program, insert: <u>and Children's Medical Services Network program</u>

To include the CMS Network in the full pay provision :
On line 53 after the period, insert: <u>(d) The Department of Health is authorized to place limits on enrollment in the Children's Medical Services Network program by these children in order to avoid adverse selection. In addition, the Department of Health may offer a reduced benefit package to these children in order to limit program costs for such families. The number of children participating in the Children's Medical Services Network program whose family income exceeds 200 percent of the federal poverty level must not exceed 10 percent of total enrollees in the in the Children's Medical Services Network program.</u>

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

1 A bill to be entitled
2 An act relating to the Florida KidCare program; amending
3 s. 409.814, F.S.; authorizing eligibility for coverage in
4 the Florida KidCare program for additional categories of
5 children; providing an effective date.
6
7 Be It Enacted by the Legislature of the State of Florida:
8
9 Section 1. Subsections (2) and (5) of section 409.814,
10 Florida Statutes, are amended to read:
11 409.814 Eligibility.--A child who has not reached 19 years
12 of age whose family income is equal to or below 200 percent of
13 the federal poverty level is eligible for the Florida KidCare
14 program as provided in this section. For enrollment in the
15 Children's Medical Services Network, a complete application
16 includes the medical or behavioral health screening. If,
17 subsequently, an individual is determined to be ineligible for
18 coverage, he or she must immediately be disenrolled from the
19 respective Florida KidCare program component.
20 (2) A child who is not eligible for Medicaid, but who is
21 eligible for the Florida KidCare program, may obtain health
22 benefits coverage under any of the other components listed in s.
23 409.813 if such coverage is approved and available in the county
24 in which the child resides. However, a child who is eligible for
25 Medikids<u>, including those eligible under subsection (5),</u> may
26 participate in the Florida Healthy Kids program only if the
27 child has a sibling participating in the Florida Healthy Kids

28 program and the child's county of residence permits such
29 enrollment.
30 (5) A child whose family income is above 200 percent of
31 the federal poverty level or a child who is excluded under the
32 provisions of subsection (4) may apply for coverage and shall be
33 allowed to participate in the Florida KidCare program, excluding
34 the Medicaid program, but is subject to the following
35 provisions:
36 (a) The family is not eligible for premium assistance
37 payments and must pay the full cost of the premium, including
38 any administrative costs.
39 (b) The agency is authorized to place limits on enrollment
40 in Medikids by these children in order to avoid adverse
41 selection. The number of children participating in Medikids
42 whose family income exceeds 200 percent of the federal poverty
43 level must not exceed 10 percent of total enrollees in the
44 Medikids program.
45 (c) The board of directors of the Florida Healthy Kids
46 Corporation is authorized to place limits on enrollment of these
47 children in order to avoid adverse selection. In addition, the
48 board is authorized to offer a reduced benefit package to these
49 children in order to limit program costs for such families. The
50 number of children participating in the Florida Healthy Kids
51 program whose family income exceeds 200 percent of the federal
52 poverty level must not exceed 10 percent of total enrollees in
53 the Florida Healthy Kids program.

54 (d) Children described in this subsection are not counted
55 in the annual enrollment ceiling for the Florida KidCare
56 program.
57 Section 2. This act shall take effect July 1, 2006.

HB 311

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 311 Vaccine Production Facilities
SPONSOR(S): Cretul and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 706

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

SUMMARY ANALYSIS

Across the nation, concerns over vaccine shortages and production have increased due to threats of both bioterrorism and pandemic influenza virus. Efforts to bolster vaccine production and accessibility are now a focus of government policy to better address general health issues and the threat to domestic security.

HB 311 addresses the issue of vaccine shortage in Florida by providing incentives for the production of vaccines in Florida. The bill:

- Provides incentives for vaccine production facilities established in or relocated in Florida to produce vaccines for the prevention of communicable disease.
- Exempts vaccine manufactures located in Florida from liability
- Establishes a loan and loan guarantee program within the Department of Health (DOH) to increase the financing available to fund the costs incurred by new or expanded production facilities in the state that produce vaccines.
- Requires the Department of Health to purchase a portion of vaccines produced in the state by vaccine manufactures for a specified period of time.

If enacted, the bill takes effect upon becoming law.

This bill has a fiscal impact.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Maintain Public Security: The bill may increase the physical security of Floridians were it to result in an increase in the quantity and accessibility of vaccines.

Provide Limited Government: The bill may increase the work for governmental organizations by creating a loan guarantee program and industry outreach program to be administered by the Department of Health.

B. EFFECT OF PROPOSED CHANGES:

Effect

This bill addresses the issue of vaccine shortage specifically for Florida. The bill provides incentives for vaccine production facilities established in Florida or relocated to Florida to produce certain vaccines. It exempt vaccine manufactures from liability; establish a loan and loan guarantee program within the Department of Health for the construction or relocation of such facilities; and require the Department of Health to purchase a portion of vaccines produced in the state by these facilities for a specified period of time.

Background

Social Benefits of Vaccines

In the United States, vaccines exist for preventing 11 once common childhood diseases and for preventing diseases responsible for high rates of sickness and death among adults. Vaccines provide a wide range of social benefits, including reducing the medical costs of diseases that are prevented, and enhancing the length, quality, and productivity of life.[1]

The Costs and Challenges of Vaccine Production

Vaccine production is "painfully slow compared with other sectors of drug and medical technology markets."[2] A 1985 Institute of Medicine (IOM) report on vaccine development describes the "technical problems, high research and development costs, the expense and logistics of clinical testing and surveillance of reactions, the risk of litigation" in the vaccine market.[3] A modern manufacturing vaccine production facility can cost $300 million to $500 million and take three to five years to build.[4] In 2002, the Tufts University Center for the Study of Drug Development estimated that it took an investment of $802 million to develop a new vaccine. An expert panel convened by the Department of Defense (DoD) estimated development costs at $300-$400 million per vaccine.[5]

---

[1] Institute of Medicine, August 2003. "Financing Vaccines in the 21st Century: Assuring Access and Availability." National Academies Press. Full text available at http://www.nap.edu.

[2] Gottlieb, S., and Calfee J.E.. 11/1/2004. "Putting Markets to Work in Vaccine Manufacturing." *American Enterprise Institute for Public Policy Research.* http://www.aei.org/publications/pubID.21659/pub_detail.asp.

[3] Institute of Medicine, Division of Health Promotion and Disease Prevention, *Vaccine Supply and Innovation* (Washington, D.C.: National Academy Press, 1985).

[4] Agres, Ted. "Vaccine Supplies Remain Sickly." Column by *Washington Times deputy managing editor.* Published in Drug Discovery & Development. http://www.dddmag.com/ShowPR.aspx?PUBCODE=016&ACCT=1600000100&ISSUE=0505&RELTYPE=PR&ORIGRELTYPE=PNP&PRODCODE=00000000&PRODLETT=AG

[5] Rettig, R.A. and Brower, J.B. 2003. "The Acquisition of Drugs and Biologics for Chemical and Biological Warfare Defense: Department of Defense Interactions with the Food and Drug Administration." Prepared for the Office of the Secretary of Defense by the National Defense Research Institute and RAND Health. Available online at http://www.rand.org/pubs/monograph_reports/2005/RAND_MR1659.sum.pdf.

The U.S. has a very expensive process for regulating the manufacture of biologics, and especially the flu vaccine because companies must gain approval for a new product every year from the FDA. In addition, techniques and equipment for manufacturing other biologics[6] have advanced dramatically. The processes for producing vaccines must adhere to strict regulation of development and manufacturing.[7] While advances in these technologies help ensure the public safety, they also add costs to the manufacturing process.

Decline of Manufacturing Capacity

The number of producers of recommended vaccines for the US market has declined from more than 25 companies 30 years ago to only 5 today.[8] The factors for the reduction of manufactures of vaccines include:

- Narrow profit margins associated with the cost of producing vaccines and uncertain demand.
- Fear of litigation.
- A number of mergers and acquisitions of vaccine manufacturers into larger companies.
- Globalization of the market.

Liability

Liability has discouraged manufacturers from investing in vaccine development. Vaccines are given to millions of healthy people, and because they are grown from living organisms instead of synthesized chemicals, they are prone to uncertainties in the manufacturing process. This makes vaccines targets for tort litigation on behalf of anyone who suffers any sort of illness after vaccination. Congress implemented the National Vaccine Injury Compensation Program (VICP) on October 1, 1988 as an effort to make sure that children injured as a result of a routinely recommended vaccine could be quickly compensated. This no-fault compensation system restricted the scope for liability and helped stem the exodus of manufacturers from the childhood vaccine industry. However after 20 years, the VICP is perhaps insufficient to cover recent trends in litigation against vaccine manufacturers, and the viability of the VICP is threatened.[9]

Federal law provisions enacted through the Department of Defense Appropriations Act, 2006 (See Comment Section), provides additional protection from liability for vaccine and pharmaceutical manufacturers under certain conditions.[10] Federal law further details that because the FDA is responsible for testing the safety of vaccines and pharmaceuticals, lawsuits against manufacturers of FDA-approved products are to be held in federal and not state court.

Federal Role in Vaccine Administration

The FDA is legally responsible for regulating the pharmaceutical industry and ensuring that drugs and vaccines released to the public are safe and effective.

The National Immunization Program of the Centers for Disease Control and Prevention (CDC) administers the vaccine purchase program for the federal government. Each state government has its own immunization program, which estimates the level of vaccines needed to assure access to immunization among underserved groups of children and adults. The CDC negotiates a federal contract for each vaccine product, using large volume purchase as leverage to obtain discounts on the

---

[6] Biologics (biological products) include a wide range of products such as vaccines, blood and blood components, gene therapy, allergenics, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics tend to be heat sensitive and susceptible to microbial contamination.

[7] Gottlieb, S., and Calfee J.E.. 11/1/2004. "Putting Markets to Work in Vaccine Manufacturing." *American Enterprise Institute for Public Policy Research.* http://www.aei.org/publications/pubID.21659/pub_detail.asp.

[8] Institute of Medicine, August 2003. "Financing Vaccines in the 21st Century: Assuring Access and Availability." National Academies Press. Full text available at http://www.nap.edu.

[9] Offit, Dr. Paul. "Vaccine History Shows Need to Update VICP." November 15, 2005. *The Hill.* http://www.hillnews.com/thehill/export/TheHill/News/Frontpage/111505/offit.html

[10] H.R. 2863, Department of Defense Appropriations Act, 2006.

manufacturer's list price. The states also rely upon the federal discount price for vaccines purchased with state revenues. Although the discount has declined significantly in recent years, the discount pricing process also has the effect of deflating payments to pharmaceutical which tends to discourage future investments in vaccine development.

Florida's Role in Vaccine Administration

States have an important role in setting immunization policy and establishing an immunization infrastructure. Policies for immunization requirements, including minimum school and day care entry requirements, are made almost exclusively at the state level, although cities occasionally impose additional requirements. Each state also establishes an immunization infrastructure to monitor infectious disease outbreaks, administer federal immunization grants, manage centralized supplies of vaccine, direct professional and public education efforts, and otherwise promote immunization policies. The DOH plays a key role in this aspect. The DOH Bureau of Statewide Pharmaceutical Services has been responsible for administering and managing annual statewide contracts for pharmaceuticals, including vaccines since 1993. The DOH Bureau of Immunization promotes, monitors and provides technical assistance to facilitate the completion of childhood immunizations and adult immunization.

Recently, Florida joined the Minnesota Multi-state Contracting Alliance for Pharmacy (MMCAP), a free and voluntary group purchasing organization for pharmaceuticals. Drugs purchased through MMCAP are for the benefit of all state agencies and political subdivisions that utilize pharmaceuticals for their clients. Previous to joining MMCAP, Florida did its own drug bids. Existing Florida contracts for pharmaceuticals were cancelled effective September 14, 2003. At this time, Florida only accesses the pharmaceuticals and vaccines offered by MMCAP.[11]

Section 288.108

288.108, F.S., delineates a framework to attract, retain, and provide favorable conditions for the growth of certain high-impact facilities provides widespread economic benefits to Florida citizens. This section allows the Office or Tourism Trade and Economic Development (office) to engage in activities to attract high impact[12] business to Florida. The office may, in consultation with Enterprise Florida, Inc., negotiate qualified high-impact business performance grant awards for any single qualified high-impact business. In negotiating grant awards, the office is required to consider the following guidelines in conjunction with other relevant applicant impact and cost information and analysis.

- A qualified high-impact business making a cumulative investment of $100 million and creating 100 jobs may be eligible for a total qualified high-impact business performance grant of $1 million to $2 million.
- A qualified high-impact business making a cumulative investment of $800 million and creating 800 jobs may be eligible for a qualified high-impact business performance grant of $10 million to $12 million.
- A qualified high-impact business, engaged in research and development, making a cumulative investment of $75 million and creating 75 jobs may be eligible for a total qualified high-impact business performance grant of $2 million to $3 million.
- A qualified high-impact business, engaged in research and development, making a cumulative investment of $150 million and creating 150 jobs may be eligible for a qualified high-impact business performance grant of $3.5 million to $4.5 million.

Section 381.003

Section 381.003, F.S., requires DOH to conduct:

- Communicable disease prevention and control program as part of fulfilling its public health mission.
- Programs for the prevention, control, and reporting of diseases of public health significance.

---

[11] More information on MMPAC contract is available online at: http://dms.myflorida.com/dms/purchasing/state_contracts_agreements_and_price_lists/state_term_contracts/pharmaceutical_purchasing_program_mmcap/complete_contract_contract_notice

[12] Defined as a business that makes invest a minimum of a $75 million and creates a minimum of 75 jobs.

- Programs for the prevention and control of vaccine-preventable diseases, including programs to immunize school children.

C. SECTION DIRECTORY:

Section 1.

Subsection (1). Requires DOH to conduct an outreach campaign to encourage pharmaceutical companies located in the state to produce vaccines for the prevention of communicable diseases. The bill further requires DOH to encourage such companies located outside the state to establish vaccine manufacturing companies within the state.

Subsection (2). Limits the civil liabilities of any business located in the state that manufactures vaccines approved by the United States Food and Drug Administration (FDA) to prevent communicable diseases.

Subsection (3). Requires DOH to establish a loan guarantee program for manufacturers who locate to the State of Florida for the purposes or producing vaccines for the prevention of communicable diseases.

Subsection (4). Requires DOH to enter into an agreement with vaccine manufacturers located in Florida to purchase a portion of vaccines from these companies for a specified period of time. The purchase of such vaccines from pharmaceutical companies referenced in the bill would not be subject to the competitive procurement process currently used by the department.

Section 2. Provides an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   See Fiscal Comments

2. Expenditures:

   See Fiscal Comments

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None

2. Expenditures:

   None

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill could encourage vaccine manufactures to construct facilities in Florida or relocate, as a result there would be an increase in economic activity in specific locations in the form of construction, job creation and related services and commerce.

D. FISCAL COMMENTS:

Increased economic activity as a result of vaccine manufactures to construct facilities in Florida or relocate to Florida would generate tax revenue for the state.

According to DOH, the bill would have a fiscal impact on the DOH. However, no specific estimates where provided. The following provisions of the bill would require a specific appropriation to DOH.

- The bill requires DOH to establish a loan guarantee program for manufacturers who locate to the State of Florida for the purposes or producing vaccines for the prevention of communicable diseases.

- The bill requires DOH to enter into an agreement with vaccine manufacturers located in Florida to purchase a portion of vaccines from these companies for a specified period of time. According to DOH analysis this could force the state to purchase vaccines it does not want at prices that are not competitive; and could leave Florida dependent on single manufacturers.

- If the bill becomes law and the DOH is required to purchase vaccines from specified companies, it could jeopardize the Florida's membership in the MMCAP buying group for both vaccines and for other pharmaceutical products. This could result in substantial changes in the price and purchasing of pharmaceuticals.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None

B. RULE-MAKING AUTHORITY:

No additional rule-making authority is required as a result of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

On December 30, 2005, President Bush signed into law the "Public Readiness and Emergency Preparedness Act" (PREP Act) as part of the 2006 Defense Appropriations Act (H.R. 2863). The PREP Act offers targeted liability protections to those involved in the development, manufacturing, and deployment of pandemic and epidemic products and security countermeasures. The Act creates a shield of immunity for claims arising out of, related to, or resulting from the administration or the use of a covered countermeasure (i.e., vaccines, countermeasures, devices and certain other products). This immunity covers a wide range of uses, including design, development, testing, manufacturing, distribution, administration, use, and other activities so that the protections can be applied as broadly as possible.

The immunity created by the Act can be overcome, but only upon a showing of willful misconduct that proximately caused a serious injury or death. The Act creates a single new Federal cause of action related to claims arising out of the use of pandemic and epidemic products and security countermeasures. To meet the "willful misconduct" exception, a plaintiff must show that acts or omissions were undertaken to "intentionally achieve a wrongful purpose." Most significantly, prior to any claim of willful misconduct, the Food and Drug Administration or Department of Justice must take and complete a specific enforcement action establishing the willful misconduct. Plaintiffs must specifically detail their claims, and there are mandatory penalties for counsel which file frivolous or baseless suits.

If claims can proceed, there are other restrictions, such as a limit on damages and reductions for collateral benefits received by a plaintiff.

The liability protections under the PREP Act are triggered when the Secretary of Health and Human Services makes a declaration that a disease or other threat constitutes a public health emergency, or that there is a credible risk of such a threat. This flexibility allows the Secretary to be proactive and prepare the nation's infrastructure for threats that are real, but may not be occurring in the immediate future.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

1 A bill to be entitled
2 An act relating to vaccine production facilities;
3 providing incentives for vaccine production facilities to
4 produce certain vaccines; exempting certain business
5 entities from liability under certain circumstances;
6 establishing a loan and loan guarantee program; requiring
7 the Department of Health to purchase a portion of vaccines
8 produced in the state for a specified period of time;
9 providing an effective date.
10
11 WHEREAS, the adequacy of our country's supply of vaccines
12 has been called into question because of the growing demand for
13 the influenza vaccine and other vaccines in response to the
14 exhortations of public health officials, and
15 WHEREAS, this growing demand for vaccines has increased the
16 pressure on the nation's domestic suppliers and created the
17 potential for a major public health crisis, and
18 WHEREAS, the issue of the inadequacy of vaccine supplies to
19 meet the needs of our citizens, and particularly to protect the
20 public against influenza, which kills some 36,000 Americans each
21 year, has now advanced to the forefront of the public health
22 agenda, and
23 WHEREAS, urgent action is needed to augment the limited
24 domestic vaccine supply, especially the supply of influenza
25 vaccine, in order to protect the health of the American public,
26 not only those individuals who are most at risk from vaccine-
27 preventable diseases but also the rest of the population as
28 well, and

29 WHEREAS, given the impediment to the increased production
30 of vaccines created by the regulatory requirements imposed by
31 the United States Food and Drug Administration, the state should
32 offer financial incentives to pharmaceutical manufacturers to
33 increase the production of vaccines and thereby ensure their
34 availability in quantities that are adequate to protect the most
35 vulnerable individuals in the state and to permit the rest of
36 the citizens of the state who wish to be vaccinated to receive
37 this protection as well, NOW, THEREFORE,
38
39 Be It Enacted by the Legislature of the State of Florida:
40
41 Section 1. Vaccine production facilities; incentives for
42 vaccine production; liability; loan program.--
43 (1) The Department of Health shall conduct an outreach
44 campaign to encourage pharmaceutical companies located in this
45 state to produce vaccines for the prevention of communicable
46 diseases and to encourage pharmaceutical companies located
47 outside of this state to establish facilities in this state to
48 produce vaccines for the prevention of communicable diseases.
49 (2) A business, corporation, sole proprietorship,
50 partnership, subchapter S corporation, limited liability
51 corporation, nonprofit corporation, consortium, or other
52 business entity located in this state that in good faith
53 develops or produces vaccines for the prevention of communicable
54 diseases shall not be held liable for civil damages for any act
55 or omission, except for knowing and willful acts or omissions,
56 in the development or production of vaccines for the prevention

57 of communicable diseases that are approved for market
58 distribution by the United States Food and Drug Administration.
59 (3) The Department of Health shall establish a loan and
60 loan guarantee program to increase the financing available to
61 fund the costs incurred by new or expanded production facilities
62 in the state that produce vaccines for the prevention of
63 communicable diseases, including, but not be limited to, the
64 influenza virus. Loans or loan guarantees shall be made
65 available to pharmaceutical companies, partnerships of such
66 companies, and consortia of such companies, provided that the
67 production facility meets the requirements of the United States
68 Food and Drug Administration to ensure the safety, efficacy,
69 purity, and potency of the vaccines produced at the facility.
70 (4) The Department of Health shall enter into an agreement
71 with each production facility that commences production of
72 vaccines for the prevention of communicable diseases to purchase
73 a portion of all vaccines produced at the facility that are
74 approved by the United States Food and Drug Administration to
75 ensure the safety, efficacy, purity, and potency of the vaccine.
76 Such an agreement may be for no more than 1 year. The department
77 shall take all actions that are necessary to encourage
78 physicians, nurses, health care facilities, pharmacies, and
79 other entities that dispense vaccines in the state to obtain a
80 portion of their vaccine supply from vaccine production
81 facilities currently located in the state or facilities that
82 commence production of vaccines in the state after July 1, 2006.
83 Section 2. This act shall take effect July 1, 2006.

Bill No. **HB 311**

COUNCIL/COMMITTEE ACTION

ADOPTED	__	(Y/N)
ADOPTED AS AMENDED	__	(Y/N)
ADOPTED W/O OBJECTION	__	(Y/N)
FAILED TO ADOPT	__	(Y/N)
WITHDRAWN	__	(Y/N)
OTHER	____	

---

1 Council/Committee hearing bill: Health Care General Committee
2 Representative(s) Cretul offered the following:
3
4 **Amendment (with title amendments)**
5 Remove line(s) 41-82 and insert:
6 Section 1. Vaccine production facilities; incentives for
7 vaccine production; liability.--
8 (1) Enterprise Florida, Inc., as the principal economic
9 development organization for the state under s. 288.9015,
10 Florida Statutes, shall conduct an outreach campaign to
11 encourage pharmaceutical companies located in this state to
12 produce vaccines for the prevention of communicable diseases and
13 to encourage pharmaceutical companies located outside of this
14 state to establish facilities in this state to produce vaccines
15 for the prevention of communicable diseases.
16 (2) A business, corporation, sole proprietorship,
17 partnership, subchapter S corporation, limited liability
18 corporation, nonprofit corporation, consortium, or other
19 business entity located in this state that in good faith
20 develops or produces vaccines for the prevention of communicable
21 diseases shall not be held liable for civil damages for any act

22 or omission, except for knowing and willful acts or omissions,
23 in the development or production of vaccines for the prevention
24 of communicable diseases that are approved for market
25 distribution by the United States Food and Drug Administration.
26
27 ========== T I T L E A M E N D M E N T ==========
28 Remove line(s) 6-8
29

PCB HCG 06-01

1 A bill to be entitled
2 An act relating to emergency management; amending s.
3 252.355, F.S.; specifying additional agencies that are
4 required to provide registration information to special
5 needs clients and persons with disabilities or special
6 needs who receive services from such agencies for purposes
7 of inclusion within the registry of persons with special
8 needs maintained by local emergency management agencies;
9 providing that the Department of Community Affairs shall
10 be the designated lead agency responsible for community
11 education and outreach to the general public, including
12 special needs clients, regarding registration as a person
13 with special needs, special needs shelters, and general
14 information regarding shelter stays; requiring the
15 department to disseminate educational and outreach
16 information through local emergency management offices;
17 requiring the department to coordinate community education
18 and outreach related to special needs shelters with
19 specified agencies and entities; providing that specified
20 confidential and exempt information relating to
21 registration of persons with special needs be provided to
22 the Department of Health; creating s. 252.3568, F.S.;
23 providing for evacuation for persons with pets; amending
24 s. 381.0303, F.S.; providing for the operation,
25 maintenance, and closure of special needs shelters;
26 removing a condition of specified funding as a
27 prerequisite to the assumption of lead responsibility by
28 the Department of Health for specified coordination with

29 respect to the development of a plan for the staffing and
30 medical management of special needs shelters; providing
31 that the local Children's Medical Services offices shall
32 assume lead responsibility for specified coordination with
33 respect to the development of a plan for the staffing and
34 medical management of pediatric special needs shelters;
35 requiring such plans to conform to the local comprehensive
36 emergency management plan; requiring county governments to
37 assist in the process of coordinating the recruitment of
38 health care practitioners to staff local special needs
39 shelters; providing that the appropriate county health
40 department, Children's Medical Services office, and local
41 emergency management agency shall jointly determine the
42 responsibility for medical supervision in a special needs
43 shelter; providing that state employees with a
44 preestablished role in disaster response may be called
45 upon to serve in times of disaster in specified
46 capacities; requiring the Secretary of Elderly Affairs to
47 convene a multiagency emergency special needs shelter
48 response team or teams to assist local areas that are
49 severely impacted by a natural or manmade disaster that
50 required the use of special needs shelters; providing
51 duties and responsibilities of multiagency response teams;
52 authorizing local emergency management agencies to request
53 the assistance of a multiagency response team; providing
54 for the inclusion of specified state agency
55 representatives on each multiagency response team;
56 authorizing hospitals and nursing homes that are used to

57 shelter special needs persons during or after an
58 evacuation to submit invoices for reimbursement to the
59 Department of Health; requiring the department to specify
60 by rule expenses that are reimbursable and the rate of
61 reimbursement for services; prescribing means of and
62 procedures for reimbursement; providing eligibility for
63 reimbursement of health care facilities to whom special
64 needs shelter clients have been discharged by a
65 multiagency response team upon closure of a special needs
66 shelter; providing requirements with respect to such
67 reimbursement; prescribing means of and procedures for
68 reimbursement; disallowing specified reimbursements;
69 revising the role of the special needs shelter interagency
70 committee with respect to the planning and operation of
71 special needs shelters; providing required functions of
72 the committee; providing that the committee shall
73 recommend guidelines to establish a statewide database to
74 collect and disseminate special needs registration
75 information; revising the composition of the special needs
76 shelter interagency committee; requiring the inclusion of
77 specified rules with respect to special needs shelters and
78 specified minimum standards therefore; providing
79 requirements with respect to emergency management plans
80 submitted by a home health agency, nurse registry, or
81 hospice to a county health department for review; removing
82 a condition of specified funding as a prerequisite to the
83 submission of such plans; amending s. 252.385, F.S.;
84 requiring the Division of Emergency Management of the

85 Department of Community Affairs to prepare and submit a
86 statewide emergency shelter plan to the Governor and the
87 Cabinet for approval; providing plan requirements;
88 requiring the Department of Health to assist the division
89 in determining the estimated need for special needs
90 shelter space; requiring inspection of public hurricane
91 evacuation shelter facilities by local emergency
92 management agencies prior to activation of such
93 facilities; amending s. 400.492, F.S.; providing that
94 nurse registries, hospices, and durable medical equipment
95 providers shall prepare and maintain a comprehensive
96 emergency management plan; providing that home health,
97 hospice, and durable medical equipment provider agencies
98 shall not be required to continue to provide care to
99 patients in emergency situations that are beyond their
100 control and that make it impossible to provide services;
101 authorizing home health agencies, nurse registries,
102 hospices, and durable medical equipment providers to
103 establish links to local emergency operations centers to
104 determine a mechanism to approach areas within a disaster
105 area in order for the agency to reach its clients;
106 providing that the presentation of home care or hospice
107 clients to the special needs shelter without the home
108 health agency or hospice making a good faith effort to
109 provide services in the shelter setting constitutes
110 abandonment of the client; requiring regulatory review in
111 such cases; amending s. 408.831, F.S.; providing that
112 entities regulated or licensed by the Agency for Health

113 Care Administration may exceed their licensed capacity to
114 act as a receiving facility under specified circumstances;
115 providing requirements while such entities are in an
116 overcapacity status; providing for issuance of an inactive
117 license to such licensees under specified conditions;
118 providing requirements and procedures with respect to the
119 issuance and reactivation of an inactive license;
120 providing fees; creating s. 252.357, F.S., requiring the
121 Florida Comprehensive Emergency Management Plan to permit
122 the Agency for Health Care Administration to initially
123 contact nursing homes in disaster areas for specified
124 monitoring purposes; requiring the agency to publish an
125 emergency telephone number for use by nursing homes;
126 providing an effective date.
127
128 Be It Enacted by the Legislature of the State of Florida:
129
130 Section 1. Section 252.355, Florida Statutes, is amended
131 to read:
132 252.355 Registry of persons with special needs; notice.--
133 (1) In order to meet the special needs of persons who
134 would need assistance during evacuations and sheltering because
135 of physical, mental, <u>cognitive impairment,</u> or sensory
136 disabilities, each local emergency management agency in the
137 state shall maintain a registry of persons with special needs
138 located within the jurisdiction of the local agency. The
139 registration shall identify those persons in need of assistance
140 and plan for resource allocation to meet those identified needs.

141 To assist the local emergency management agency in identifying
142 such persons, home health agencies, hospices, nurse registries,
143 home medical equipment providers, the Department of Children and
144 Family Services, Department of Health, Agency for Health Care
145 Administration, Department of Education, Agency for Persons with
146 Disabilities, ~~Department of Labor and Employment Security,~~ and
147 Department of Elderly Affairs shall provide registration
148 information to all of their special needs clients and to all
149 people with disabilities or special needs who receive services
150 ~~incoming clients as a part of the intake process~~. The registry
151 shall be maintained year-round. The registration program shall
152 give persons with special needs the option of preauthorizing
153 emergency response personnel to enter their homes during search
154 and rescue operations if necessary to assure their safety and
155 welfare following disasters.
156 (2) The Department of Community Affairs shall be the
157 designated lead agency responsible for community education and
158 outreach to the general public, including special needs clients,
159 regarding registration and special needs shelters and general
160 information regarding shelter stays. The Department of Community
161 Affairs shall disseminate such educational and outreach
162 information through the local emergency management offices. The
163 department shall coordinate the development of curriculum and
164 dissemination of all community education and outreach related to
165 special needs shelters with the Clearinghouse on Disability
166 Information of the Governor's Working Group on the Americans
167 with Disabilities Act, the Department of Children and Family
168 Services, the Department of Health, the Agency for Health Care

169 Administration, the Department of Education, the Agency for
170 Persons with Disabilities, and the Department of Elderly
171 Affairs. The special needs shelter is considered a public
172 facility when it is activated for a disaster. Under the
173 Americans with Disabilities Act (ADA), Public Law 101.336,
174 businesses and organizations that serve the public must allow
175 people with disabilities to bring their service animals into all
176 areas of the facility where customers are normally allowed to
177 go.
178 (3) ~~(2)~~ On or before January 1 ~~May 1~~ of each year each
179 electric utility in the state shall semi-annually notify
180 residential customers in its service area of the availability of
181 the registration program available through their local emergency
182 management agency.
183 (4) ~~(3)~~ All records, data, information, correspondence, and
184 communications relating to the registration of persons with
185 special needs as provided in subsection (1) are confidential and
186 exempt from the provisions of s. 119.07(1), except that such
187 information shall be available to other emergency response
188 agencies, as determined by the local emergency management
189 director, and to the Department of Health in the furtherance of
190 their duties and responsibilities.
191 (5) ~~(4)~~ All appropriate agencies and community-based
192 service providers, including home health care providers
193 hospices, nurse registries, and home medical equipment
194 providers, shall assist emergency management agencies by
195 collecting registration information for persons with special
196 needs as part of program intake processes, establishing programs

197 to increase the awareness of the registration process, and
198 educating clients about the procedures that may be necessary for
199 their safety during disasters. Clients of state or federally
200 funded service programs with physical, mental, cognitive
201 impairment, or sensory disabilities who need assistance in
202 evacuating, or when in shelters, must register as persons with
203 special needs.
204 Section 2. Section 252.3568, Florida Statutes, is created
205 to read:
206 252.3568 Emergency sheltering of persons with pets.—
207 (1) GENERAL PROVISIONS.—In accordance with the provisions
208 of s. 252.35, the division shall address evacuation of persons
209 with pets with the shelter component of the state comprehensive
210 emergency management plan. The Department of Agriculture and
211 Consumer Services shall assist the division in determining
212 strategies regarding this activity.
213 Section 3. Section 381.0303, Florida Statutes, is amended
214 to read:
215 381.0303 ~~Health practitioner recruitment for~~ Special needs
216 shelters.--
217 (1) PURPOSE.--The purpose of this section is to provide
218 for the operation, maintenance, and closure of special needs
219 shelters and to designate the Department of Health, through its
220 county health departments, as the lead agency for coordination
221 of the recruitment of health care practitioners, as defined in
222 s. 456.001(4), to staff special needs shelters in times of
223 emergency or disaster and to provide resources to the department
224 to carry out this responsibility. However, nothing in this

225 section prohibits a county health department from entering into
226 an agreement with a local emergency management agency to assume
227 the lead responsibility for recruiting health care
228 practitioners.
229 (2) SPECIAL NEEDS SHELTER PLAN; STAFFING; CLOSURE; STATE
230 AGENCY ASSISTANCE ~~AND STAFFING.--~~Provided funds have been
231 appropriated to support ~~medical services~~ disaster coordinator
232 positions in county health departments,
233 (a) The department shall assume lead responsibility for
234 the ~~local~~ coordination of local medical and health care
235 providers, the American Red Cross, and other interested parties
236 in developing a plan for the staffing and medical management of
237 special needs shelters. The local Children's Medical Services
238 offices shall assume lead responsibility for the local
239 coordination of local medical and health care providers, the
240 American Red Cross, and other interested parties in developing a
241 plan for the staffing and medical management of pediatric
242 special needs shelters. Plans shall conform to ~~The plan shall be~~
243 ~~in conformance with~~ the local comprehensive emergency management
244 plan.
245 (b) ~~(a)~~ County health departments shall, in conjunction
246 with the local emergency management agencies, have the lead
247 responsibility for coordination of the recruitment of health
248 care practitioners to staff local special needs shelters. County
249 health departments shall assign their employees to work in
250 special needs shelters when those employees are needed to
251 protect the health and safety of special needs persons ~~of~~
252 ~~patients~~. County governments shall assist the Department of

253 Health with non-medical staffing and operating of special needs
254 shelters. The local health department and emergency management
255 agency shall coordinate these efforts to ensure appropriate
256 staffing in special needs shelters.
257 (c) ~~(b)~~ The appropriate county health department,
258 Children's Medical Services office, and local emergency
259 management agency shall jointly decide ~~determine~~ who has
260 responsibility for medical supervision in each ~~a~~ special needs
261 shelter and shall notify the Department of Community Affairs
262 Division of Emergency Management and the Department of Health of
263 their decision.
264 (d) ~~(c)~~ Local emergency management agencies shall be
265 responsible for the designation, operation and infrastructure of
266 special needs shelters during times of emergency or disaster and
267 the closure of the facilities following an emergency or
268 disaster. The emergency management agency and the local health
269 department shall coordinate these efforts to ensure appropriate
270 designation, operation and infrastructure in special needs
271 shelters. County health departments shall assist the local
272 emergency management agency with regard to the management of
273 medical services in special needs shelters. However, nothing in
274 this section prohibits a county health department from entering
275 into an alternative agreement with a local emergency management
276 agency to assume the lead responsibility for special needs
277 shelter supplies and equipment.
278 (e) State employees with a preestablished role provided by
279 the employee's respective agency in disaster response unless
280 they have other mandated response activities that preclude

281 participation, are subject to serve in times of disaster
282 commensurate with their knowledge, skills, and abilities and any
283 needed activities related to the situation.
284 (f) The Secretary of Elderly Affairs, or his or her
285 designee, shall convene, at any time that he or she deems
286 appropriate and necessary, a multiagency special needs shelter
287 discharge planning team or teams to assist local areas that are
288 severely impacted by a natural or manmade disaster that requires
289 the use of special needs shelters. Multiagency special needs
290 shelter discharge planning teams shall provide assistance to
291 local emergency management agencies with the continued
292 operation or closure of the shelters, and with the discharge of
293 special needs clients to alternate facilities if necessary.
294 Local emergency management agencies may request the assistance
295 of a multiagency special needs shelter discharge planning team
296 by alerting statewide emergency management officials of the
297 necessity for additional assistance in their area. The Secretary
298 of Elder Affairs shall work with other state agencies prior to
299 any natural disasters for which warnings are provided to ensure
300 that multiagency special needs shelter discharge planning teams
301 are ready to assemble and deploy rapidly upon a determination by
302 state emergency management officials that a disaster area
303 requires assistance. The Secretary of Elder Affairs may call
304 upon any state agency or office to provide staff to assist a
305 multiagency special needs shelter discharge planning team or
306 teams. Unless the secretary determines that the nature or
307 circumstances surrounding the disaster do not warrant
308 participation from a particular agency's staff, each multiagency

309 special needs shelter discharge planning team shall include at
310 least one representative from each of the following state
311 agencies:
312 1. Department of Elderly Affairs.
313 2. Department of Health.
314 3. Department of Children and Family Services.
315 4. Department of Veterans' Affairs.
316 5. Department of Community Affairs.
317 6. Agency for Health Care Administration.
318 7. Agency for Persons with Disabilities.
319 (3) REIMBURSEMENT TO HEALTH CARE PRACTITIONERS AND
320 FACILITIES.--
321 (a) The Department of Health shall upon request reimburse~~,~~
322 ~~subject to the availability of funds for this purpose,~~ health
323 care practitioners, as defined in s. 456.001, provided the
324 practitioner is not providing care to a patient under an
325 existing contract, and emergency medical technicians and
326 paramedics licensed under ~~pursuant to~~ chapter 401, for medical
327 care provided at the request of the department in special needs
328 shelters or at other locations during times of emergency or a
329 declared ~~major~~ disaster. Reimbursement for health care
330 practitioners, except for physicians licensed under ~~pursuant to~~
331 chapter 458 or chapter 459, shall be based on the average hourly
332 rate that such practitioners were paid according to the most
333 recent survey of Florida hospitals conducted by the Florida
334 Hospital Association or other nationally or state recognized
335 data source. Reimbursement shall be requested on forms prepared
336 by the Department of Health and shall be paid as specified in

337 paragraph (d).
338 (b) Hospitals, nursing homes, assisted living facilities,
339 and hospices that are used to shelter special needs persons
340 during or after an evacuation may submit invoices for
341 reimbursement to the department. The department shall develop a
342 form for reimbursement and shall specify by rule which expenses
343 are reimbursable and the rate of reimbursement for each service.
344 Reimbursement for the services described in this paragraph shall
345 be paid as specified in paragraph (d).
346 (c) If, upon closure of a special needs shelter, a
347 multiagency special needs shelter discharge planning team
348 determines that it is necessary to discharge special needs
349 shelter persons to other health care facilities, such as nursing
350 homes, assisted living facilities, and community residential
351 group homes, the receiving facilities shall be eligible for
352 reimbursement for services provided to the individuals for up to
353 90 days. Any facility eligible for reimbursement under this
354 paragraph shall submit invoices for reimbursement on forms
355 developed by the department. A facility must show proof of a
356 written request from a representative of an agency serving on
357 the multiagency special needs shelter discharge planning team
358 that the individual for whom the facility is seeking
359 reimbursement for services rendered was referred to that
360 facility from a special needs shelter. Reimbursement for the
361 services described in this paragraph shall be paid as specified
362 in paragraph (d).
363 (d) If a Presidential Disaster Declaration has been issued
364 ~~made~~, and the Federal Government makes funds available, the

365 department shall use those ~~such~~ funds for reimbursement of
366 eligible expenditures. In other situations, or if federal funds
367 do not fully compensate the department for reimbursements
368 permissible under ~~reimbursement made pursuant to~~ this section,
369 the department shall process a budget amendment to obtain
370 reimbursement from unobligated, unappropriated moneys in the
371 General Revenue Fund. The department shall not provide
372 reimbursement to facilities under this subsection for services
373 provided to a special needs person if, during the period of time
374 in which the services were provided, the individual was enrolled
375 in another state-funded program such as Medicaid or another
376 similar program; or entities providing health insurance as
377 defined in s. 624.603 or health maintenance organizations or
378 prepaid health clinics as defined in chapter 641, which would
379 otherwise pay for the same services. Travel expense and per diem
380 costs shall be reimbursed pursuant to s. 112.061.
381 (4) HEALTH CARE PRACTITIONER REGISTRY.--The department may
382 use the registries established in ss. 401.273 and 456.38 when
383 health care practitioners are needed to staff special needs
384 shelters or to assist with other disaster related activities.
385 (5) SPECIAL NEEDS SHELTER INTERAGENCY COMMITTEE.--The
386 Secretary ~~Department~~ of Health may establish a special needs
387 shelter interagency committee and serve as or appoint a designee
388 to serve as the committee's chair. The department shall provide
389 any necessary staff and resources to support the committee in
390 the performance of its duties~~, to be chaired and staffed by the~~
391 ~~department~~. The committee shall address and resolve problems
392 related to special needs shelters not addressed in the state

393 comprehensive emergency medical plan and shall consult on ~~serve~~
394 ~~as an oversight committee to monitor~~ the planning and operation
395 of special needs shelters.
396 (a) The committee shall ~~may~~:
397 1. Develop, negotiate and regularly review any necessary
398 interagency agreements.
399 2. Undertake other such activities as the department deems
400 necessary to facilitate the implementation of this section.
401 3. Submit recommendations to the Legislature as necessary.
402 (b) The special needs shelter interagency committee shall
403 be composed of representatives of emergency management, health,
404 medical, and social services organizations. Membership shall
405 include, but shall not be limited to, representatives of the
406 Departments of Health, Community Affairs, Children and Family
407 Services, Elderly Affairs, ~~Labor and Employment Security,~~ and
408 Education; the Agency for Health Care Administration; the
409 Florida Medical Association; the Florida Osteopathic Medical
410 Association; Associated Home Health Industries of Florida, Inc.;
411 the Florida Nurses Association; the Florida Health Care
412 Association; the Florida Assisted Living Affiliation
413 ~~Association~~; the Florida Hospital Association; the Florida
414 Statutory Teaching Hospital Council; the Florida Association of
415 Homes for the Aging; the Florida Emergency Preparedness
416 Association; the American Red Cross; Florida Hospices and
417 Palliative Care, Inc.; Florida Association of Health Plans,
418 Florida Hospital Association, Private Care Association; ~~and~~ the
419 Salvation Army; the Florida Association of Aging Services
420 Providers; the American Association of Retired Persons (AARP)

421 and the Florida Renal Coalition.
422 (c) Meetings of the committee shall be held in
423 Tallahassee, and members of the committee shall serve at the
424 expense of the agencies or organizations they represent. The
425 committee shall make every effort to use teleconference or video
426 conference capabilities in order to ensure statewide input and
427 participation.
428 (6) RULES.--The department has the authority to adopt
429 rules necessary to implement this section. Rules shall ~~may~~
430 include:
431 (a) The definition of a special needs person ~~patient~~,
432 including eligibility criteria for individuals with physical,
433 mental, cognitive impairment or sensory disabilities and the
434 services a special needs person can expect to receive.
435 (b) The process for special needs shelter health care
436 practitioner and facility reimbursement for services provided in
437 a disaster event.
438 (c) Guidelines for special needs shelter staffing levels to
439 provide services.
440 (d) The definition of and standards for special needs
441 shelter supplies and equipment.
442 (e) Compliance with applicable service animal laws.
443 (f) Standards for the special needs shelter registration
444 process including guidelines for addressing the needs of
445 unregistered persons in need of a special needs shelter.
446 (g) Standards for addressing the needs of families that
447 are eligible for special needs shelter services, including the
448 needs of families with multiple dependents where only one

449 dependent is eligible for the special needs shelter, and the
450 needs of adults with special needs who are caregivers for
451 individuals without special needs.
452 (h) The requirement of the county health departments seek
453 the participation of hospitals, nursing homes, assisted living
454 facilities, home health agencies, hospice providers, nurse
455 registries and home medical equipment providers and other health
456 and medical emergency preparedness stakeholders in pre-event
457 planning activities.
458 (7) ~~REVIEW OF~~ EMERGENCY MANAGEMENT PLANS; CONTINUITY OF
459 CARE.--Each emergency management plan submitted to a county
460 health department by a home health agency pursuant to s.
461 400.492, by a nurse registry pursuant to s. 400.506, a hospice
462 pursuant to s. 400.610 or a home medical equipment provider
463 pursuant to s. 400.925, shall include how the home health
464 agency, nurse registry, hospice or home medical equipment
465 provider will continue to provide staff or equipment to perform
466 the same type and quantity of services to their patients who
467 evacuate to special needs shelters as was provided to those
468 patients prior to evacuation. The submission of emergency
469 management plans to county health departments by home health
470 agencies pursuant to s. 400.497(8)(c) and (d) and by nurse
471 registries pursuant to s. 400.506(16)(e) and by hospice programs
472 pursuant to s. 400.610(1)(b)and by home medical equipment
473 providers pursuant to s. 400.934(20)(a) is conditional upon the
474 receipt of an appropriation by the department to establish
475 ~~medical services~~ disaster coordinator positions in county health
476 departments unless the secretary of the department and a local

477 county commission jointly determine to require such plans to be
478 submitted based on a determination that there is a special need
479 to protect public health in the local area during an emergency.
480 Section 3. Subsections (2) and (4) of section 252.385,
481 Florida Statutes, are amended to read:
482 252.385 Public shelter space.--
483 (2)(a) The division shall administer a program to survey
484 existing schools, universities, community colleges, and other
485 state-owned, municipally owned, and county-owned public
486 buildings and any private facility that the owner, in writing,
487 agrees to provide for use as a public hurricane evacuation
488 shelter to identify those that are appropriately designed and
489 located to serve as such shelters. The owners of the facilities
490 must be given the opportunity to participate in the surveys. The
491 Board of Regents, district school boards, community college
492 boards of trustees, and the Department of Education are
493 responsible for coordinating and implementing the survey of
494 public schools, universities, and community colleges with the
495 division or the local emergency management agency.
496 (b) By January 31 of each even-numbered year, the Division
497 of Emergency Management of the Department of Community Affairs
498 shall prepare and submit a statewide emergency shelter plan to
499 the Governor and the Cabinet for approval, subject to the
500 requirements for approval provided in s. 1013.37(2). The plan
501 must also identify the general location and square footage of
502 special needs shelters, by regional planning council region,
503 during the next 5 years. The Department of Health shall assist
504 the division in determining the estimated need for special needs

505 shelter space and the adequacy of the facility to meet the needs
506 of special needs persons, based on information from the special
507 needs registration and other information.
508 (4)(a) Public facilities, including schools, postsecondary
509 education facilities, and other facilities owned or leased by
510 the state or local governments, but excluding hospitals, hospice
511 care facilities, assisted living facilities, or nursing homes,
512 which are suitable for use as public hurricane evacuation
513 shelters shall be made available at the request of the local
514 emergency management agencies. The local emergency management
515 agency shall inspect a designated facility to determine its
516 readiness prior to activating such facility for a specific
517 hurricane or disaster. Such agencies shall coordinate with the
518 appropriate school board, university, community college, or
519 local governing board when requesting the use of such facilities
520 as public hurricane evacuation shelters.
521 (b) The Department of Management Services shall
522 incorporate provisions for the use of suitable leased public
523 facilities as public hurricane evacuation shelters into lease
524 agreements for state agencies. Suitable leased public facilities
525 include leased public facilities that are solely occupied by
526 state agencies and have at least 2,000 square feet of net floor
527 area in a single room or in a combination of rooms having a
528 minimum of 400 square feet in each room. The net square footage
529 of floor area must be determined by subtracting from the gross
530 square footage the square footage of spaces such as mechanical
531 and electrical rooms, storage rooms, open corridors, restrooms,
532 kitchens, science or computer laboratories, shop or mechanical

533 areas, administrative offices, records vaults, and crawl spaces.
534 (c) The Department of Management Services shall, in
535 consultation with local and state emergency management agencies,
536 assess Department of Management Services facilities to identify
537 the extent to which each facility has public hurricane
538 evacuation shelter space. The Department of Management Services
539 shall submit proposed facility retrofit projects that
540 incorporate hurricane protection enhancements to the department
541 for assessment and inclusion in the annual report prepared in
542 accordance with subsection (3).
543 Section 5. Section 400.492, Florida Statutes, is amended
544 to read:
545 400.492 Provision of services during an emergency.--Each
546 home health agency shall prepare and maintain a comprehensive
547 emergency management plan that is consistent with the standards
548 adopted by national or state accreditation organizations and
549 consistent with the local special needs plan. The plan shall be
550 updated annually and shall provide for continuing home health,
551 services during an emergency that interrupts patient care or
552 services in the patient's home. The plan shall include how the
553 home health agency will continue to provide staff to perform the
554 same type and quantity of services to their patients who
555 evacuate to special needs shelters as staff were providing to
556 those patients prior to evacuation. The plan shall describe how
557 the home health agency establishes and maintains an effective
558 response to emergencies and disasters, including: notifying
559 staff when emergency response measures are initiated; providing
560 for communication between staff members, county health

561 departments, and local emergency management agencies, including
562 a backup system; identifying resources necessary to continue
563 essential care or services or referrals to other organizations
564 subject to written agreement; and prioritizing and contacting
565 patients who need continued care or services.
566 (1) Each patient record for patients who are listed in the
567 registry established pursuant to s. 252.355 shall include a
568 description of how care or services will be continued in the
569 event of an emergency or disaster. The home health agency shall
570 discuss the emergency provisions with the patient and the
571 patient's caregivers, including where and how the patient is to
572 evacuate, procedures for notifying the home health agency in the
573 event that the patient evacuates to a location other than the
574 shelter identified in the patient record, and a list of
575 medications and equipment which must either accompany the
576 patient or will be needed by the patient in the event of an
577 evacuation.
578 (2) Each home health agency shall maintain a current
579 prioritized list of patients who need continued services during
580 an emergency. The list shall indicate how services shall be
581 continued in the event of an emergency or disaster for each
582 patient and if the patient is to be transported to a special
583 needs shelter, and shall indicate if the patient is receiving
584 skilled nursing services and the patient's medication and
585 equipment needs. The list shall be furnished to county health
586 departments and to local emergency management agencies, upon
587 request.
588 (3) Home health agencies shall not be required to continue

589 to provide care to patients in emergency situations that are
590 beyond their control and that make it impossible to provide
591 services, such as when roads are impassable or when patients do
592 not go to the location specified in their patient records. Home
593 health agencies may establish links to local emergency
594 operations centers to determine a mechanism to approach areas
595 within the disaster area in order for the agency to reach its
596 clients. The presentation of home care clients to a special
597 needs shelter without the home health agency making a good faith
598 effort to provide services in the shelter setting will
599 constitute abandonment of the client and shall constitute a
600 Class II deficiency, subject to sanctions provided in section
601 400.484 (2) (b) Florida Statutes.
602 (4) Notwithstanding the provisions of s. 400.464(2) or any
603 other provision of law to the contrary, a home health agency may
604 provide services in a special needs shelter located in any
605 county.
606 Section 6. Subsection (8) of section 400.497, Florida
607 Statutes, is amended to read:
608 400.497 Rules establishing minimum standards.--The agency
609 shall adopt, publish, and enforce rules to implement this part,
610 including, as applicable, ss. 400.506 and 400.509, which must
611 provide reasonable and fair minimum standards relating to:
612 (8) Preparation of a comprehensive emergency management
613 plan pursuant to s. 400.492.
614 (c) The plan is subject to review and approval by the
615 county health department. During its review, the county health
616 department shall contact state and local health and medical

617 stakeholders during its review when necessary. ~~ensure that the~~
618 ~~following agencies, at a minimum, are given the opportunity to~~
619 ~~review the plan:~~
620 ~~1. The local emergency management agency.~~
621 ~~2. The Agency for Health Care Administration.~~
622 ~~3. The local chapter of the American Red Cross or other~~
623 ~~lead sheltering agency.~~
624 ~~4. The district office of the Department of Children and~~
625 ~~Family Services.~~
626 The county health department shall complete its review to
627 ensure that the plan is in accordance with the criteria set in
628 the Agency for Health Care Administration rule within 90 days
629 after receipt of the plan and shall either approve the plan or
630 advise the home health agency of necessary revisions.
631 If the home health agency fails to submit a plan or fails
632 to submit the requested information or revisions to the county
633 health department within 30 days after written notification from
634 the county health department, the county health department shall
635 notify the Agency for Health Care Administration. The agency
636 shall notify the home health agency that such failure
637 constitutes a deficiency, subject to a fine of $5,000 per
638 occurrence. If the plan is not submitted, information is not
639 provided or revisions are not made as requested, the agency may
640 impose the fine.
641 (d) For any home health agency that operates in more than
642 one county, the Department of Health shall review the plan,
643 after consulting with state and local health and medical
644 stakeholders, when necessary ~~all of the county health~~

645 ~~departments, the agency, and all the local chapters of the~~
646 ~~American Red Cross or other lead sheltering agencies in the~~
647 ~~areas of operation for that particular home health agency~~. The
648 Department of Health shall complete its review within 90 days
649 after receipt of the plan and shall either approve the plan or
650 advise the home health agency of necessary revisions. The
651 Department of Health shall make every effort to avoid imposing
652 differing requirements based on differences between counties on
653 the home health agency.
654 Section 7. Paragraph (a) of subsection (16) of section
655 400.506, Florida Statutes, is amended to read:
656 400.506 Licensure of nurse registries; requirements;
657 penalties.--
658 (16) Each nurse registry shall prepare and maintain a
659 comprehensive emergency management plan that is consistent with
660 the criteria in this subsection and with the local special needs
661 plan. The plan shall be updated annually. The plan shall include
662 how the nurse registry will continue to provide staff to perform
663 the same type and quantity of services to their patients who
664 evacuate to special needs shelters as staff were providing to
665 those patients prior to evacuation. The plan shall specify how
666 the nurse registry shall facilitate the provision of continuous
667 care by persons referred for contract to persons who are
668 registered pursuant to s. 252.355 during an emergency that
669 interrupts the provision of care or services in private
670 residencies. Nurse registries may establish links to local
671 emergency operations centers to determine a mechanism to
672 approach areas within the disaster area in order for the

673 provider to reach its clients. The presentation of nurse
674 registry clients to a special needs shelter without the nurse
675 registry provider making a good faith effort to provide services
676 in the shelter setting will constitute a Class II deficienty
677 subject to sanctions provided in s. 400.484 (2) (b), F.S..
678 (e) The comprehensive emergency management plan required
679 by this subsection is subject to review and approval by the
680 county health department. During its review, the county health
681 department shall contact state and local health and medical
682 stakeholders during its review, when necessary ~~ensure that, at a~~
683 ~~minimum, the local emergency management agency, the Agency for~~
684 ~~Health Care Administration, and the local chapter of the~~
685 ~~American Red Cross or other lead sheltering agency are given the~~
686 ~~opportunity to review the plan.~~ ~~T~~he county health department
687 shall complete its review to ensure that the plan is in
688 accordance with the criteria set in the Agency for Health Care
689 Administration rule within 90 days after receipt of the plan and
690 shall either approve the plan or advise the nurse registry of
691 necessary revisions.
692 If a nurse registry fails to submit a plan or fails to
693 submit requested information or revisions to the county health
694 department with 30 days after written notification from the
695 county health department, the county health department shall
696 notify the Agency for Health Care Administration. The agency
697 shall notify the nurse registry that such failure constitutes a
698 deficiency, subject to a fine of $5,000 per occurrence. If the
699 plan is not submitted, information is not provided, or revisions
700 are not made as requested, the agency may impose the fine.

701 (f) For any nurse registry that operates in more than one
702 county, the Department of Health shall review the plan. The
703 Department of Health shall make every effort to avoid imposing
704 differing requirements based on differences between counties on
705 the nurse registry.
706 Section 8. Paragraphs (a) and (b) of subsection (1) of
707 section 400.610, Florida Statutes, are amended to read:
708 400.610 Administration and management of a hospice.--
709 (1) A hospice shall have a clearly defined organized
710 governing body, consisting of a minimum of seven persons who are
711 representative of the general population of the community
712 served. The governing body shall have autonomous authority and
713 responsibility for the operation of the hospice and shall meet
714 at least quarterly. The governing body shall:
715 (b)1. Prepare and maintain a comprehensive emergency
716 management plan that provides for continuing hospice services in
717 the event of an emergency that is consistent with local special
718 needs plans. The plan shall include provisions for ensuring
719 continuing care to hospice patients who go to special needs
720 shelters. The plan shall include how the hospice provider will
721 continue to provide staff to perform the same type and quantity
722 of services to their patients who evacuate to special needs
723 shelters as staff were providing to those patients prior to
724 evacuation. The plan is subject to review and approval by the
725 county health department, except as provided in subparagraph 2.
726 During its review, the county health department shall contact
727 state and local health and medical stakeholders, when necessary
728 ~~ensure that the department, the agency, and the local chapter of~~

729 ~~the American Red Cross or other lead sheltering agency have an~~
730 ~~opportunity to review and comment on the plan~~. The county health
731 department shall complete its review to ensure that the plan is
732 in accordance with the criteria set in the Department of Elderly
733 Affairs rule within 90 days after receipt of the plan and shall
734 either approve the plan or advise the hospice of necessary
735 revisions. Hospice providers may establish links to local
736 emergency operations centers to determine a mechanism to
737 approach areas within the disaster area in order for the
738 provider to reach its clients. The presentation of hospice
739 clients to a special needs shelter without the hospice provider
740 making a good faith effort to provide services in the shelter
741 setting will constitute abandonment of the client.
742 2. For any hospice that operates in more than one county,
743 the Department of Health during its ~~shall~~ review shall contact
744 state and local health and medical stakeholders, when necessary
745 ~~the plan, after consulting with all of the county health~~
746 ~~departments, the agency, and all the local chapters of the~~
747 ~~American Red Cross or other lead sheltering agency in the areas~~
748 ~~of operation for that particular hospice~~. The Department of
749 Health shall complete its review to ensure that the plan is in
750 accordance with the criteria set in the Department of Elderly
751 Affairs rule within 90 days after receipt of the plan and shall
752 either approve the plan or advise the hospice of necessary
753 revisions. The Department of Health shall make every effort to
754 avoid imposing on the hospice differing requirements based on
755 differences between counties.
756 Section 9. Subsection (13), subsection (15), and

757 subsection (16) of section 400.925, Florida Statutes, are
758 amended to read:
759 400.925 Definitions.--As used in this part, the term:
760 (13) Life-supporting or life-sustaining equipment means a
761 device that is essential to or that yields information that is
762 essential to, the restoration or continuation of a bodily
763 function important to the continuation of human life. Life-
764 supporting or life-sustaining equipment includes apnea monitors,
765 enteral feeding pumps, infusion pumps, portable home dialysis
766 equipment, and ventilator equipment and supplies for all related
767 equipment, including oxygen equipment and related respiratory
768 equipment.
769 Section 10. Section 400.934, Florida Statutes, is amended
770 to read:
771 400.934 Minimum standards.--As a requirement of licensure,
772 home medical equipment providers shall:
773 (20) Prepare and maintain a comprehensive emergency
774 management plan that meets minimum criteria established by the
775 agency in rule pursuant to 400.935, F.S. The plan shall be
776 updated annually and shall provide for continuing home medical
777 equipment services for life-supporting or life-sustaining
778 equipment, as defined in 400.925, F.S., during an emergency that
779 interrupts home medical equipment services in the patient's
780 home. The plan shall include how the home medical equipment
781 provider will continue to provide equipment to perform the same
782 type and quantity of services to their patients who evacuate to
783 special needs shelters as staff were providing to those patients
784 prior to evacuation. The plan shall describe how the home

785 medical provider establishes and maintains an effective response
786 to emergencies and disasters, including: notifying staff when
787 emergency response measures are initiated; providing for
788 communication between staff members, county health departments,
789 and local emergency management agencies, including a backup
790 system; identifying resources necessary to continue essential
791 care or services or referrals to other organizations subject to
792 written agreement; and prioritizing and contacting consumers who
793 need continued medical equipment services and supplies.
794 (a) The plan is subject to review and approval by the
795 county health department. During its review, the county health
796 department shall contact state and local health and medical
797 stakeholders, when necessary. The county health department shall
798 complete its review to ensure that the plan is in accordance
799 with the criteria set in the Agency for Health Care
800 Administration rule within 90 days after receipt of the plan.
801 If a home medical equipment provider fails to submit a plan
802 or fails to submit requested information or revisions to the
803 county health department within 30 days after written
804 notification from the county health department, the county
805 health department shall notify the Agency for Health Care
806 Administration. The agency shall notify the home medical
807 equipment provider that such failure constitutes a deficiency,
808 subject to a fine of $5,000 per occurrence. If the plan is not
809 submitted, information is not provided, or revisions are not
810 made as requested, the agency may impose the fine.
811 (b) For any home medical equipment provider that operates
812 in more than one county, the Department of Health shall review

813 the plan. The Department of Health shall make every effort to
814 avoid imposing differing requirements based on differences
815 between counties on the home medical equipment provider.
816 (1) Each home medical equipment provider shall maintain a
817 current prioritized list of patients who needs continued
818 services during an emergency. The list shall indicate how
819 services shall be continued in the event of an emergency or
820 disaster for each consumer and if the consumer is to be
821 transported to a special needs shelter, and shall indicate if
822 the consumer has life-supporting or life-sustaining equipment,
823 including the specific type of equipment and related supplies.
824 The list shall be furnished to county health departments and to
825 local emergency management agencies, upon request.
826 (2) Home medical equipment providers may establish links
827 to local emergency operations centers to determine a mechanism
828 to approach areas within the disaster in order for the provider
829 to reach its patients.
830 Section 11. Section 400.935, Florida Statutes, is amended
831 to read:
832 400.935 Rules establishing minimum standards.--The agency
833 shall adopt, publish, and enforce rules to implement this part,
834 which must provide reasonable and fair minimum standards
835 relating to:
836 (10) Home medical equipment requiring home medical
837 equipment services.
838 (11) Preparation of a comprehensive emergency management
839 plan pursuant to s. 400.934.
840 (a) The Agency for Health Care Administration shall adopt

841 rules establishing minimum criteria for the plan, including
842 maintaining patient equipment and supply lists that can
843 accompany patients who are transported from their homes, in
844 consultation with the Department of Health and the Department of
845 Community Affairs.
846 Section 12. Section 408.831, Florida Statutes, is amended
847 to read:
848 408.831 Denial, suspension, or revocation of a license,
849 registration, certificate, or application.--
850 (1) In addition to any other remedies provided by law, the
851 agency may deny each application or suspend or revoke each
852 license, registration, or certificate of entities regulated or
853 licensed by it:
854 (a) If the applicant, licensee, registrant, or certificate
855 holder, or, in the case of a corporation, partnership, or other
856 business entity, if any officer, director, agent, or managing
857 employee of that business entity or any affiliated person,
858 partner, or shareholder having an ownership interest equal to 5
859 percent or greater in that business entity, has failed to pay
860 all outstanding fines, liens, or overpayments assessed by final
861 order of the agency or final order of the Centers for Medicare
862 and Medicaid Services, not subject to further appeal, unless a
863 repayment plan is approved by the agency; or
864 (b) For failure to comply with any repayment plan.
865 (2) In reviewing any application requesting a change of
866 ownership or change of the licensee, registrant, or
867 certificateholder, the transferor shall, prior to agency
868 approval of the change, repay or make arrangements to repay any

869 amounts owed to the agency. Should the transferor fail to repay
870 or make arrangements to repay the amounts owed to the agency,
871 the issuance of a license, registration, or certificate to the
872 transferee shall be delayed until repayment or until
873 arrangements for repayment are made.
874 (3) Entities subject to this section may exceed their
875 licensed capacity to act as a receiving facility in accordance
876 with an emergency operations plan for clients of evacuating
877 providers from a geographic area where an evacuation order has
878 been issued by a local authority having jurisdiction. While in
879 an overcapacity status, each provider must furnish or arrange
880 for appropriate care and services to all clients. In addition,
881 the agency may approve requests for overcapacity beyond 15 days,
882 which approvals shall be based upon satisfactory justification
883 and need as provided by the receiving and sending facility.
884 (4) An inactive license may be issued to a licensee
885 subject to this section when the provider is located in a
886 geographic area where a state of emergency was declared by the
887 Governor of Florida if the provider:
888 (a) Suffered damage to the provider's operation during
889 that state of emergency.
890 (b) Is currently licensed.
891 (c) Does not have a provisional license.
892 (d) Will be temporarily unable to provide services but is
893 reasonably expected to resume services within 12 months.
894
895 An inactive license may be issued for a period not to exceed 12
896 months but may be renewed by the agency for up to 12 additional

897 months upon demonstration to the agency of progress toward
898 reopening. A request by a licensee for an inactive license or to
899 extend the previously approved inactive period must be submitted
900 in writing to the agency, accompanied by written justification
901 for the inactive license which states the beginning and ending
902 dates of inactivity and includes a plan for the transfer of any
903 clients to other providers and appropriate licensure fees. Upon
904 agency approval, the licensee shall notify clients of any
905 necessary discharge or transfer as required by authorizing
906 statutes or applicable rules. The beginning of the inactive
907 licensure period shall be the date the provider ceases
908 operations. The end of the inactive period shall become the
909 licensee expiration date and all licensure fees must be current,
910 paid in full, and may be prorated. Reactivation of an inactive
911 license requires the prior approval by the agency of a renewal
912 application, including payment of licensure fees and agency
913 inspections indicating compliance with all requirements of this
914 part and applicable rules and statutes.
915 (5) ~~(3)~~ This section provides standards of enforcement
916 applicable to all entities licensed or regulated by the Agency
917 for Health Care Administration. This section controls over any
918 conflicting provisions of chapters 39, 381, 383, 390, 391, 393,
919 394, 395, 400, 408, 468, 483, and 641 or rules adopted pursuant
920 to those chapters.
921 Section 14. Section 252.357, Florida Statutes, is created
922 to read:
923 252.357 Monitoring of nursing homes during disaster.--The
924 Florida Comprehensive Emergency Management Plan shall permit the

925 Agency for Health Care Administration, working from the agency's
926 offices or in the Emergency Operations Center, ESF-8, to make
927 initial contact with each nursing home in the disaster area. The
928 agency, by July 15, 2006, and annually thereafter, shall publish
929 on the Internet an emergency telephone number that can be used
930 by nursing homes to contact the agency on a schedule established
931 by the agency to report requests for assistance. The agency may
932 also provide the telephone number to each facility when it makes
933 the initial facility call.
934 Section 15. This act shall take effect July 1, 2006.

Bill No. **PCB HCG 06-01**

COUNCIL/COMMITTEE ACTION

ADOPTED	__	(Y/N)
ADOPTED AS AMENDED	__	(Y/N)
ADOPTED W/O OBJECTION	__	(Y/N)
FAILED TO ADOPT	__	(Y/N)
WITHDRAWN	__	(Y/N)
OTHER	____	

---

1 Council/Committee hearing bill: Health Care General
2 Representative(s) Harrell offered the following:
3
4 **Amendment (with title amendment)**
5 Remove everything after the enacting clause and insert:
6 Section 1. Section 252.355, Florida Statutes, is amended
7 to read:
8 252.355 Registry of persons with special needs; notice.--
9 (1) In order to meet the special needs of persons who
10 would need assistance during evacuations and sheltering because
11 of physical, mental, cognitive impairment, or sensory
12 disabilities, each local emergency management agency in the
13 state shall maintain a registry of persons with special needs
14 located within the jurisdiction of the local agency. The
15 registration shall identify those persons in need of assistance
16 and plan for resource allocation to meet those identified needs.
17 To assist the local emergency management agency in identifying
18 such persons, home health agencies, hospices, nurse registries,
19 home medical equipment providers, the Department of Children and
20 Family Services, Department of Health, Agency for Health Care
21 Administration, Department of Education, Agency for Persons with
22 Disabilities, ~~Department of Labor and Employment Security,~~ and

23 Department of Elderly Affairs shall provide registration
24 information to all of their special needs clients and to all
25 people with disabilities or special needs who receive services
26 ~~incoming clients as a part of the intake process~~. The registry
27 shall be maintained year-round ~~updated annually~~. The
28 registration program shall give persons with special needs the
29 option of preauthorizing emergency response personnel to enter
30 their homes during search and rescue operations if necessary to
31 assure their safety and welfare following disasters.
32 (2) The Department of Community Affairs shall be the
33 designated lead agency responsible for community education and
34 outreach to the general public, including special needs clients,
35 regarding registration and special needs shelters and general
36 information regarding shelter stays. The Department of Community
37 Affairs shall disseminate such educational and outreach
38 information through the local emergency management offices. The
39 department shall coordinate the development of curriculum and
40 dissemination of all community education and outreach related to
41 special needs shelters with the Clearinghouse on Disability
42 Information of the Governor's Working Group on the Americans
43 with Disabilities Act, the Department of Children and Family
44 Services, the Department of Health, the Agency for Health Care
45 Administration, the Department of Education, the Agency for
46 Persons with Disabilities, and the Department of Elderly
47 Affairs. The special needs shelter is considered a public
48 facility when it is activated for a disaster. Under the
49 Americans with Disabilities Act (ADA), Public Law 101.336,
50 businesses and organizations that serve the public must allow
51 people with disabilities to bring their service animals into all
52 areas of the facility where customers are normally allowed to
53 go.

54 ~~(2) On or before May 1 of each year each electric utility~~
55 ~~in the state shall annually notify residential customers in its~~
56 ~~service area of the availability of the registration program~~
57 ~~available through their local emergency management agency.~~
58 (3) Each electric utility in the state shall notify
59 residential customers in its service area of the availability of
60 the registration program available through their local emergency
61 management agency in either of the following ways:
62 (a) Upon the initiation of new residential service with
63 the electric utility, and one time for all residential customers
64 between January 1 and May 31 of each year, or
65 (b) Two times for all residential customers between
66 January 1 and May 31 of each year.
67
68 The notification required above may be made by any available
69 means including but not limited to written, electronic or verbal
70 notification. The notification may be made concurrently with
71 any other notification to residential customers required by law
72 or rule.
73 (4) ~~(3)~~ All records, data, information, correspondence, and
74 communications relating to the registration of persons with
75 special needs as provided in subsection (1) are confidential and
76 exempt from the provisions of s. 119.07(1), except that such
77 information shall be available to other emergency response
78 agencies, as determined by the local emergency management
79 director, and to the Department of Health in the furtherance of
80 its duties and responsibilities.
81 (5) ~~(4)~~ All appropriate agencies and community-based
82 service providers, including home health care providers, ~~and~~
83 hospices, nurse registries, and home medical equipment
84 providers, shall assist emergency management agencies by

85 collecting registration information for persons with special
86 needs as part of program intake processes, establishing programs
87 to increase the awareness of the registration process, and
88 educating clients about the procedures that may be necessary for
89 their safety during disasters. Clients of state or federally
90 funded service programs with physical, mental, cognitive
91 impairment, or sensory disabilities who need assistance in
92 evacuating, or when in shelters, must register as persons with
93 special needs.
94 Section 2. Section 252.3568, Florida Statutes, is created
95 to read:
96 252.3568 Emergency sheltering of persons with pets.--
97 (1) GENERAL PROVISIONS.--In accordance with the provisions
98 of s. 252.35, the division shall address evacuation of persons
99 with pets in the shelter component of the state comprehensive
100 emergency management plan. The Department of Agriculture and
101 Consumer Services shall assist the division in determining
102 strategies regarding this activity.
103 Section 3. Section 252.357, Florida Statutes, is created
104 to read:
105 252.357 Monitoring of nursing homes during disaster.--The
106 Florida Comprehensive Emergency Management Plan shall permit the
107 Agency for Health Care Administration, working from the agency's
108 offices or in the Emergency Operations Center, ESF-8, to make
109 initial contact with each nursing home in the disaster area. The
110 agency, by July 15, 2006, and annually thereafter, shall publish
111 on the Internet an emergency telephone number that may be used
112 by nursing homes to contact the agency on a schedule established
113 by the agency to report requests for assistance. The agency may
114 also provide the telephone number to each facility when it makes
115 the initial facility call.

116 Section 4. Subsections (2) and (4) of section 252.385,
117 Florida Statutes, are amended to read:
118 252.385 Public shelter space.--
119 (2)(a) The division shall administer a program to survey
120 existing schools, universities, community colleges, and other
121 state-owned, municipally owned, and county-owned public
122 buildings and any private facility that the owner, in writing,
123 agrees to provide for use as a public hurricane evacuation
124 shelter to identify those that are appropriately designed and
125 located to serve as such shelters. The owners of the facilities
126 must be given the opportunity to participate in the surveys. The
127 Board of Regents, district school boards, community college
128 boards of trustees, and the Department of Education are
129 responsible for coordinating and implementing the survey of
130 public schools, universities, and community colleges with the
131 division or the local emergency management agency.
132 (b) By January 31 of each even-numbered year, the Division
133 of Emergency Management of the Department of Community Affairs
134 shall prepare and submit a statewide emergency shelter plan to
135 the Governor and the Cabinet for approval, subject to the
136 requirements for approval provided in s. 1013.37(2). The plan
137 shall also identify the general location and square footage of
138 special needs shelters, by regional planning council region,
139 during the next 5 years. The Department of Health shall assist
140 the division in determining the estimated need for special needs
141 shelter space and the adequacy of the facility to meet the needs
142 of special needs persons, based on information from the special
143 needs registration and other information.
144 (c) The division shall include information on the
145 availability of pet friendly shelters in the statewide emergency
146 shelter plan.

147 (4)(a) Public facilities, including schools, postsecondary
148 education facilities, and other facilities owned or leased by
149 the state or local governments, but excluding hospitals, hospice
150 care facilities, assisted living facilities, or nursing homes,
151 which are suitable for use as public hurricane evacuation
152 shelters shall be made available at the request of the local
153 emergency management agencies. The local emergency management
154 agency shall inspect a designated facility to determine its
155 readiness prior to activating such facility for a specific
156 hurricane or disaster. Such agencies shall coordinate with the
157 appropriate school board, university, community college, or
158 local governing board when requesting the use of such facilities
159 as public hurricane evacuation shelters.
160 (b) The Department of Management Services shall
161 incorporate provisions for the use of suitable leased public
162 facilities as public hurricane evacuation shelters into lease
163 agreements for state agencies. Suitable leased public facilities
164 include leased public facilities that are solely occupied by
165 state agencies and have at least 2,000 square feet of net floor
166 area in a single room or in a combination of rooms having a
167 minimum of 400 square feet in each room. The net square footage
168 of floor area ~~must~~ shall be determined by subtracting from the
169 gross square footage the square footage of spaces such as
170 mechanical and electrical rooms, storage rooms, open corridors,
171 restrooms, kitchens, science or computer laboratories, shop or
172 mechanical areas, administrative offices, records vaults, and
173 crawl spaces.
174 (c) The Department of Management Services shall, in
175 consultation with local and state emergency management agencies
176 assess the Department of Management Services facilities to
177 identify the extent to which each facility has public hurricane

178 evacuation shelter space. The Department of Management Services
179 shall submit proposed facility retrofit projects that
180 incorporate hurricane protection enhancements to the department
181 for assessment and inclusion in the annual report prepared in
182 accordance with subsection (3).
183 Section 5. Section 381.0303, Florida Statutes, is amended
184 to read:
185 381.0303 ~~Health practitioner recruitment for~~ Special needs
186 shelters.--
187 (1) PURPOSE.--The purpose of this section is to provide
188 for the operation, maintenance, and closure of special needs
189 shelters and to designate the Department of Health, through its
190 county health departments, as the lead agency for coordination
191 of the recruitment of health care practitioners, as defined in
192 s. 456.001(4), to staff special needs shelters in times of
193 emergency or disaster and to provide resources to the department
194 to carry out this responsibility. However, nothing in this
195 section prohibits a county health department from entering into
196 an agreement with a local emergency management agency to assume
197 the lead responsibility for recruiting health care
198 practitioners.
199 (2) SPECIAL NEEDS SHELTER PLAN; STAFFING; CLOSURE; STATE
200 AGENCY ASSISTANCE ~~AND STAFFING~~.--Provided funds have been
201 appropriated to support ~~medical services~~ disaster coordinator
202 positions in county health departments~~,~~:
203 (a) The department shall assume lead responsibility for
204 the ~~local~~ coordination of local medical and health care
205 providers, the American Red Cross, and other interested parties
206 in developing a plan for the staffing and medical management of
207 special needs shelters. The local Children's Medical Services
208 offices shall assume lead responsibility for the coordination of

209 local medical and health care providers, the American Red Cross,
210 and other interested parties in developing a plan for the
211 staffing and medical management of pediatric special needs
212 shelters. Plans shall conform to ~~The plan shall be in~~
213 ~~conformance with~~ the local comprehensive emergency management
214 plan.

215 (b) ~~(a)~~ County health departments shall, in conjunction
216 with the local emergency management agencies, have the lead
217 responsibility for coordination of the recruitment of health
218 care practitioners to staff local special needs shelters. County
219 health departments shall assign their employees to work in
220 special needs shelters when those employees are needed to
221 protect the health and safety of special needs persons ~~of~~
222 ~~patients~~. County governments shall assist the Department of
223 Health with non-medical staffing and operating of special needs
224 shelters. The local health department and emergency management
225 agency shall coordinate these efforts to ensure appropriate
226 staffing in special needs shelters.

227 (c) ~~(b)~~ The appropriate county health department,
228 Children's Medical Services office, and local emergency
229 management agency shall jointly decide ~~determine~~ who has
230 responsibility for medical supervision in each ~~a~~ special needs
231 shelter and shall notify the department of Community Affairs
232 Division of Emergency Management and the Department of Health of
233 their decision.

234 (d) ~~(c)~~ Local emergency management agencies shall be
235 responsible for the designation, ~~and~~ operation, and
236 infrastructure of special needs shelters during times of
237 emergency or disaster and the closure of the facilities
238 following an emergency or disaster. The emergency management
239 agency and the local health department shall coordinate these

240 efforts to ensure appropriate designation, operation and
241 infrastructure in special needs shelters. County health
242 departments shall assist the local emergency management agency
243 with regard to the management of medical services in special
244 needs shelters. However, nothing in this section prohibits a
245 county health department from entering into an alternative
246 agreement with a local emergency management agency to assume the
247 lead responsibility for special needs shelter supplies and
248 equipment.
249 (e) State employees with a pre-established role provided
250 by the employee's respective agency in disaster response unless
251 they have other mandated response activities that preclude
252 participation, are subject to serve in times of disaster
253 commensurate with their knowledge, skills, and abilities and any
254 needed activities related to the situation.
255 (f) The Secretary of Elderly Affairs, or his or her
256 designee, shall convene, at any time that he or she deems
257 appropriate and necessary, a multiagency special needs shelter
258 discharge planning team or teams to assist local areas that are
259 severely impacted by a natural or manmade disaster that requires
260 the use of special needs shelters. Multiagency special needs
261 shelter discharge planning teams shall provide assistance to
262 local emergency management agencies with the continued operation
263 or closure of the shelters, as well as with the discharge of
264 special needs clients to alternate facilities if necessary.
265 Local emergency management agencies may request the assistance
266 of a multiagency special needs shelter discharge planning team
267 by alerting statewide emergency management officials of the
268 necessity for additional assistance in their area. The Secretary
269 of Elderly Affairs is encouraged to proactively work with other
270 state agencies prior to any natural disasters for which warnings

271 are provided to ensure that multiagency special needs shelter
272 discharge planning teams are ready to assemble and deploy
273 rapidly upon a determination by state emergency management
274 officials that a disaster area requires additional assistance.
275 The Secretary of Elderly Affairs may call upon any state agency
276 or office to provide staff to assist a multiagency special needs
277 shelter discharge planning team or teams. Unless the secretary
278 determines that the nature or circumstances surrounding the
279 disaster do not warrant participation from a particular agency's
280 staff, each multiagency special needs shelter discharge planning
281 team shall include at least one representative from each of the
282 following state agencies:
283 1. Department of Elderly Affairs.
284 2. Department of Health.
285 3. Department of Children and Family Services.
286 4. Department of Veterans' Affairs.
287 5. Department of Community Affairs.
288 6. Agency for Health Care Administration.
289 7. Agency for Persons with Disabilities.
290 (3) REIMBURSEMENT TO HEALTH CARE PRACTITIONERS AND
291 FACILITIES.--
292 (a) The Department of Health shall upon request reimburse~~,~~
293 ~~subject to the availability of funds for this purpose,~~ health
294 care practitioners, as defined in s. 456.001, provided the
295 practitioner is not providing care to a patient under an
296 existing contract, and emergency medical technicians and
297 paramedics licensed under ~~pursuant to~~ chapter 401, for medical
298 care provided at the request of the department in special needs
299 shelters or at other locations during times of emergency or a
300 declared ~~major~~ disaster. Reimbursement for health care
301 practitioners, except for physicians licensed under ~~pursuant to~~

302 chapter 458 or chapter 459, shall be based on the average hourly
303 rate that such practitioners were paid according to the most
304 recent survey of Florida hospitals conducted by the Florida
305 Hospital Association or other nationally or state recognized
306 data source. Reimbursement shall be requested on forms prepared
307 by the Department of Health and shall be paid as specified in
308 paragraph (c).
309 (b) If, upon closure of a special needs shelter, a
310 multiagency special needs shelter discharge planning team
311 determines that it is necessary to discharge special needs
312 persons to other health care facilities, such as hospitals,
313 nursing homes, assisted living facilities, and community
314 residential homes, the receiving facilities shall be eligible
315 for reimbursement for services provided to the individuals for
316 up to 90 days. Any facility eligible for reimbursement under
317 this paragraph shall submit invoices for reimbursement on forms
318 developed by the department. A facility must show proof of a
319 written request from a representative of an agency serving on
320 the multiagency special needs shelter discharge planning team
321 that the individual for whom the facility is seeking
322 reimbursement for services rendered was referred to that
323 facility from a special needs shelter. The department shall
324 specify by rule which expenses are reimbursable and the rate of
325 reimbursement for each service. Reimbursement for the services
326 described in this paragraph shall be paid as specified in
327 paragraph (c).
328 (c) If a Presidential Disaster Declaration has been issued
329 ~~made, and the Federal Government makes funds available~~, the
330 department shall request federal ~~use such funds for~~
331 reimbursement of eligible expenditures. In other situations, or
332 if federal funds do not fully compensate the department for

333 reimbursements permissible under ~~reimbursement made pursuant to~~
334 this section, the department shall process a budget amendment to
335 obtain reimbursement from unobligated, unappropriated moneys in
336 the General Revenue Fund. The department shall not provide
337 reimbursement to facilities under this subsection for services
338 provided to a special needs person if, during the period of time
339 in which the services were provided, the individual was enrolled
340 in another state-funded program, such as Medicaid or another
341 similar program, or entities providing health insurance as
342 defined in s. 624.603 or health maintenance organizations or
343 prepaid health clinics as defined in chapter 641, which would
344 otherwise pay for the same services. Travel expense and per diem
345 costs shall be reimbursed pursuant to s. 112.061.
346 (4) HEALTH CARE PRACTITIONER REGISTRY.--The department may
347 use the registries established in ss. 401.273 and 456.38 when
348 health care practitioners are needed to staff special needs
349 shelters or to assist with other disaster related activities
350 ~~staff disaster medical assistance teams~~.
351 (5) SPECIAL NEEDS SHELTER INTERAGENCY COMMITTEE.--The
352 Secretary ~~Department~~ of Health may establish a special needs
353 shelter interagency committee and serve as or appoint a designee
354 to serve as the committee's chair. The department shall provide
355 any necessary staff and resources to support the committee in
356 the performance of its duties~~, to be chaired and staffed by the~~
357 ~~department~~. The committee shall address and resolve problems
358 related to special needs shelters not addressed in the state
359 comprehensive emergency medical plan and shall consult on ~~serve~~
360 ~~as an oversight committee to monitor~~ the planning and operation
361 of special needs shelters.
362 (a) The committee shall ~~may~~:

363 1. Develop, ~~and~~ negotiate and regularly review any
364 necessary interagency agreements.
365 2. Undertake other such activities as the department deems
366 necessary to facilitate the implementation of this section.
367 3. Submit recommendations to the Legislature as necessary.
368 (b) The special needs shelter interagency committee shall
369 be composed of representatives of emergency management, health,
370 medical, and social services organizations. Membership shall
371 include, but shall not be limited to, representatives of the
372 Departments of Health, Community Affairs, Children and Family
373 Services, Elderly Affairs, ~~Labor and Employment Security,~~ and
374 Education; the Agency for Health Care Administration; the
375 Florida Medical Association; the Florida Osteopathic Medical
376 Association; Associated Home Health Industries of Florida, Inc.;
377 the Florida Nurses Association; the Florida Health Care
378 Association; the Florida Assisted Living Affiliation
379 ~~Association~~; the Florida Hospital Association; the Florida
380 Statutory Teaching Hospital Council; the Florida Association of
381 Homes for the Aging; the Florida Emergency Preparedness
382 Association; the American Red Cross; Florida Hospices and
383 Palliative Care, Inc.; the Association of Community Hospitals
384 and Health Systems; the Florida Association of Health
385 Maintenance Organizations; the Florida League of Health Systems;
386 Private Care Association; ~~and~~ the Salvation Army; the Florida
387 Association of Aging Services Providers; AARP, and the Florida
388 Renal Coalition.
389 (c) Meetings of the committee shall be held in
390 Tallahassee, and members of the committee shall serve at the
391 expense of the agencies or organizations they represent. The
392 committee shall make every effort to use teleconference or video

393 conference capabilities in order to ensure statewide input and
394 participation.
395 (6) RULES.--The department has the authority to adopt
396 rules necessary to implement this section. Rules shall ~~may~~
397 include:
398 (a) The ~~a~~ definition of a special needs person, including
399 eligibility criteria for individuals with physical, mental,
400 cognitive impairment or sensory disabilities and the services a
401 special needs person can expect to receive in a special needs
402 shelter. ~~patient, specify physician reimbursement, and designate~~
403 ~~which county health departments will have responsibility for~~
404 ~~implementation of subsections (2) and (3)~~.
405 (b) The process for special needs shelter health care
406 practitioner and facility reimbursement for services provided in
407 a disaster event.
408 (c) Guidelines for special needs shelter staffing levels
409 to provide services.
410 (d) The definition of and standards for special needs
411 shelter supplies and equipment, including durable medical
412 equipment.
413 (e) Compliance with applicable service animal laws.
414 (f) Standards for the special needs shelter registration
415 process including guidelines for addressing the needs of
416 unregistered persons in need of a special needs shelter.
417 (g) Standards for addressing the needs of families where
418 only one dependent is eligible for the special needs shelter,
419 and the needs of adults with special needs who are caregivers
420 for individuals without special needs.
421 (h) The requirement of the county health departments to
422 seek the participation of hospitals, nursing homes, assisted
423 living facilities, home health agencies, hospice providers,

424 nurse registries and home medical equipment providers, dialysis
425 centers, and other health and medical emergency preparedness
426 stakeholders in pre-event planning activities.
427 (7) ~~REVIEW OF~~ EMERGENCY MANAGEMENT PLANS; CONTINUITY OF
428 CARE.--Each emergency management plan submitted to a county
429 health department by a home health agency pursuant to s.
430 400.492, by a nurse registry pursuant to s. 400.506, by a
431 hospice pursuant to s. 400.610, or a home medical equipment
432 provider pursuant to s. 400.925, shall specify how the home
433 health agency, nurse registry, hospice or home medical equipment
434 provider will continue to provide staff or equipment to perform
435 the same type and quantity of services to their patients who
436 evacuate to special needs shelters as was provided to those
437 patients prior to evacuation. The submission of Emergency
438 management plans to county health departments by home health
439 agencies pursuant to s. 400.497(8)(c) and (d) and by nurse
440 registries pursuant to s. 400.506(16)(e) and by hospice programs
441 pursuant to s. 400.610(1)(b) and by home medical equipment
442 providers pursuant to s. 400.934(20)(a) is conditional upon the
443 receipt of an appropriation by the department to establish
444 ~~medical services~~ disaster coordinator positions in county health
445 departments unless the secretary of the department and a local
446 county commission jointly determine to require such plans to be
447 submitted based on a determination that there is a special need
448 to protect public health in the local area during an emergency.
449 Section 6. Section 400.492, Florida Statutes, is amended
450 to read:
451 400.492 Provision of services during an emergency.--Each
452 home health agency shall prepare and maintain a comprehensive
453 emergency management plan that is consistent with the standards
454 adopted by national or state accreditation organizations and

455 consistent with the local special needs plan. The plan shall be
456 updated annually and shall provide for continuing home health
457 services during an emergency that interrupts patient care or
458 services in the patient's home. The plan shall include how the
459 home health agency will continue to provide staff to perform the
460 same type and quantity of services to their patients who
461 evacuate to special needs shelters as staff were providing to
462 those patients prior to evacuation. The plan shall describe how
463 the home health agency establishes and maintains an effective
464 response to emergencies and disasters, including: notifying
465 staff when emergency response measures are initiated; providing
466 for communication between staff members, county health
467 departments, and local emergency management agencies, including
468 a backup system; identifying resources necessary to continue
469 essential care or services or referrals to other organizations
470 subject to written agreement; and prioritizing and contacting
471 patients who need continued care or services.
472 (1) Each patient record for patients who are listed in the
473 registry established pursuant to s. 252.355 shall include a
474 description of how care or services will be continued in the
475 event of an emergency or disaster. The home health agency shall
476 discuss the emergency provisions with the patient and the
477 patient's caregivers, including where and how the patient is to
478 evacuate, procedures for notifying the home health agency in the
479 event that the patient evacuates to a location other than the
480 shelter identified in the patient record, and a list of
481 medications and equipment which must either accompany the
482 patient or will be needed by the patient in the event of an
483 evacuation.
484 (2) Each home health agency shall maintain a current
485 prioritized list of patients who need continued services during

486 an emergency. The list shall indicate how services shall be
487 continued in the event of an emergency or disaster for each
488 patient and if the patient is to be transported to a special
489 needs shelter, and shall indicate if the patient is receiving
490 skilled nursing services and the patient's medication and
491 equipment needs. The list shall be furnished to county health
492 departments and to local emergency management agencies, upon
493 request.
494 (3) Home health agencies shall not be required to continue
495 to provide care to patients in emergency situations that are
496 beyond their control and that make it impossible to provide
497 services, such as when roads are impassable or when patients do
498 not go to the location specified in their patient records. Home
499 health agencies may establish links to local emergency
500 operations centers to determine a mechanism to approach areas
501 within the disaster area in order for the agency to reach its
502 clients. The presentation of a home health agency client to a
503 special needs shelter without the home health agency making a
504 good faith effort to provide services in the shelter setting
505 will constitute abandonment of the client and shall constitute a
506 Class II deficiency, subject to sanctions provided in section
507 400.484(2)(b) Florida Statutes. For the purposes of this
508 section, "good faith effort" may be demonstrated by documented
509 attempts of staff to follow procedures as outlined in the home
510 health agency's comprehensive emergency management plan and the
511 patient's record, providing continuing care for those patients
512 who have been identified as needing care by the home health
513 agency in the event of an emergency pursuant to s. 400.492(1).
514 (4) Notwithstanding the provisions of s. 400.464(2) or any
515 other provision of law to the contrary, a home health agency may

516 provide services in a special needs shelter located in any
517 county.
518 Section 7. Subsection (8) of section 400.497, Florida
519 Statutes, is amended to read:
520 400.497 Rules establishing minimum standards.--The agency
521 shall adopt, publish, and enforce rules to implement this part,
522 including, as applicable, ss. 400.506 and 400.509, which ~~must~~
523 shall provide reasonable and fair minimum standards relating to:
524 (8) Preparation of a comprehensive emergency management
525 plan pursuant to s. 400.492.
526 (c) The plan is subject to review and approval by the
527 county health department. During its review, the county health
528 department shall contact state and local health and medical
529 stakeholders during its review when necessary ~~ensure that the~~
530 ~~following agencies, at a minimum, are given the opportunity to~~
531 ~~review the plan:~~
532 ~~1. The local emergency management agency.~~
533 ~~2. The Agency for Health Care Administration.~~
534 ~~3. The local chapter of the American Red Cross or other~~
535 ~~lead sheltering agency.~~
536 ~~4. The district office of the Department of Children and~~
537 ~~Family Services~~.
538 The county health department shall complete its review to
539 ensure that the plan is in accordance with the criteria set in
540 the Agency for Health Care Administration rule within 90 ~~60~~ days
541 after receipt of the plan and shall either approve the plan or
542 advise the home health agency of necessary revisions.
543 If the home health agency fails to submit a plan or fails
544 to submit the requested information or revisions to the county
545 health department within 30 days after written notification from
546 the county health department, the county health department shall

547 notify the Agency for Health Care Administration. The agency
548 shall notify the home health agency that such failure
549 constitutes a deficiency, subject to a fine of $5,000 per
550 occurrence. If the plan is not submitted, information is not
551 provided or revisions are not made as requested, the agency may
552 impose the fine.
553 (d) For any home health agency that operates in more than
554 one county, the Department of Health shall review the plan,
555 after consulting with state and local health and medical
556 stakeholders, when necessary ~~all of the county health~~
557 ~~departments, the agency, and all the local chapters of the~~
558 ~~American Red Cross or other lead sheltering agencies in the~~
559 ~~areas of operation for that particular home health agency~~. The
560 Department of Health shall complete its review within 90 days
561 after receipt of the plan and shall either approve the plan or
562 advise the home health agency of necessary revisions. The
563 Department of Health shall make every effort to avoid imposing
564 differing requirements based on differences between counties on
565 the home health agency.
566 Section 8. Paragraph (a) of subsection (16) of section
567 400.506, Florida Statutes, is amended to read:
568 400.506 Licensure of nurse registries; requirements;
569 penalties.--
570 (16) Each nurse registry shall prepare and maintain a
571 comprehensive emergency management plan that is consistent with
572 the criteria in this subsection and with the local special needs
573 plan. The plan shall be updated annually. The plan shall include
574 how the nurse registry will continue to provide staff to perform
575 the same type and quantity of services to their patients who
576 evacuate to special needs shelters as staff were providing to
577 those patients prior to evacuation. The plan shall specify how

578 the nurse registry shall facilitate the provision of continuous
579 care by persons referred for contract to persons who are
580 registered pursuant to s. 252.355 during an emergency that
581 interrupts the provision of care or services in private
582 residencies. Nurse registries may establish links to local
583 emergency operations centers to determine a mechanism to
584 approach areas within the disaster area in order for the
585 provider to reach its clients. The presentation of nurse
586 registry clients to a special needs shelter without the nurse
587 registry provider making a good faith effort to provide services
588 in the shelter setting will constitute a Class II deficiency
589 subject to sanctions provided in s. 400.484 (2) (b), F.S. For
590 the purposes of this section, "good faith effort" may be
591 demonstrated by documented attempts of staff to follow
592 procedures as outlined in the nurse registry's comprehensive
593 emergency management plan, providing continuing care for those
594 patients who have been identified as needing care by the nurse
595 registry in the event of an emergency pursuant to s. 400.506(1).
596 (e) The comprehensive emergency management plan required
597 by this subsection is subject to review and approval by the
598 county health department. During its review, the county health
599 department shall contact state and local health and medical
600 stakeholders, when necessary ~~ensure that, at a minimum, the~~
601 ~~local emergency management agency, the Agency for Health Care~~
602 ~~Administration, and the local chapter of the American Red Cross~~
603 ~~or other lead sheltering agency are given the opportunity to~~
604 ~~review the plan~~. The county health department shall complete its
605 review to ensure that the plan is in accordance with the
606 criteria set in the Agency for Health Care Administration rule
607 within 90 ~~60~~ days after receipt of the plan and shall either

608 approve the plan or advise the nurse registry of necessary
609 revisions.
610 If a nurse registry fails to submit a plan or fails to
611 submit requested information or revisions to the county health
612 department within 30 days after written notification from the
613 county health department, the county health department shall
614 notify the Agency for Health Care Administration. The agency
615 shall notify the nurse registry that such failure constitutes a
616 deficiency, subject to a fine of $5,000 per occurrence. If the
617 plan is not submitted, information is not provided, or revisions
618 are not made as requested, the agency may impose the fine.
619 (f) For any nurse registry that operates in more than one
620 county, the Department of Health shall review the plan. The
621 Department of Health shall complete its review within 90 days
622 after receipt of the plan and shall either approve the plan or
623 advise the nurse registry of necessary revisions. The Department
624 of Health shall make every effort to avoid imposing differing
625 requirements based on differences between counties on the nurse
626 registry.
627 Section 9. Paragraphs (a) and (b) of subsection (1) of
628 section 400.610, Florida Statutes, are amended to read:
629 400.610 Administration and management of a hospice.--
630 (1) A hospice shall have a clearly defined organized
631 governing body, consisting of a minimum of seven persons who are
632 representative of the general population of the community
633 served. The governing body shall have autonomous authority and
634 responsibility for the operation of the hospice and shall meet
635 at least quarterly. The governing body shall:
636 (b)1. Prepare and maintain a comprehensive emergency
637 management plan that provides for continuing hospice services in
638 the event of an emergency that is consistent with local special

639 needs plans. The plan shall include provisions for ensuring
640 continuing care to hospice patients who go to special needs
641 shelters. The plan shall include how the hospice provider will
642 continue to provide staff to perform the same type and quantity
643 of services to their patients who evacuate to special needs
644 shelters as staff were providing to those patients prior to
645 evacuation. The plan is subject to review and approval by the
646 county health department, except as provided in subparagraph 2.
647 During its review, the county health department shall contact
648 state and local health and medical stakeholders, when necessary
649 ~~ensure that the department, the agency, and the local chapter of~~
650 ~~the American Red Cross or other lead sheltering agency have an~~
651 ~~opportunity to review and comment on the plan~~. The county health
652 department shall complete its review to ensure that the plan is
653 in accordance with the criteria set in the Department of Elderly
654 Affairs rule within 90 ~~60~~ days after receipt of the plan and
655 shall either approve the plan or advise the hospice of necessary
656 revisions. Hospice providers may establish links to local
657 emergency operations centers to determine a mechanism to
658 approach areas within the disaster area in order for the
659 provider to reach its clients. The presentation of hospice
660 clients to a special needs shelter without the hospice provider
661 making a good faith effort to provide services in the shelter
662 setting will constitute abandonment of the client subject to
663 sanction as provided by law or rule. For the purposes of this
664 section, "good faith effort" may be demonstrated by documented
665 attempts of staff to follow procedures as outlined in the
666 hospice's comprehensive emergency management plan and providing
667 continuing care for those patients who have been identified as
668 needing alternative caregiver services in the event of an
669 emergency.

670 2. For any hospice that operates in more than one county,
671 the Department of Health during its ~~shall~~ review shall contact
672 state and local health and medical stakeholders, when necessary
673 ~~the plan, after consulting with all of the county health~~
674 ~~departments, the agency, and all the local chapters of the~~
675 ~~American Red Cross or other lead sheltering agency in the areas~~
676 ~~of operation for that particular hospice~~. The Department of
677 Health shall complete its review to ensure that the plan is in
678 accordance with the criteria set in the Department of Elderly
679 Affairs rule within 90 days after receipt of the plan and shall
680 either approve the plan or advise the hospice of necessary
681 revisions. The Department of Health shall make every effort to
682 avoid imposing on the hospice differing requirements based on
683 differences between counties.
684 Section 10. Subsection (13) of section 400.925, Florida
685 Statutes, is amended to read:
686 400.925 Definitions.--As used in this part, the term:
687 (13) Life-supporting or life-sustaining equipment means a
688 device that is essential to or that yields information that is
689 essential to, the restoration or continuation of a bodily
690 function important to the continuation of human life. Life-
691 supporting or life-sustaining equipment includes apnea monitors,
692 enteral feeding pumps, infusion pumps, portable home dialysis
693 equipment, and ventilator equipment and supplies for all related
694 equipment, including oxygen equipment and related respiratory
695 equipment.
696 Section 11. Section 400.934, Florida Statutes, is created
697 to read:
698 400.934 Minimum standards.--As a requirement of licensure,
699 home medical equipment providers shall:

700 (20) Prepare and maintain a comprehensive emergency
701 management plan that meets minimum criteria established by the
702 agency in rule pursuant to 400.935, F.S. The plan shall be
703 updated annually and shall provide for continuing home medical
704 equipment services for life-supporting or life-sustaining
705 equipment, as defined in 400.925, F.S., during an emergency that
706 interrupts home medical equipment services in the patient's
707 home. The plan shall include how the home medical equipment
708 provider will continue to provide equipment to perform the same
709 type and quantity of services to their patients who evacuate to
710 special needs shelters as staff were providing to those patients
711 prior to evacuation. The plan shall describe how the home
712 medical provider establishes and maintains an effective response
713 to emergencies and disasters, including: notifying staff when
714 emergency response measures are initiated; providing for
715 communication between staff members, county health departments,
716 and local emergency management agencies, including a backup
717 system; identifying resources necessary to continue essential
718 care or services or referrals to other organizations subject to
719 written agreement; and prioritizing and contacting consumers who
720 need continued medical equipment services and supplies.
721 (a) The plan is subject to review and approval by the
722 county health department. During its review, the county health
723 department shall contact state and local health and medical
724 stakeholders, when necessary. The county health department shall
725 complete its review to ensure that the plan is in accordance
726 with the criteria set in the Agency for Health Care
727 Administration rule within 90 days after receipt of the plan.
728 If a home medical equipment provider fails to submit a plan
729 or fails to submit requested information or revisions to the
730 county health department within 30 days after written

731 notification from the county health department, the county
732 health department shall notify the Agency for Health Care
733 Administration. The agency shall notify the home medical
734 equipment provider that such failure constitutes a deficiency,
735 subject to a fine of $5,000 per occurrence. If the plan is not
736 submitted, information is not provided, or revisions are not
737 made as requested, the agency may impose the fine.
738 (b) For any home medical equipment provider that operates
739 in more than one county, the Department of Health shall review
740 the plan. The Department of Health shall complete its review
741 within 90 days after receipt of the plan and shall either
742 approve the plan or advise the home medical provider of
743 necessary revisions. The Department of Health shall make every
744 effort to avoid imposing differing requirements based on
745 differences between counties on the home medical equipment
746 provider.
747 (1) Each home medical equipment provider shall maintain a
748 current prioritized list of patients who needs continued
749 services during an emergency. The list shall indicate how
750 services shall be continued in the event of an emergency or
751 disaster for each consumer and if the consumer is to be
752 transported to a special needs shelter, and shall indicate if
753 the consumer has life-supporting or life-sustaining equipment,
754 including the specific type of equipment and related supplies.
755 The list shall be furnished to county health departments and to
756 local emergency management agencies, upon request.
757 (2) Home medical equipment providers may establish links
758 to local emergency operations centers to determine a mechanism
759 to approach areas within the disaster in order for the provider
760 to reach its patients.

761 Section 12. Section 400.935, Florida Statutes, is amended
762 to read:
763 400.935 Rules establishing minimum standards.--The agency
764 shall adopt, publish, and enforce rules to implement this part,
765 which must provide reasonable and fair minimum standards
766 relating to:
767 (10) Home medical equipment requiring home medical
768 equipment services.
769 (11) Preparation of a comprehensive emergency management
770 plan pursuant to s. 400.934.
771 (a) The Agency for Health Care Administration shall adopt
772 rules establishing minimum criteria for the plan, including
773 maintaining patient equipment and supply lists that can
774 accompany patients who are transported from their homes, in
775 consultation with the Department of Health and the Department of
776 Community Affairs.
777 Section 13. Section 408.831, Florida Statutes, is amended
778 to read:
779 408.831 Denial, suspension, or revocation of a license,
780 registration, certificate, or application.--
781 (1) In addition to any other remedies provided by law, the
782 agency may deny each application or suspend or revoke each
783 license, registration, or certificate of entities regulated or
784 licensed by it:
785 (a) If the applicant, licensee, registrant, or
786 certificateholder, or, in the case of a corporation,
787 partnership, or other business entity, if any officer, director,
788 agent, or managing employee of that business entity or any
789 affiliated person, partner, or shareholder having an ownership
790 interest equal to 5 percent or greater in that business entity,
791 has failed to pay all outstanding fines, liens, or overpayments

792 assessed by final order of the agency or final order of the
793 Centers for Medicare and Medicaid Services, not subject to
794 further appeal, unless a repayment plan is approved by the
795 agency; or
796 (b) For failure to comply with any repayment plan.
797 (2) In reviewing any application requesting a change of
798 ownership or change of the licensee, registrant, or
799 certificateholder, the transferor shall, prior to agency
800 approval of the change, repay or make arrangements to repay any
801 amounts owed to the agency. Should the transferor fail to repay
802 or make arrangements to repay the amounts owed to the agency,
803 the issuance of a license, registration, or certificate to the
804 transferee shall be delayed until repayment or until
805 arrangements for repayment are made.
806 (3) Entities subject to this section may exceed their
807 licensed capacity to act as a receiving facility in accordance
808 with an emergency operations plan for clients of evacuating
809 providers from a geographic area where an evacuation order has
810 been issued by a local authority having jurisdiction. While in
811 an overcapacity status, each provider must furnish or arrange
812 for appropriate care and services to all clients. In addition,
813 the agency shall approve requests for overcapacity beyond 15
814 days, which approvals may be based upon satisfactory
815 justification and need as provided by the receiving and sending
816 facility.
817 (4) An inactive license may be issued to a licensee
818 subject to this section when the provider is located in a
819 geographic area where a state of emergency was declared by the
820 Governor of Florida if the provider:
821 (a) Suffered damage to the provider's operation during
822 that state of emergency.

823 (b) Is currently licensed.
824 (c) Does not have a provisional license.
825 (d) Will be temporarily unable to provide services but is
826 reasonably expected to resume services within 12 months.
827
828 An inactive license may be issued for a period not to exceed 12
829 months but may be renewed by the agency for up to 6 additional
830 months upon demonstration to the agency of progress toward
831 reopening. A request by a licensee for an inactive license or to
832 extend the previously approved inactive period must be submitted
833 in writing to the agency, accompanied by written justification
834 for the inactive license which states the beginning and ending
835 dates of inactivity and includes a plan for the transfer of any
836 clients to other providers and appropriate licensure fees. Upon
837 agency approval, the licensee shall notify clients of any
838 necessary discharge or transfer as required by authorizing
839 statutes or applicable rules. The beginning of the inactive
840 licensure period shall be the date the provider ceases
841 operations. The end of the inactive period shall become the
842 licensee expiration date and all licensure fees must be current,
843 paid in full, and may be prorated. Reactivation of an inactive
844 license requires the prior approval by the agency of a renewal
845 application, including payment of licensure fees and agency
846 inspections indicating compliance with all requirements of this
847 part and applicable rules and statutes.
848 (5) ~~(3)~~ This section provides standards of enforcement
849 applicable to all entities licensed or regulated by the Agency
850 for Health Care Administration. This section controls over any
851 conflicting provisions of chapters 39, 381, 383, 390, 391, 393,
852 394, 395, 400, 408, 468, 483, and 641 or rules adopted pursuant
853 to those chapters.

854 Section 14. This act shall take effect July 1, 2006.
855
856 ========== T I T L E A M E N D M E N T ==========
857 Remove the entire title and insert:
858 A bill to be entitled
859 An act relating to emergency management; amending s. 252.355,
860 F.S.; specifying additional agencies that are required to
861 provide registration information to persons with disabilities or
862 special needs who receive services from such agencies for
863 purposes of inclusion within the registry of persons with
864 special needs maintained by local emergency management agencies;
865 providing that the Department of Community Affairs shall be the
866 designated lead agency responsible for community education and
867 outreach to the general public, including persons with special
868 needs, regarding registration as a person with special needs,
869 special needs shelters, and general information regarding
870 shelter stays; requiring the department to disseminate
871 educational and outreach information through local emergency
872 management offices; requiring the department to coordinate
873 community education and outreach related to special needs
874 shelters with specified agencies and entities; providing that
875 special needs shelters must allow persons with disabilities to
876 bring service animals into all areas of a special needs shelter;
877 providing that specified confidential and exempt information
878 relating to registration of persons with special needs be
879 provided to the Department of Health; creating s. 252.3568,
880 F.S.; requiring the Division of Emergency Management to address
881 evacuation of persons with pets in the shelter component of the
882 state comprehensive emergency management plan; creating s.
883 252.357, F.S., requiring the Florida Comprehensive Emergency
884 Management Plan to permit the Agency for Health Care

885 Administration to make initial contact with each nursing home in
886 a disaster area; requiring the agency to annually publish an
887 emergency telephone number that may be used by nursing homes to
888 contact the agency; amending s. 252.385, F.S.; revising
889 provisions relating to public shelter space; requiring the
890 Division of Emergency Management of the Department of Community
891 Affairs to biennially prepare and submit a statewide emergency
892 shelter plan to the Governor and the Cabinet for approval;
893 providing plan requirements; requiring the Department of Health
894 to assist the division in determining the estimated need for
895 special needs shelter space and the adequacy of the facility to
896 meet the needs of special needs persons; requiring the division
897 to include information on the availability of pet friendly
898 shelters in the statewide emergency shelter plan; revising those
899 facilities which are excluded as being suitable for use as
900 public hurricane evacuation shelters; requiring local emergency
901 management agencies to inspect a designated facility to
902 determine its readiness prior to activating such facility for a
903 specific hurricane or disaster; amending s. 381.0303, F.S.;
904 providing for the operation, maintenance, and closure of special
905 needs shelters; providing that the local Children's Medical
906 Services offices shall assume lead responsibility for specified
907 coordination with respect to the development of a plan for the
908 staffing and medical management of pediatric special needs
909 shelters; requiring such plans to conform to the local
910 comprehensive emergency management plan; requiring county
911 governments to assist in the process of coordinating the
912 recruitment of health care practitioners to staff local special
913 needs shelters; the Department of Health with nonmedical
914 staffing and the operation of special needs shelters; requiring
915 local health departments and emergency management agencies to

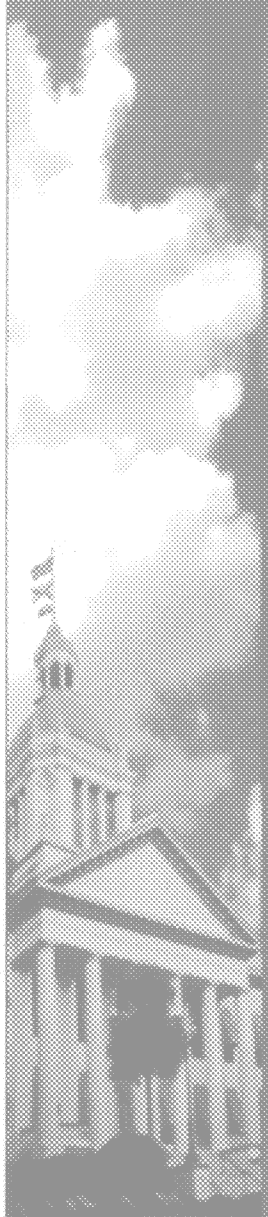
916 coordinate such efforts to ensure appropriate staffing in
917 special needs shelters;
918 providing that the appropriate county health department,
919 Children's Medical Services office, and local emergency
920 management agency shall jointly determine the responsibility for
921 medical supervision in a special needs shelter; providing
922 notification requirements; requiring local emergency management
923 agencies to be responsible for the designation, operation, and
924 infrastructure of special needs shelters during times of
925 emergency or disaster and the closure of the facilities
926 following an emergency or disaster; requiring the emergency
927 management agency and the local health department to coordinate
928 efforts to ensure appropriate designation, operation, and
929 infrastructure in special needs shelters; providing that state
930 employees with a preestablished role in disaster response may be
931 called upon to serve in times of disaster in specified
932 capacities; requiring the Secretary of Elderly Affairs to
933 convene a multiagency emergency special needs shelter discharge
934 planning team or teams to assist local areas that are severely
935 impacted by a natural or manmade disaster that required the use
936 of special needs shelters; providing duties and responsibilities
937 of multiagency discharge planning teams; authorizing local
938 emergency management agencies to request the assistance of a
939 multiagency discharge planning team; providing for the inclusion
940 of specified state agency representatives on each multiagency
941 discharge planning team; authorizing hospitals, nursing homes,
942 assisted living facilities, and hospices that are used to
943 shelter special needs persons during or after an evacuation to
944 submit invoices for reimbursement to the Department of Health;
945 requiring the department to specify by rule expenses that are
946 reimbursable and the rate of reimbursement for services;

947 prescribing means of and procedures for reimbursement; providing
948 eligibility for reimbursement of health care facilities to whom
949 special needs shelter clients have been discharged by a
950 multiagency special needs shelter discharge planning team upon
951 closure of a special needs shelter; providing requirements with
952 respect to such reimbursement; prescribing means of and
953 procedures for reimbursement; disallowing specified
954 reimbursements; revising the role of the special needs shelter
955 interagency committee with respect to the planning and operation
956 of special needs shelters; providing required functions of the
957 committee; revising the composition of the special needs shelter
958 interagency committee; requiring the department to adopt rules
959 with respect to special needs shelters; providing requirements
960 with respect to emergency management plans submitted by a home
961 health agency, nurse registry, hospice, or home medical
962 equipment provider to a county health department for review;
963 amending s. 400.492, F.S.; requiring the comprehensive emergency
964 management plan to include the means by which a home health
965 agency will continue to provide staff to provide services to
966 their patients who evacuate to special needs shelters;
967 authorizing home health agencies to establish links to local
968 emergency operations centers to determine a mechanism to
969 approach areas within a disaster area in order for the agency to
970 reach its clients; providing that the presentation of home care
971 or hospice clients to the special needs shelter without the home
972 health agency or hospice making a good faith effort to provide
973 services in the shelter setting constitutes abandonment of the
974 client and constitutes a Class II deficiency, subject to
975 sanctions under s. 400.484, F.S.; amending s. 400.497, F.S.,
976 revising requirements of a county health department with respect
977 to review of a comprehensive emergency management plan;

978 providing requirements of a county health department in the
979 event that a home health agency fails to submit a plan or fails
980 to submit requested information or revisions to the department
981 within a specified period after written notification; providing
982 notification requirements; providing for imposition of a fine;
983 amending s. 400.506, F.S., relating to licensure of nurse
984 registries; revising requirements of a nurse registry with
985 respect to the preparation of a comprehensive emergency
986 management plan; providing requirements of a county health
987 department in the event that a nurse registry fails to submit a
988 plan or fails to submit requested information or revisions to
989 the department within a specified period after written
990 notification; providing notification requirements; providing for
991 imposition of a fine; providing requirements of the Department
992 of Health with respect to review of the plan; amending s.
993 400.610, F.S.; relating to administration and management of a
994 hospice; revising requirements of a hospice with respect to the
995 preparation of a comprehensive emergency management plan that
996 provides for continuing hospice services in the event of an
997 emergency; providing that the presentation of hospice clients to
998 a special needs shelter without the hospice making a good faith
999 effort to provide services in the shelter setting constitutes
1000 abandonment of the client; providing requirements of the
1001 Department of Health with respect to review of the plan;
1002 amending s. 400.925, F.S.; defining "life-supporting or life-
1003 sustaining equipment"; amending s. 400.934, F.S.; requiring home
1004 medical equipment providers to prepare and maintain a
1005 comprehensive emergency management plan that meets minimum
1006 criteria established by the Agency for Health Care
1007 Administration as a requirement of licensure; providing
1008 procedures and requirements with respect thereto;

1009 amending s. 400.935, F.S.; requiring home medical equipment
1010 services providers to prepare a comprehensive emergency
1011 management plan; requiring the Agency for Health Care
1012 Administration to adopt rules establishing minimum criteria for
1013 the plan; amending s. 408.831, F.S.; providing that entities
1014 regulated or licensed by the Agency for Health Care
1015 Administration may exceed their licensed capacity to act as a
1016 receiving facility under specified circumstances; providing
1017 requirements while such entities are in an overcapacity status;
1018 providing for issuance of an inactive license to such licensees
1019 under specified conditions; providing requirements and
1020 procedures with respect to the issuance and reactivation of an
1021 inactive license; providing fees; creating s. 252.357, F.S.,
1022 requiring the Florida Comprehensive Emergency Management Plan to
1023 permit the Agency for Health Care Administration to initially
1024 contact nursing homes in disaster areas for specified monitoring
1025 purposes; requiring the agency to publish an emergency telephone
1026 number for use by nursing homes; providing an effective date.

oppaga



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

A Presentation to the House Health Care General Committee

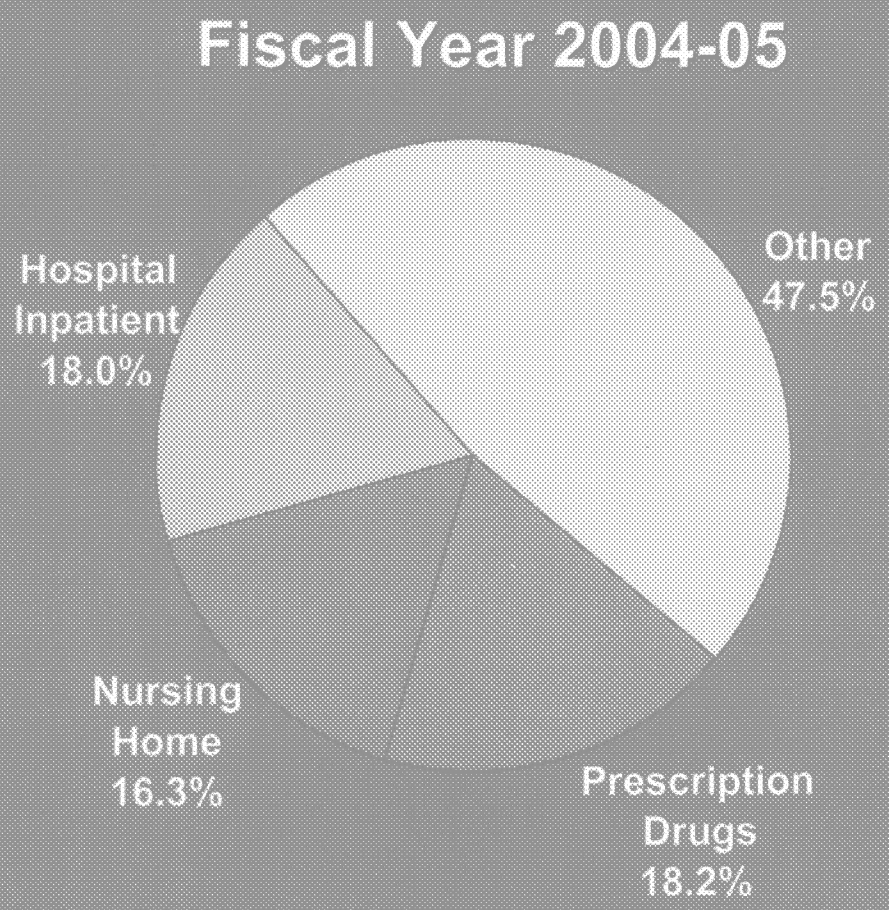
February 22, 2006

Jennifer Johnson, Senior Legislative Analyst

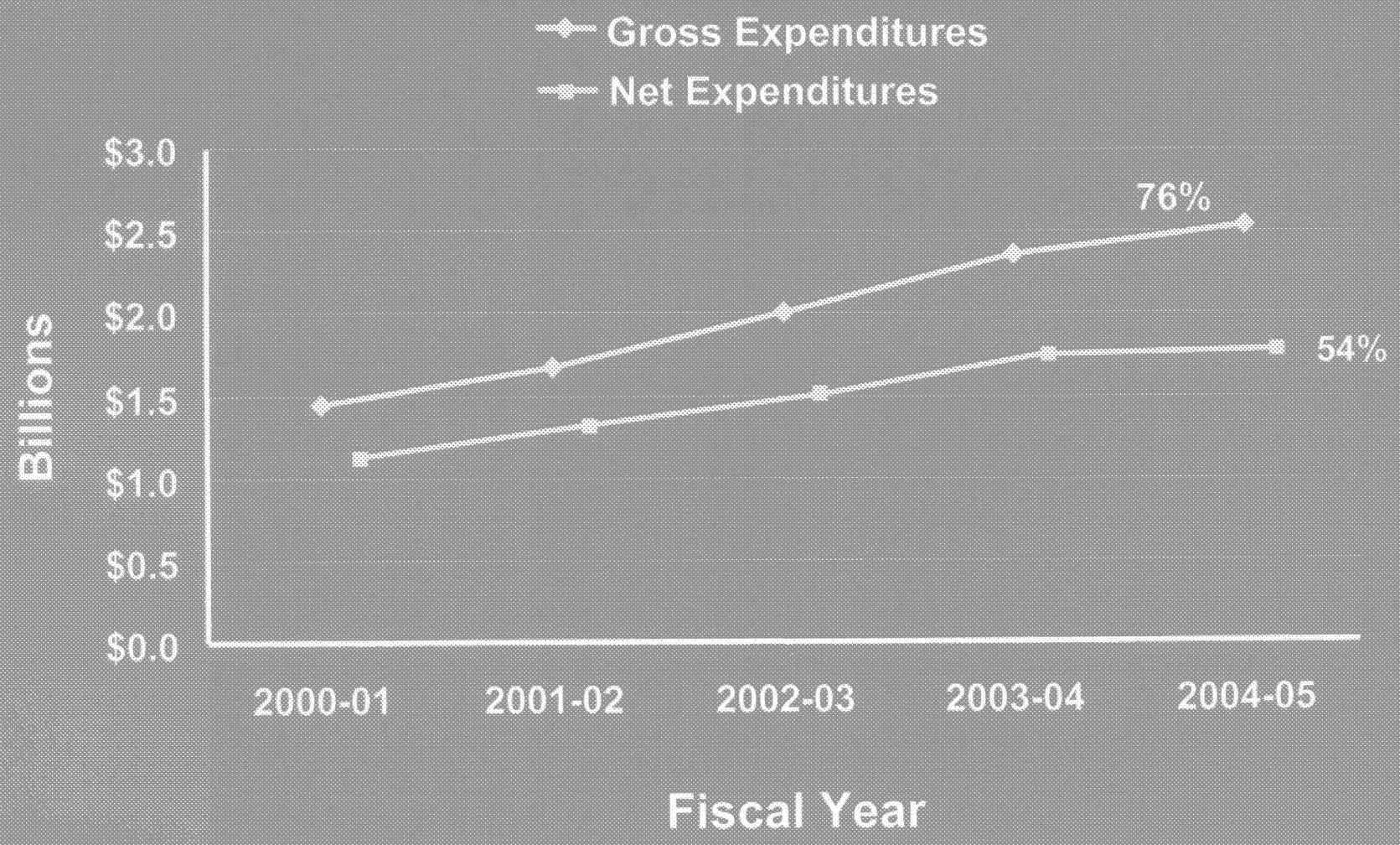
Presentation Overview

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

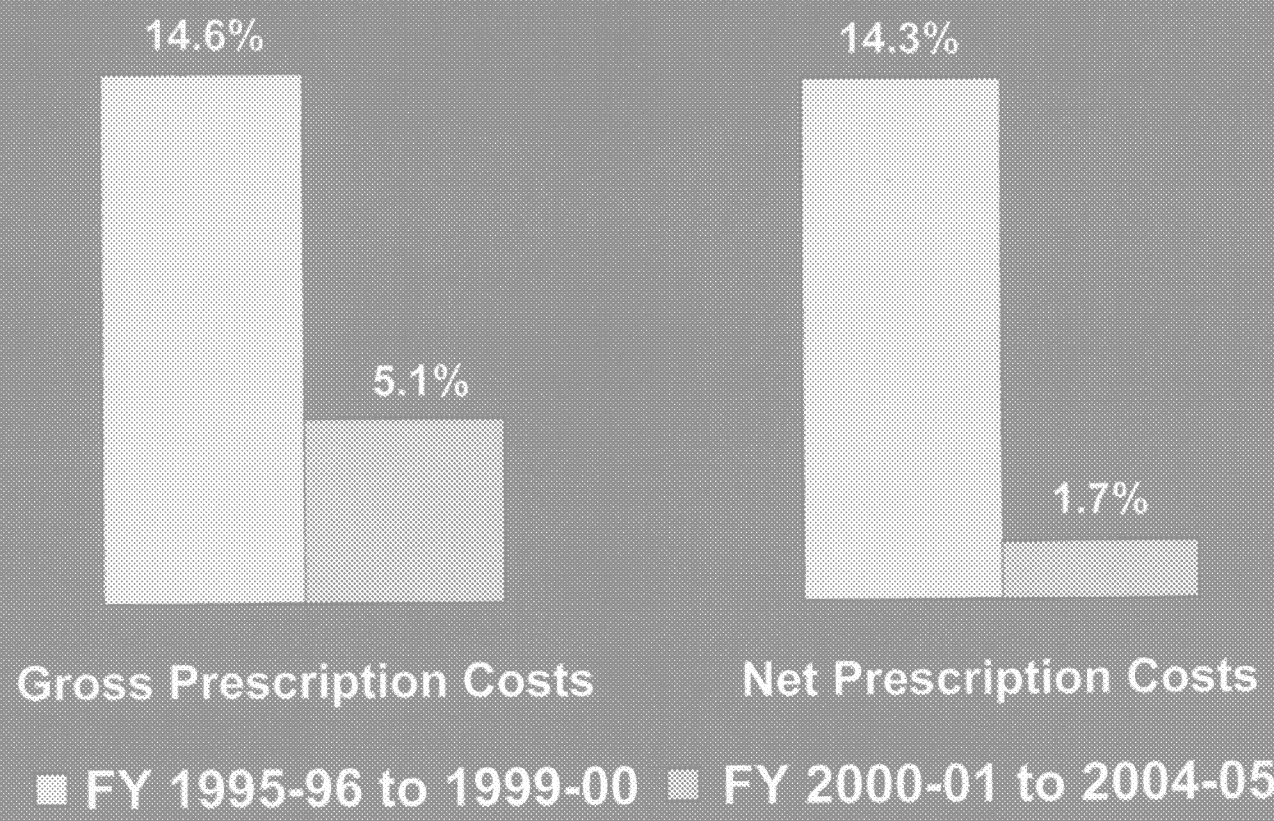
Prescription Drugs Accounted for 18.2% of Medicaid Spending



Medicaid Drug Expenditures



Average Prescription Cost Increased at a Slower Rate



Florida Medicaid Drug Prices

1. Pharmacy reimbursements
2. 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)

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'

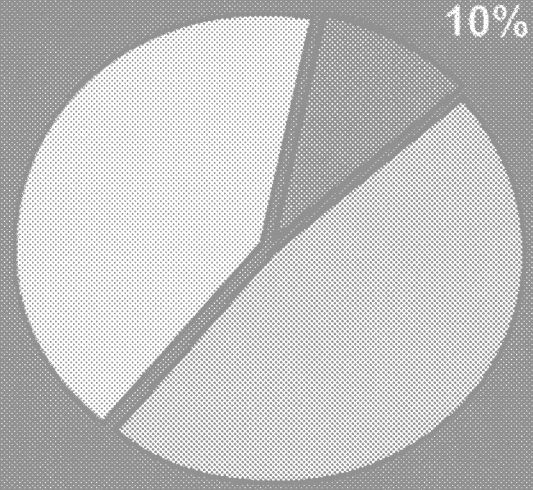
Recommendations

Modify formulas for estimating pharmacy acquisition costs

Drug 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

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

For Additional Information

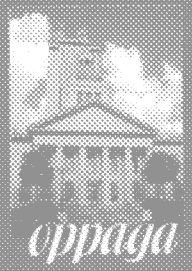
Yvonne Bigos, Chief Legislative Analyst
487-9230
Bigos.Yvonne@oppaga.fl.gov

Rae Hendlin, Senior Legislative Analyst
410-4795
Hendlin.Rae@oppaga.fl.gov

Jennifer Johnson, Senior Legislative Analyst
488-1023
Johnson.Jennifer@oppaga.fl.gov

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

Thank you



Office of Program Policy Analysis & Government Accountability

OPPAGA supports the Florida Legislature by providing evaluative research and objective analyses to promote government accountability and the efficient and effective use of public resources.

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

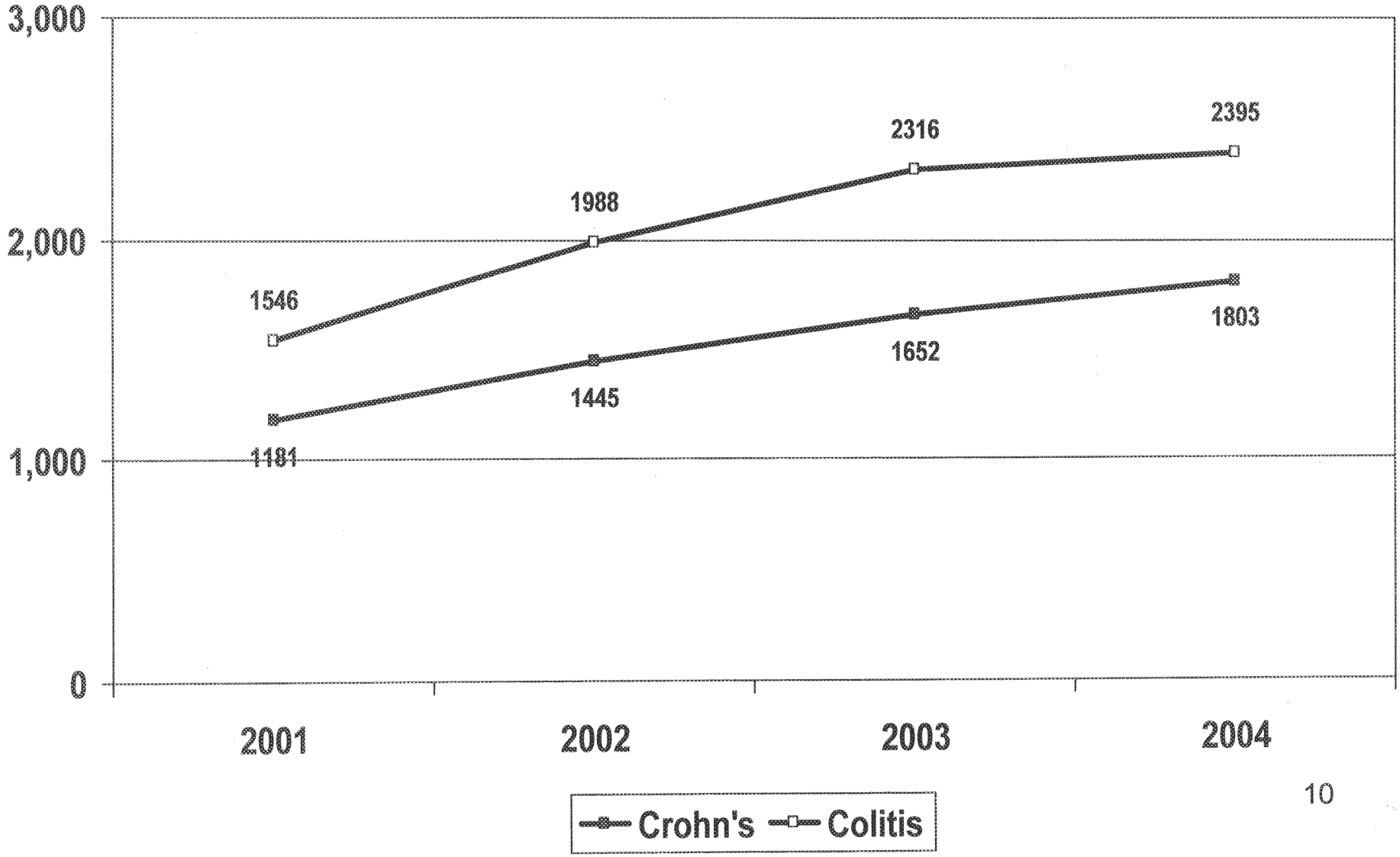
Consultations from Experts

- **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

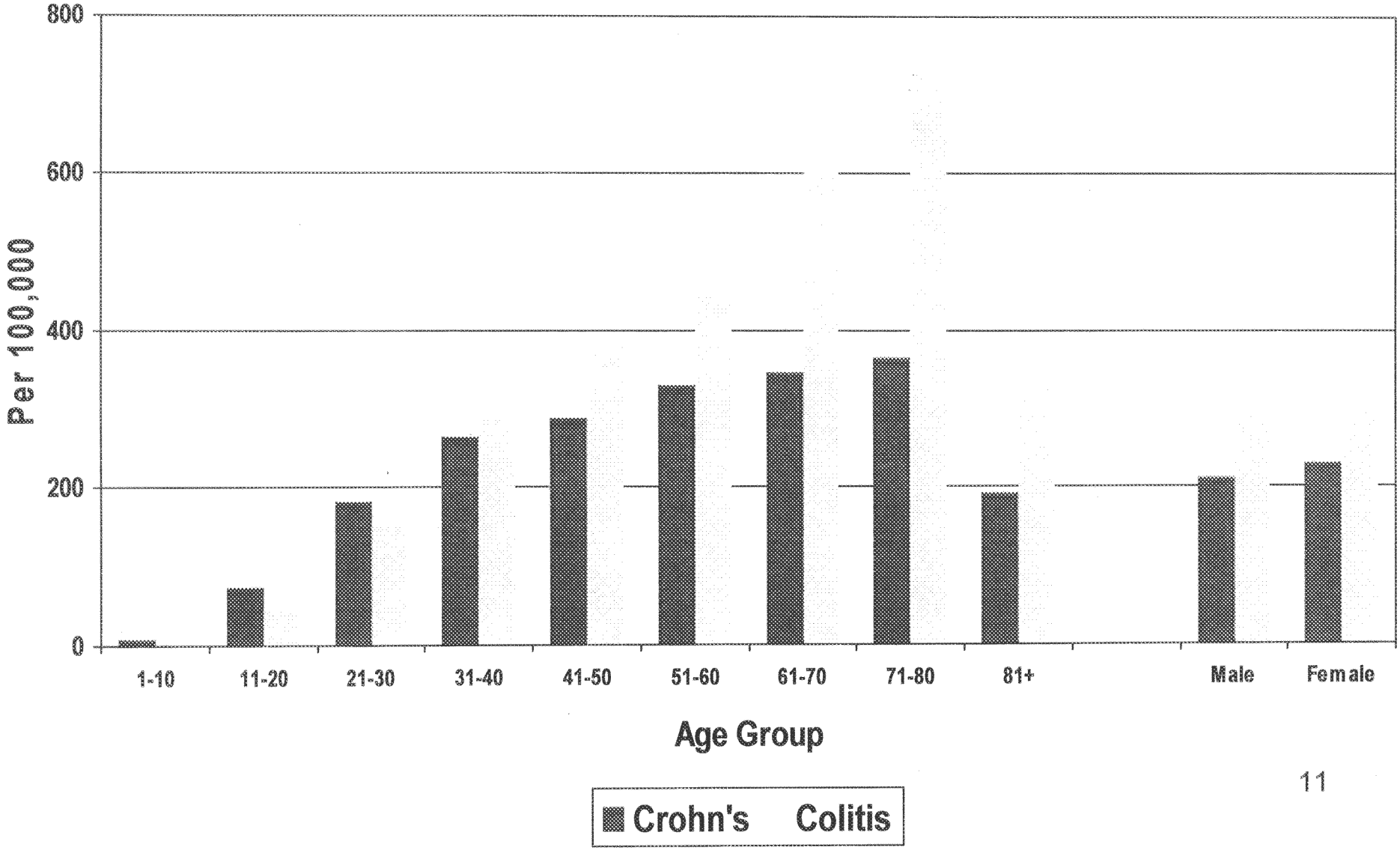
Advisory Committee

- **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

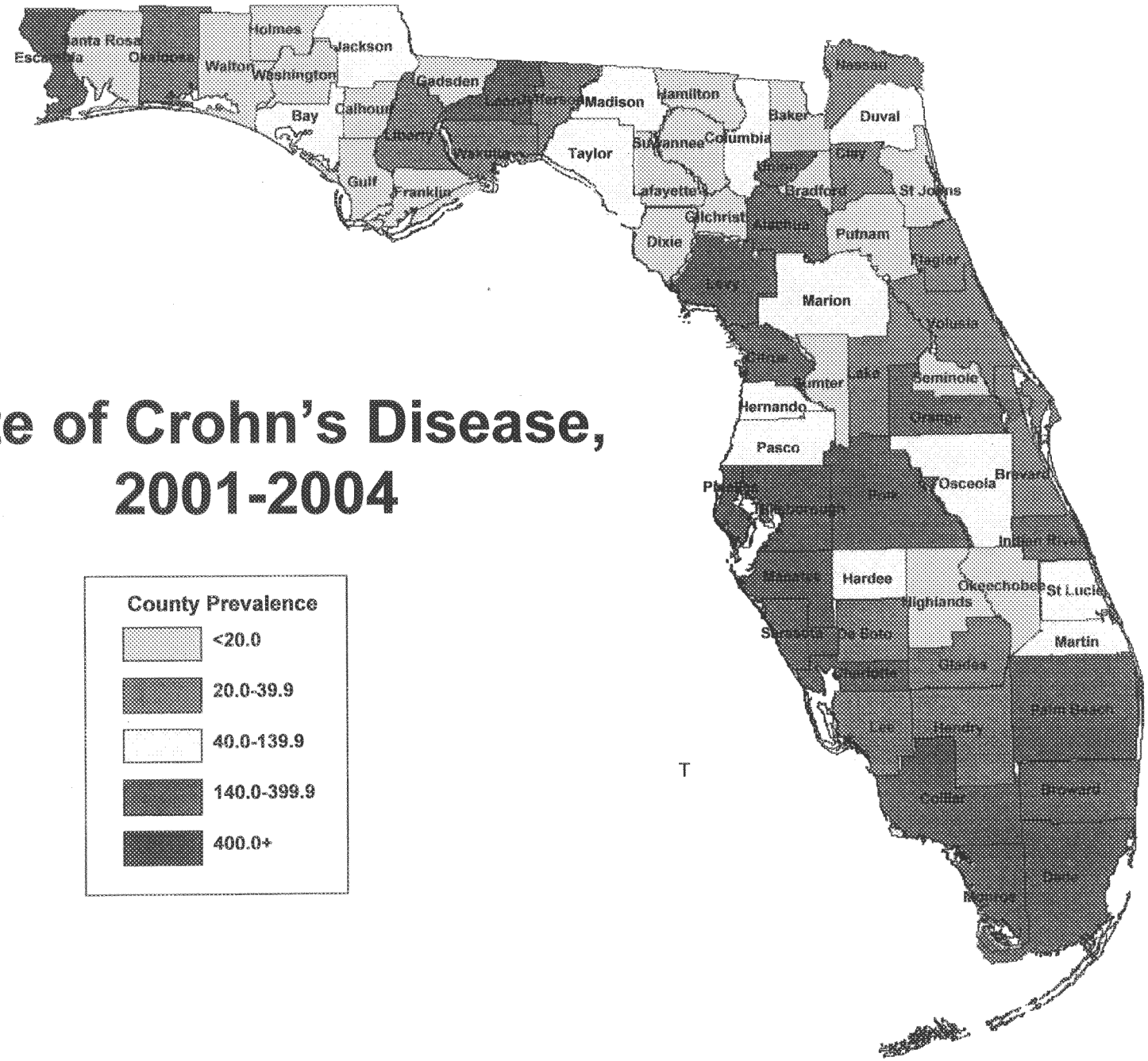
Number of New IBD Patients among BCBS Members, 2001-2004



Rate of IBD among BCBS Members 2001-2004



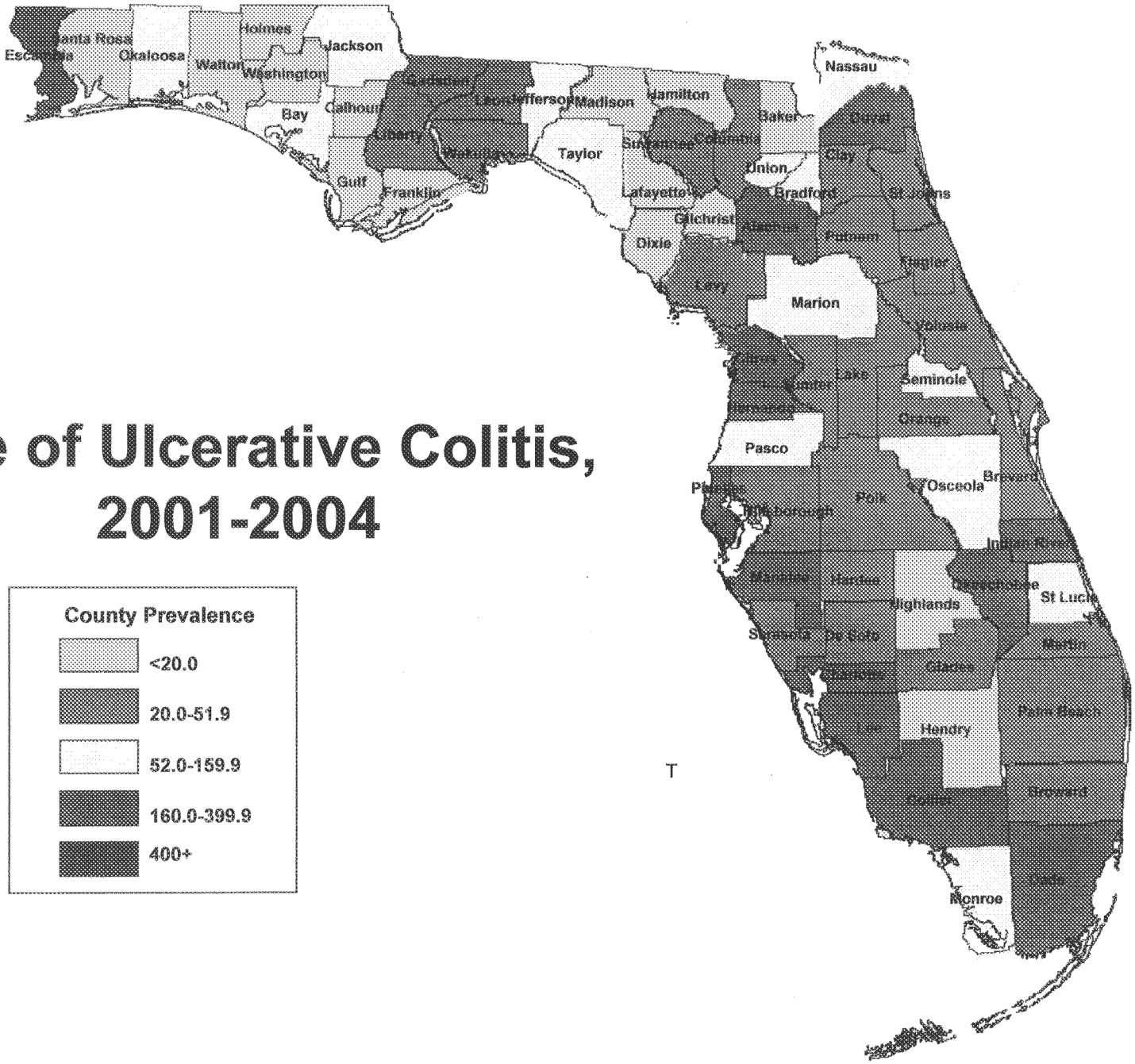
Rate of Crohn's Disease, 2001-2004



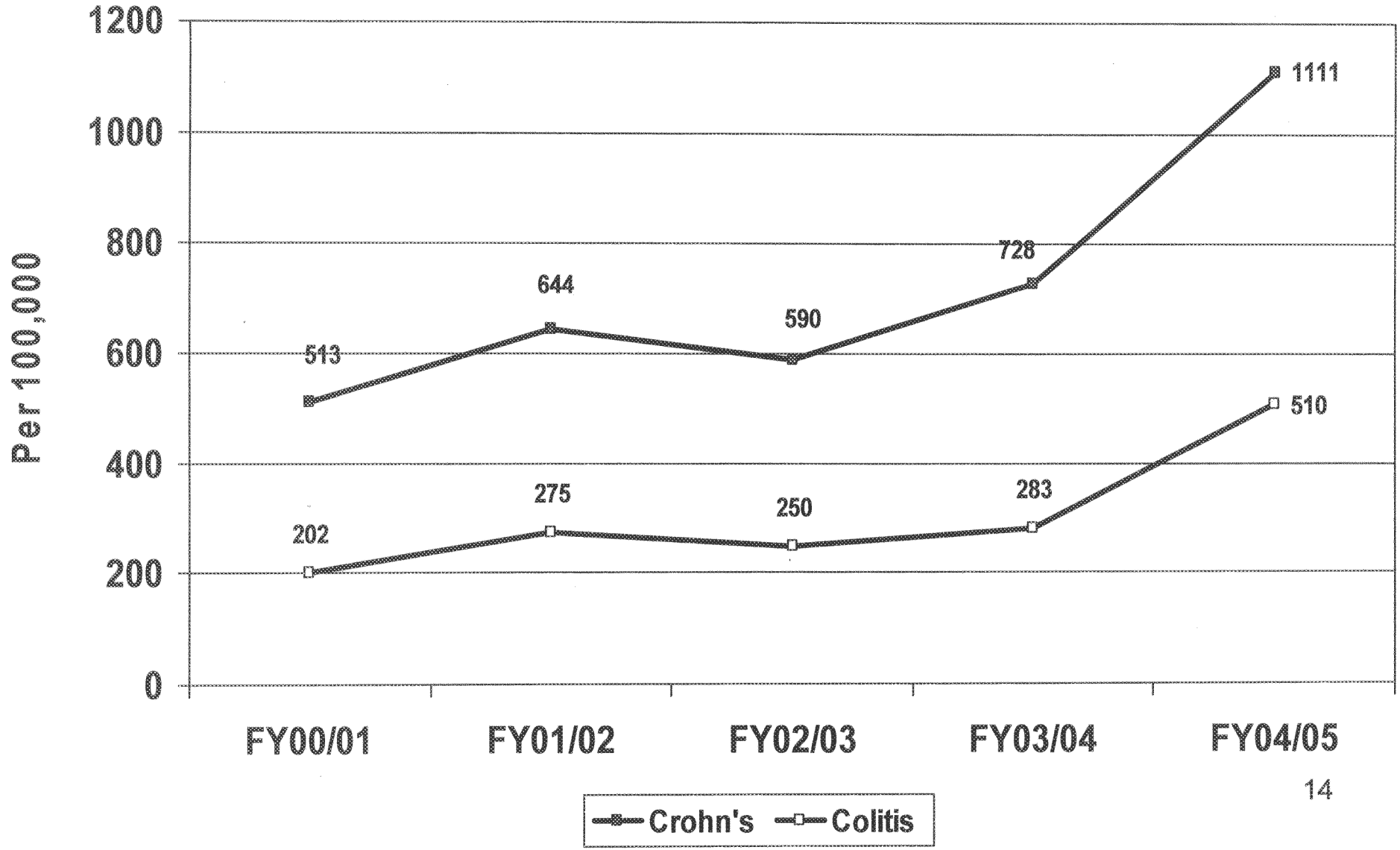
County Prevalence

- <20.0
- 20.0-39.9
- 40.0-139.9
- 140.0-399.9
- 400.0+

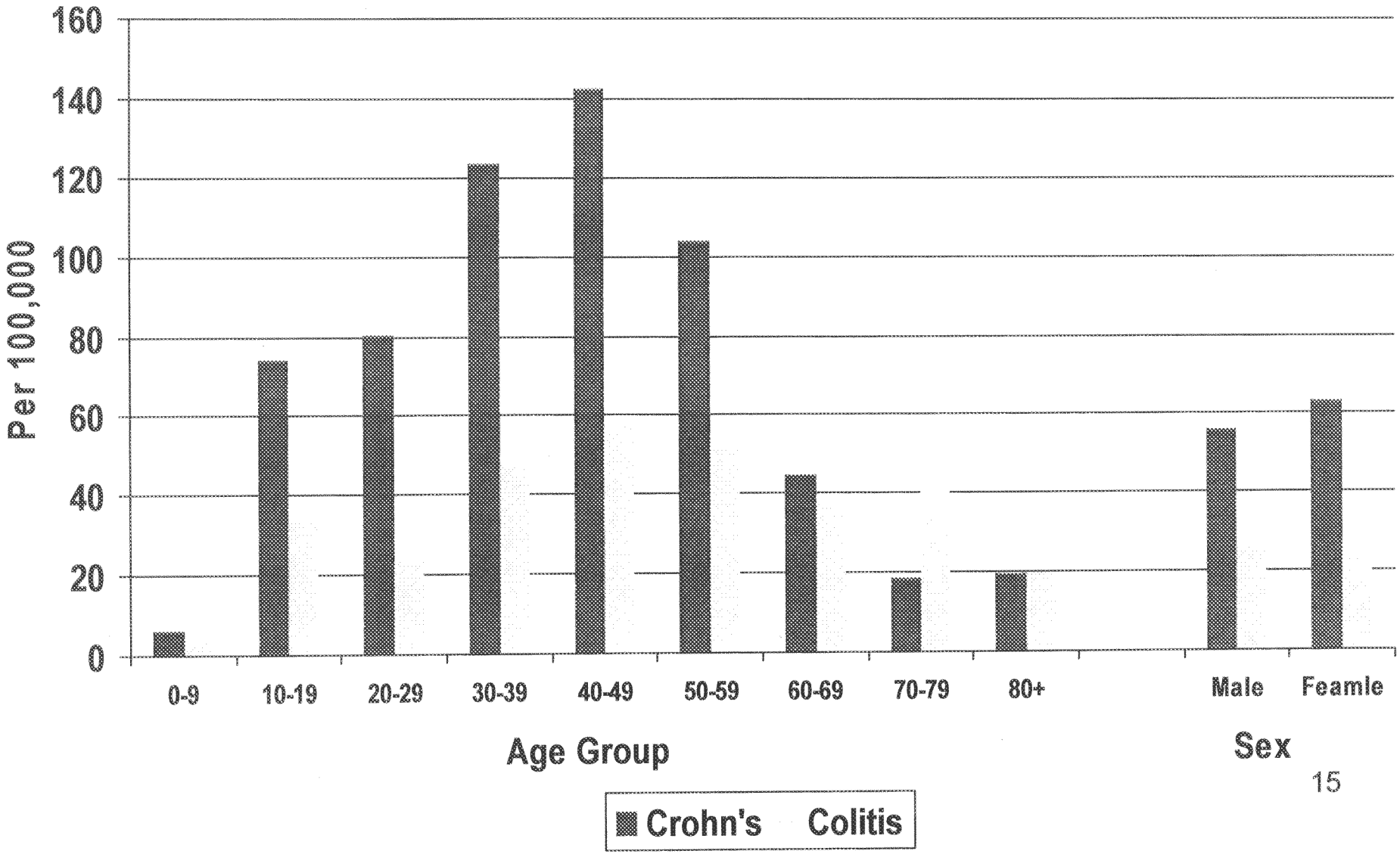
Rate of Ulcerative Colitis, 2001-2004



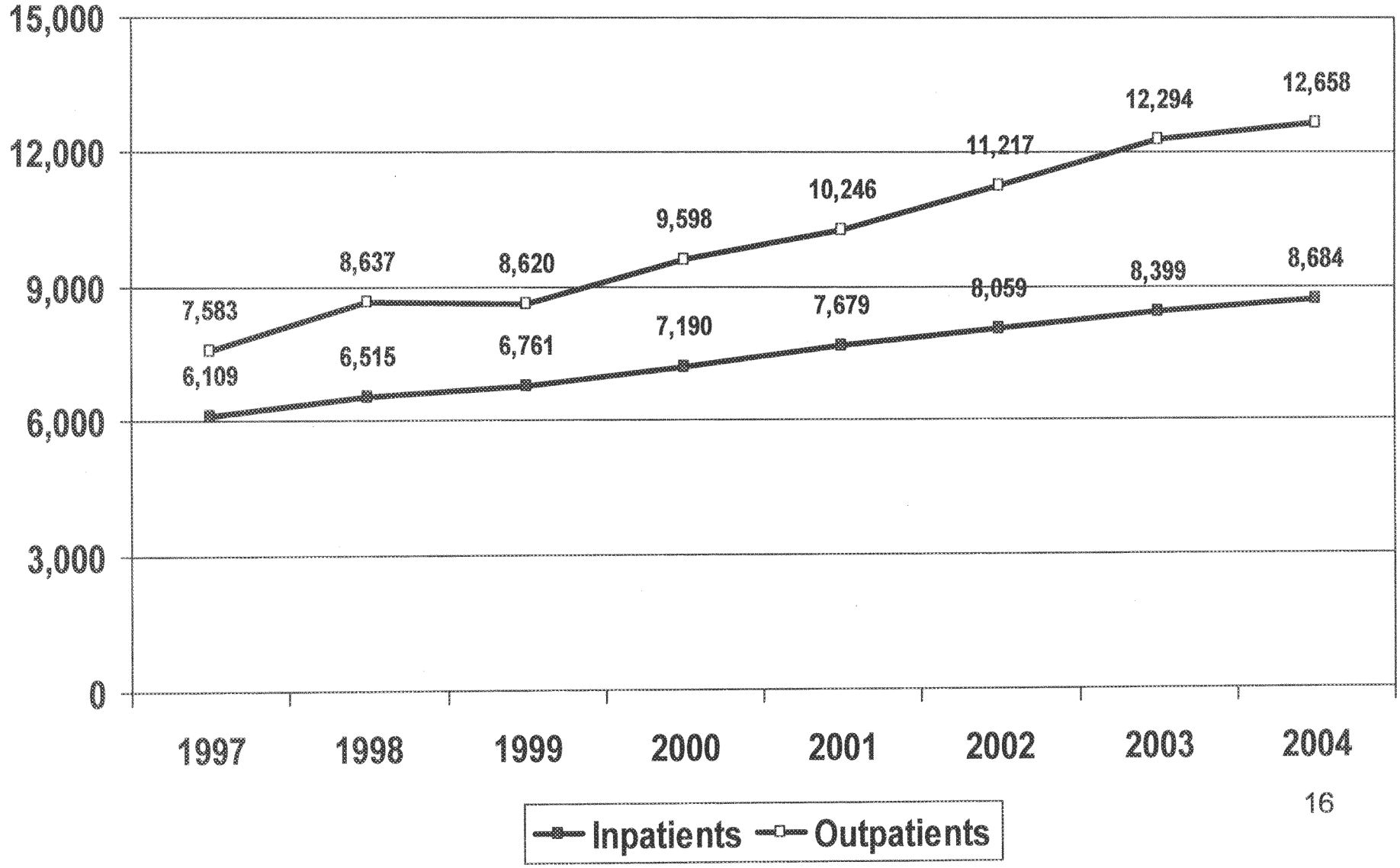
Number of New IBD Cases among Medicaid Recipients, FY00/01 – FY04/05



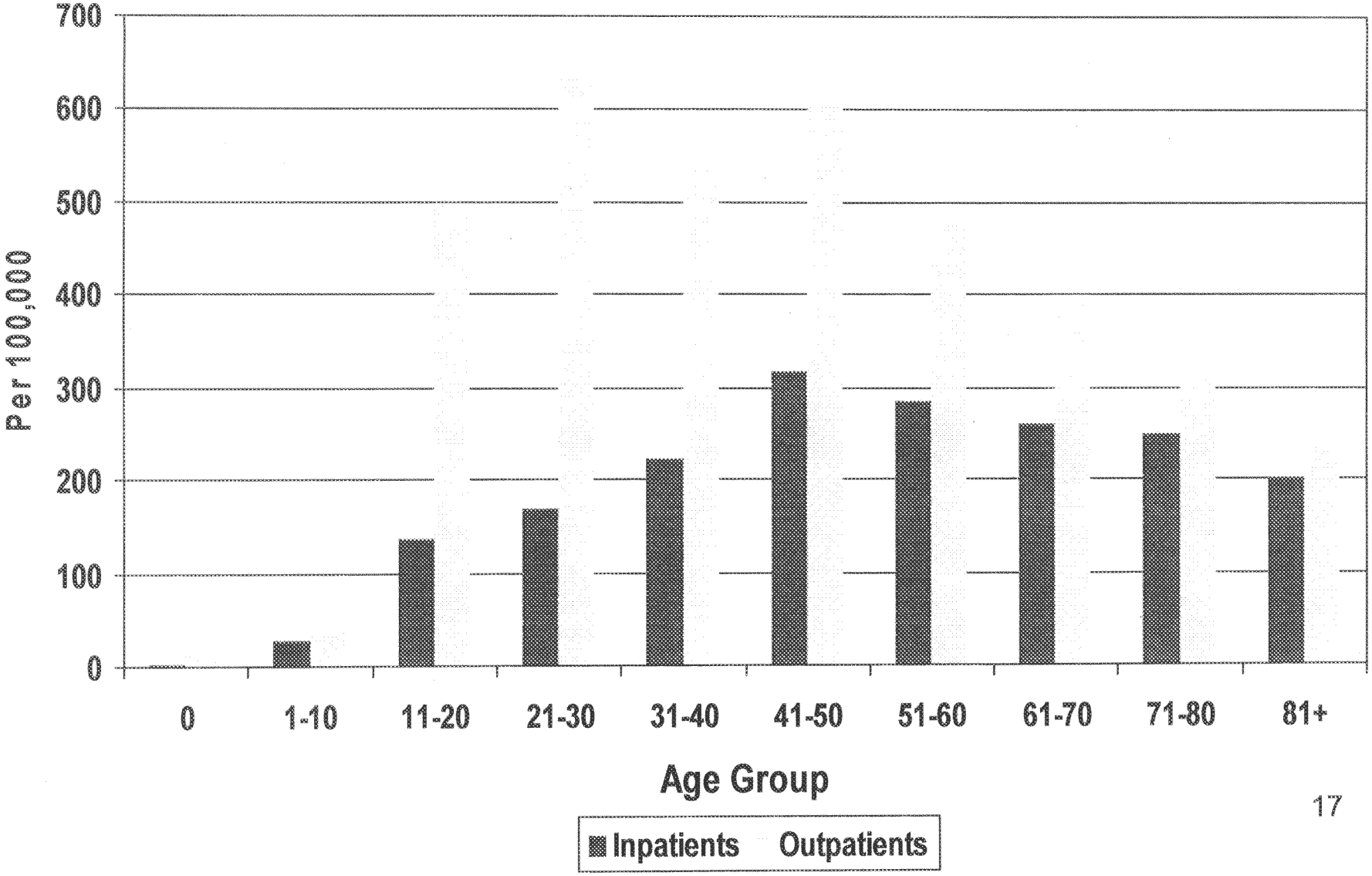
Rate of IBD among Medicaid Recipients, FY00/01- FY04/05



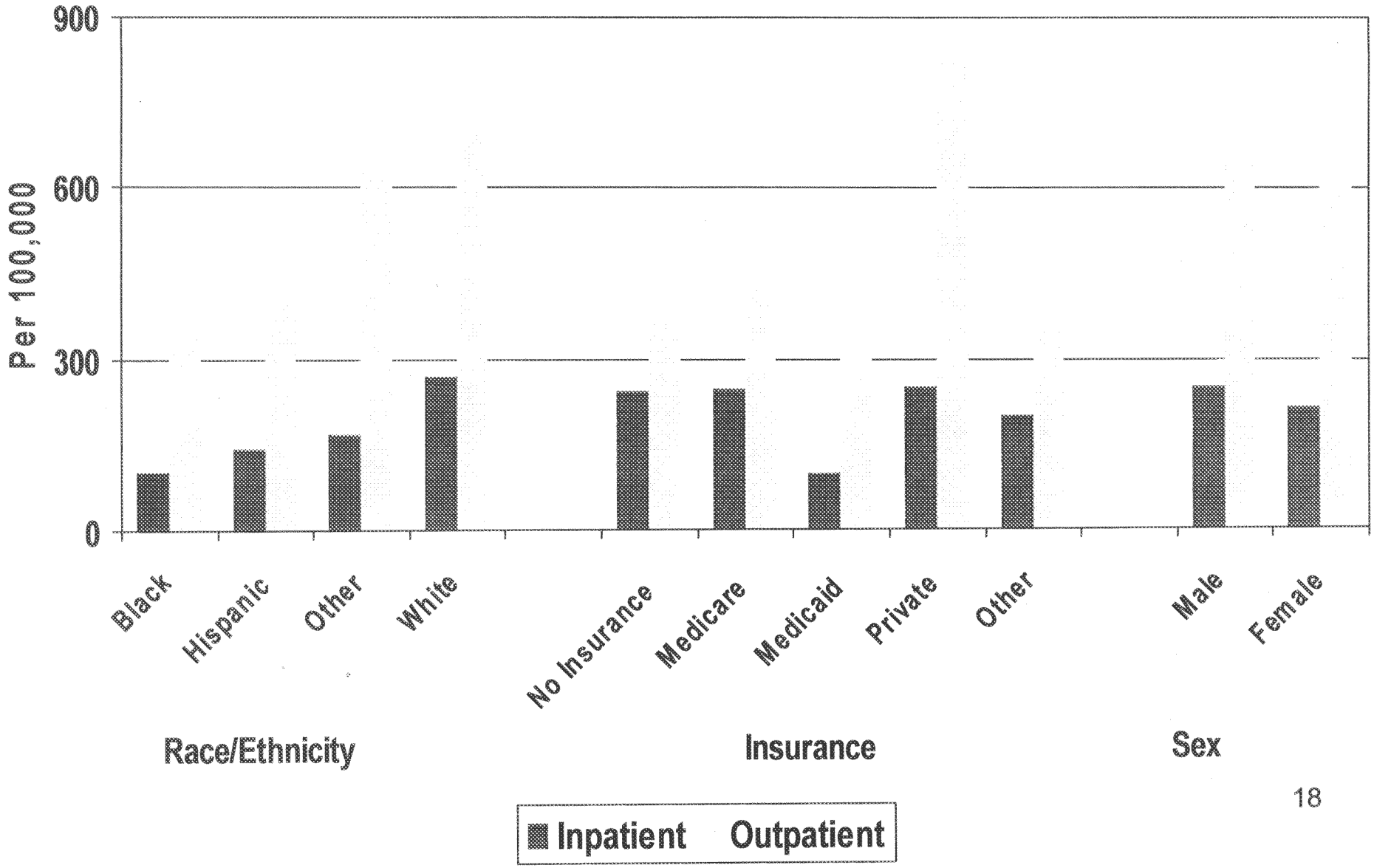
Number of IBD Inpatients and Outpatients, 1997-2004



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.

Table of Contents

BACKGROUND 4
PURPOSE OF THE STUDY 4
IMPLEMENTATION OF THE STUDY 5
Literature Review 5
Consultations from Experts 5
Advisory Committee 6
Information Dissemination 8
METHODS 8
Sources of Data 8
Blue Cross Blue Shield (BCBS) claim data 9
Medicaid data 9
Ambulatory patient data 9
Hospital discharge data 10
Gastroenterology (GI) Physician survey 10
Pediatric GI physician survey 11
IBD patient survey 11
Behavioral Risk Factor Surveillance System survey 11
Definition of IBD 12
Analysis 12
RESULTS 14
BCBS data 14
Medicaid data 19
Hospital discharge data 21
Ambulatory patient data 27
BRFSS Survey 33
GI Physician Survey 34
IBD Patient Survey 34
CONCLUSIONS 37
Estimated prevalence of Crohn's disease and ulcerative colitis 37
The Prevalence 37
Number of Patients 38
Demographic Characteristics 38
Risk factors 39
Genetic factors 39
Environmental factors 40
Recommendations for Future Studies 40
ATTACHMENTS 41
Attachment 1: GI PHYSICIAN SURVEY 41
Attachment 2: IBD PATIENT SURVEY 422

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

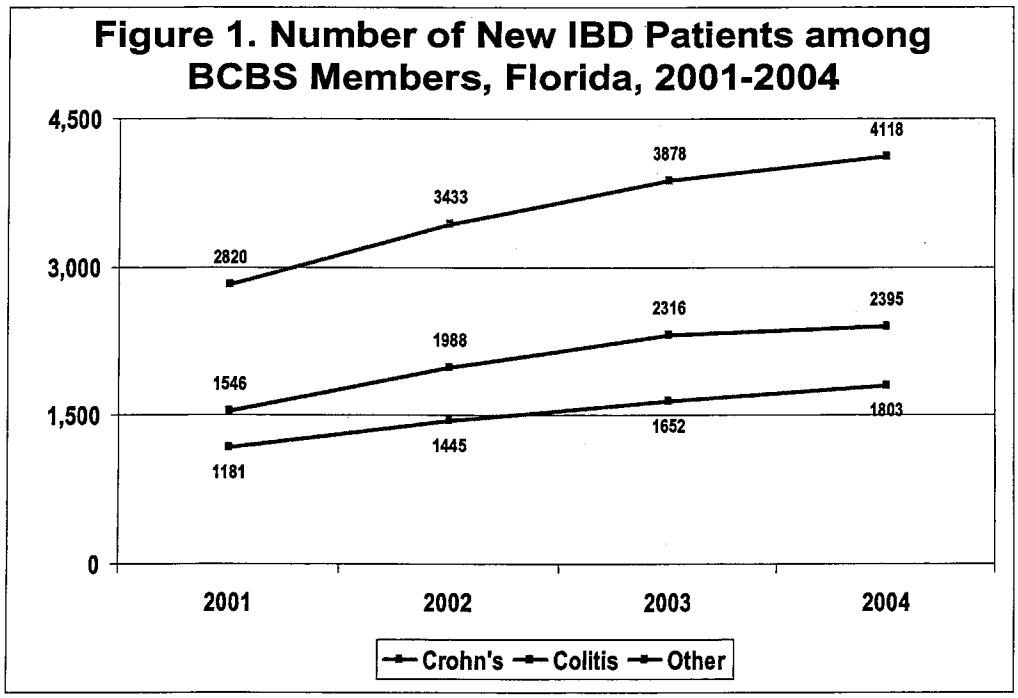
BCBS data

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

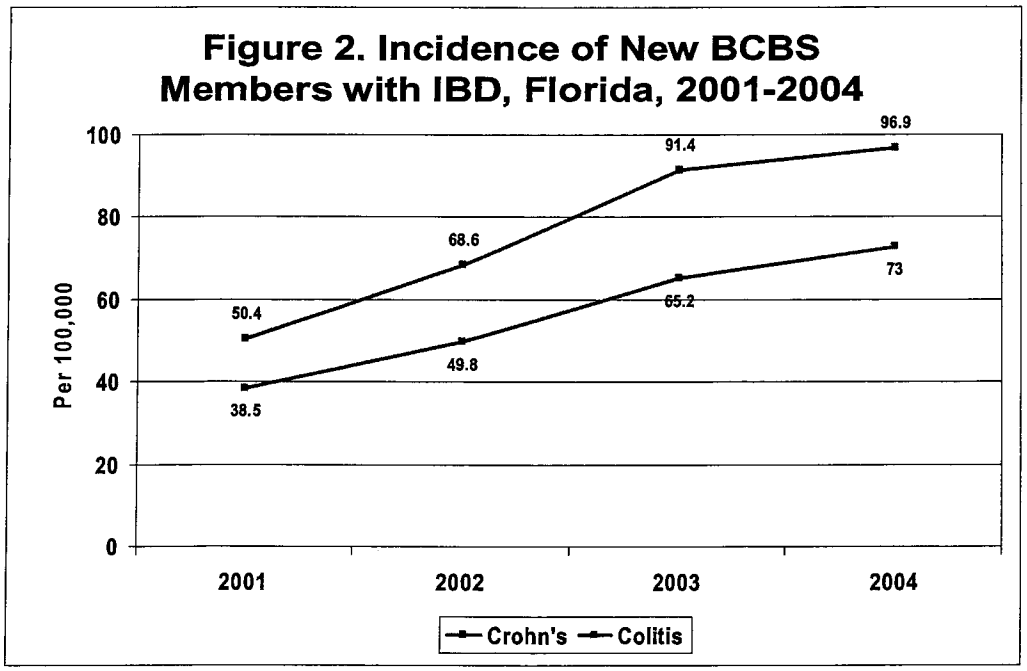
	All IBD	Crohn's	Colitis	Other	# of Members
Total	**7,144**	**1,520**	**2,061**	**3,563**	**2,742,637**
By Age Group					
1-10	**25**	**7**	**9**	**10**	**289,104**
11-20	**196**	**81**	**48**	**68**	**431,765**
21-30	**472**	**150**	**131**	**180**	**350,594**
31-40	**841**	**234**	**258**	**349**	**352,003**
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)

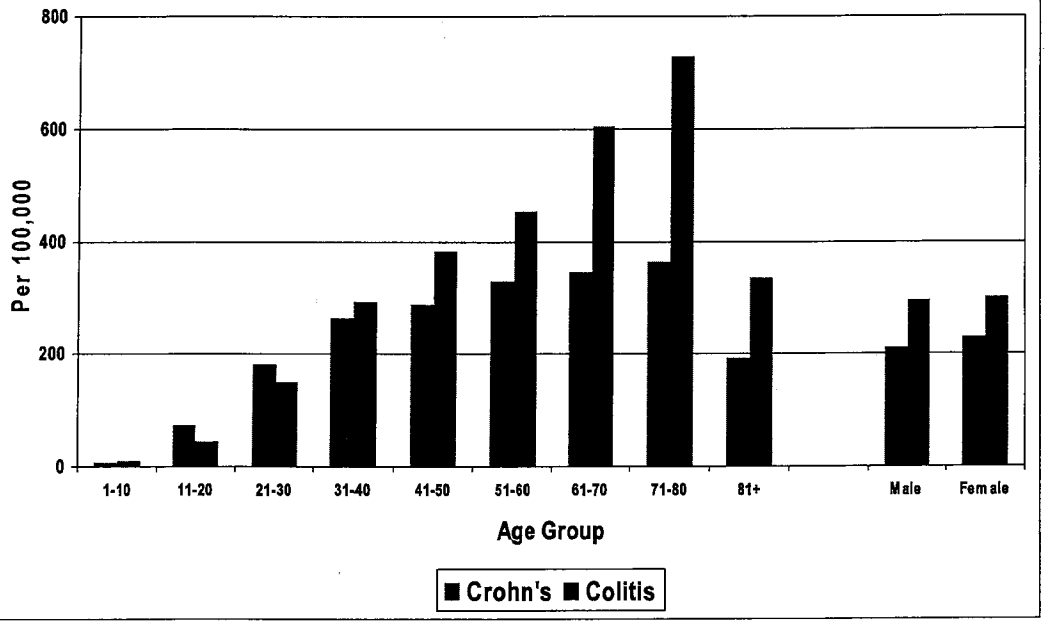


During the four-year period, the number of patients diagnosed with Crohn's disease and ulcerative colitis increased by age, and reached a peak in the 51-to-60–year-old age group (Table 1).

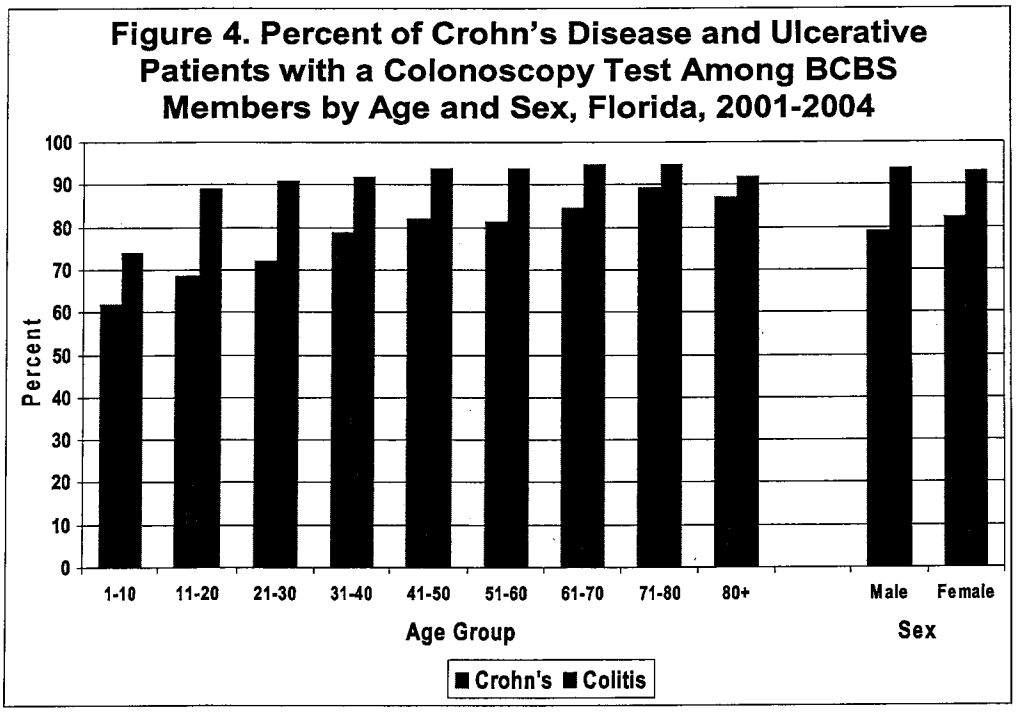
The four-year prevalence was the highest among people between the ages of 71 and 80 years. The prevalence increased by age, except among people age 81 years and older. (Figure 3)

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)

Figure 3. Prevalence of Crohn's Disease and Ulcerative Colitis among BCBS Members By Age and Sex, Florida, 2001-2004



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.

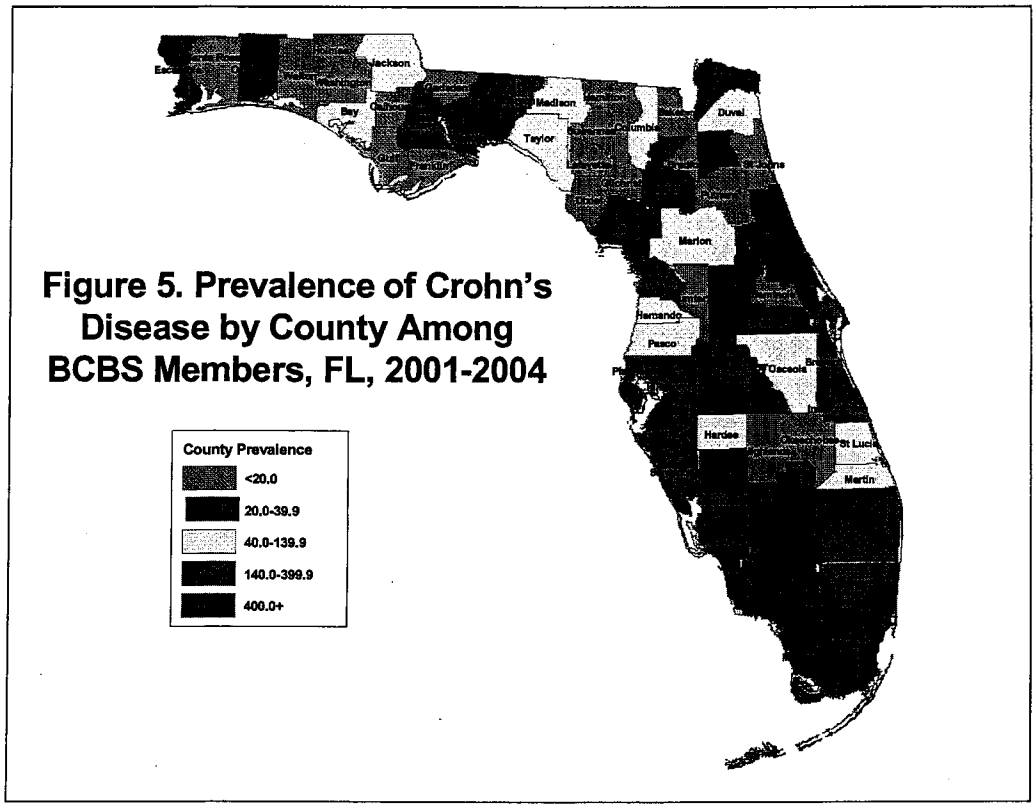


Figure 5. Prevalence of Crohn's Disease by County Among BCBS Members, FL, 2001-2004
County Prevalence
<20.0
20.0-39.9
40.0-139.9
140.0-399.9
400.0+
Jackson
Bay
Madison
Taylor
Duval
Marion
Hernando
Pasco
Osceola
Hardee
St Lucie
Martin

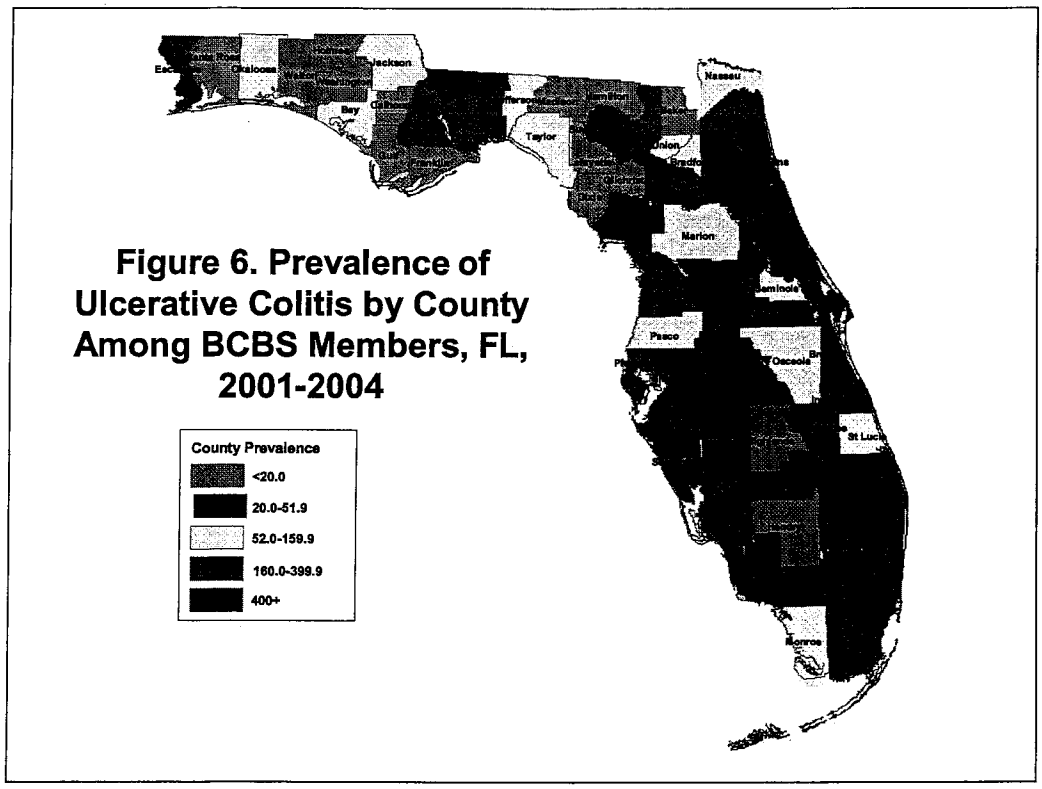


Figure 6. Prevalence of Ulcerative Colitis by County Among BCBS Members, FL, 2001-2004
County Prevalence
<20.0
20.0-51.9
52.0-159.9
160.0-399.9
400+
Okaloosa
Jackson
Bay
Taylor
Nassau
Union
Marion
Seminole
Pasco
Osceola
St Lucie
Monroe

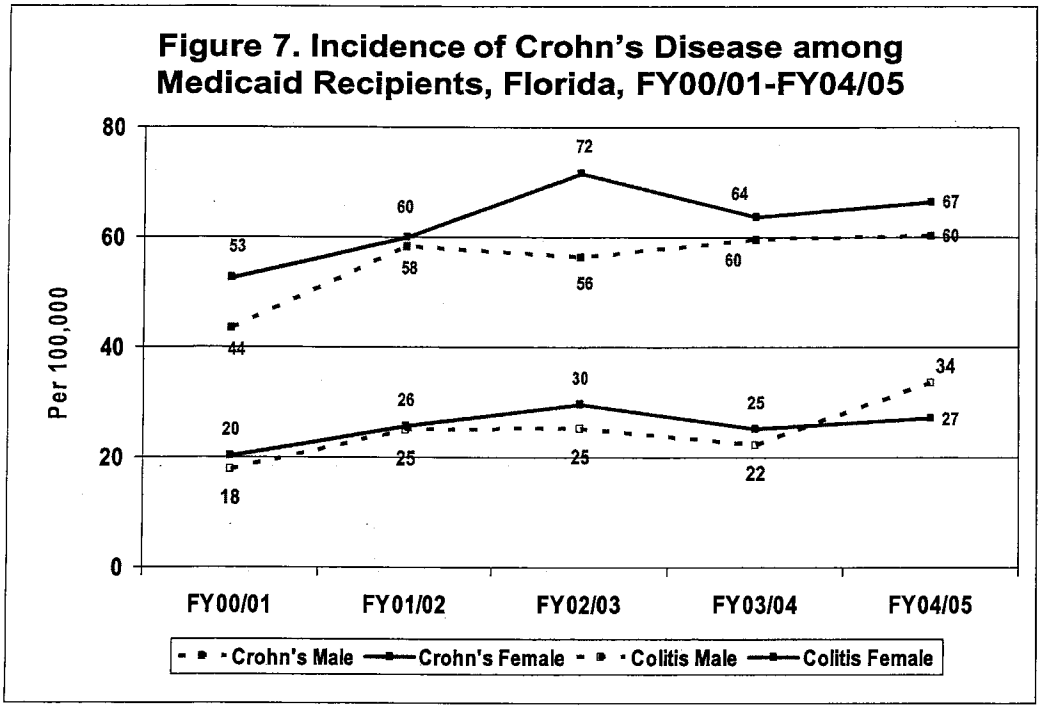
Medicaid data

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

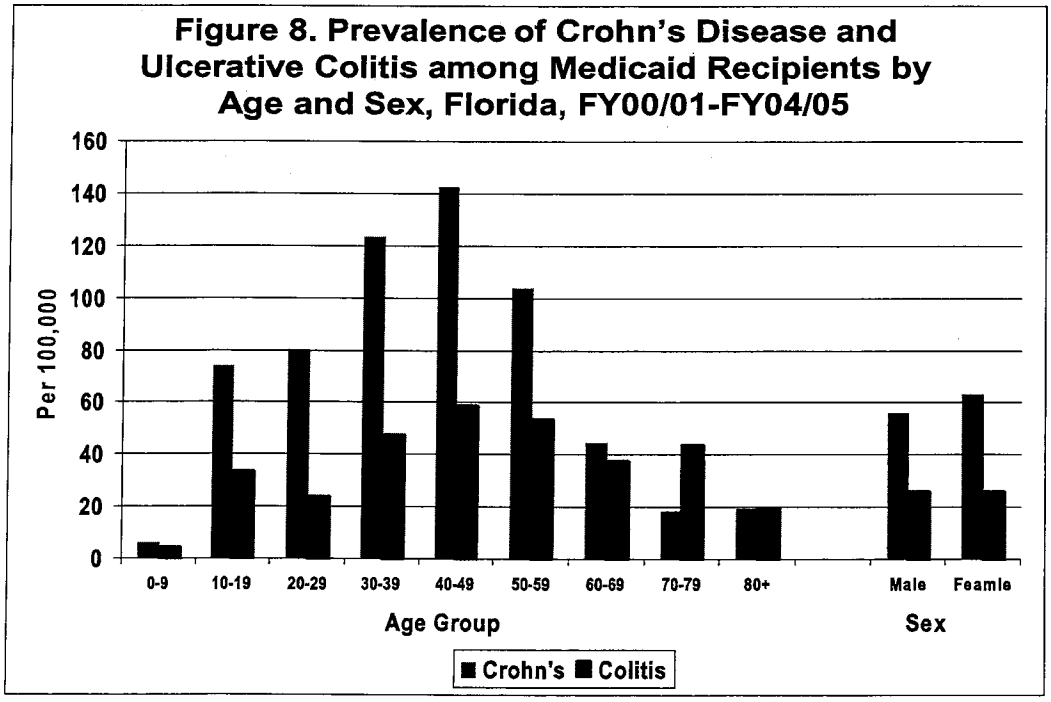
	FY00/01	FY01/2	FY02/3	FY03/4	FY04/5
# of Recipients	**1,042,369**	**1,084,413**	**895,044**	**1,170,599**	**1,730,249**
Crohn's Disease					
Total	**513**	**644**	**590**	**728**	**1,111**
Female	**348**	**416**	**406**	**474**	**733**
Male	**165**	**228**	**184**	**254**	**378**
Ulcerative Colitis					
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.

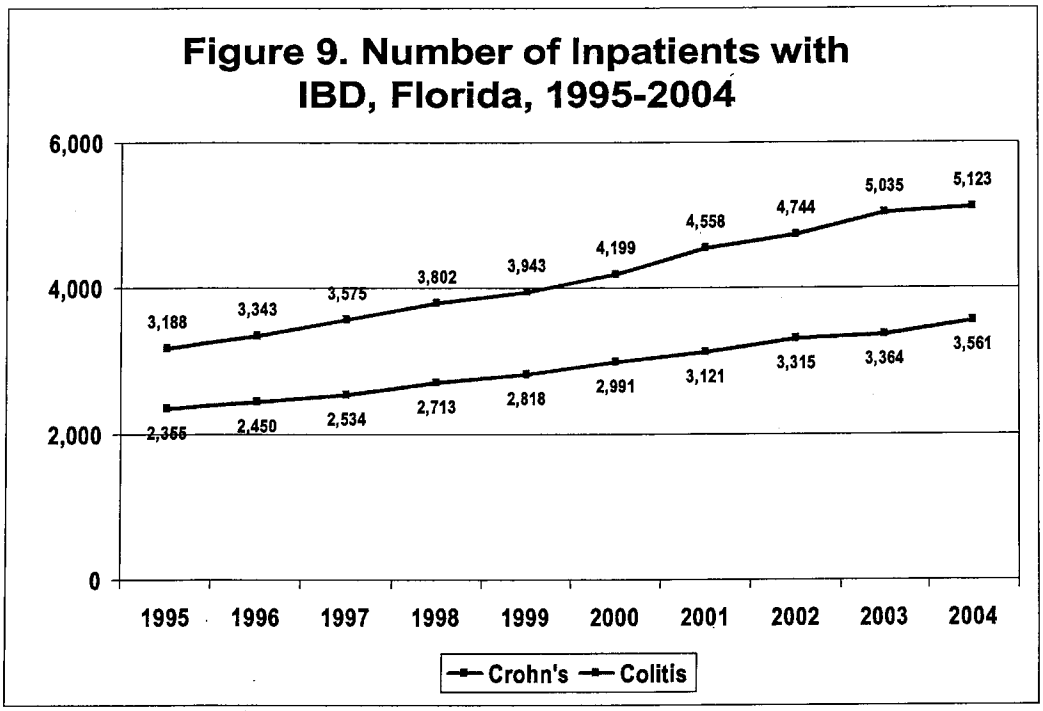
Among patients with Crohn's disease and ulcerative colitis, there were more female patients, than there were male patients. Although most Crohn's disease and ulcerative colitis patients were Whites, many patients of other races/ethnicities were diagnosed with IBD as well. (Table 3)

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

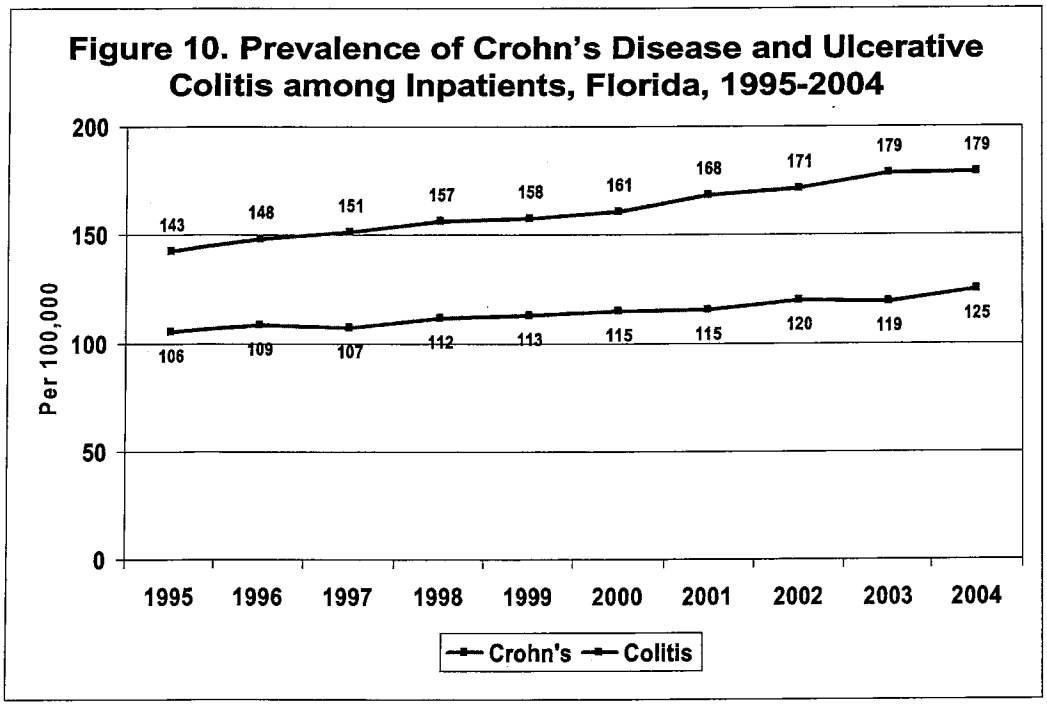
	All IBD	Crohn's	Colitis	Other		All IBD	Crohn's	Colitis	Other
Total	18770	1534	1382	16314					
By Age					By Race				
0-	246	0	0	246	Black	2,186	92	90	2,039
1-10	1,129	5	3	1,123	Hispanic	2,424	90	117	2,256
11-20	534	60	30	456	Other	442	35	34	383
21-30	1,193	158	83	987	White	13,718	1,318	1,140	11,635
31-40	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

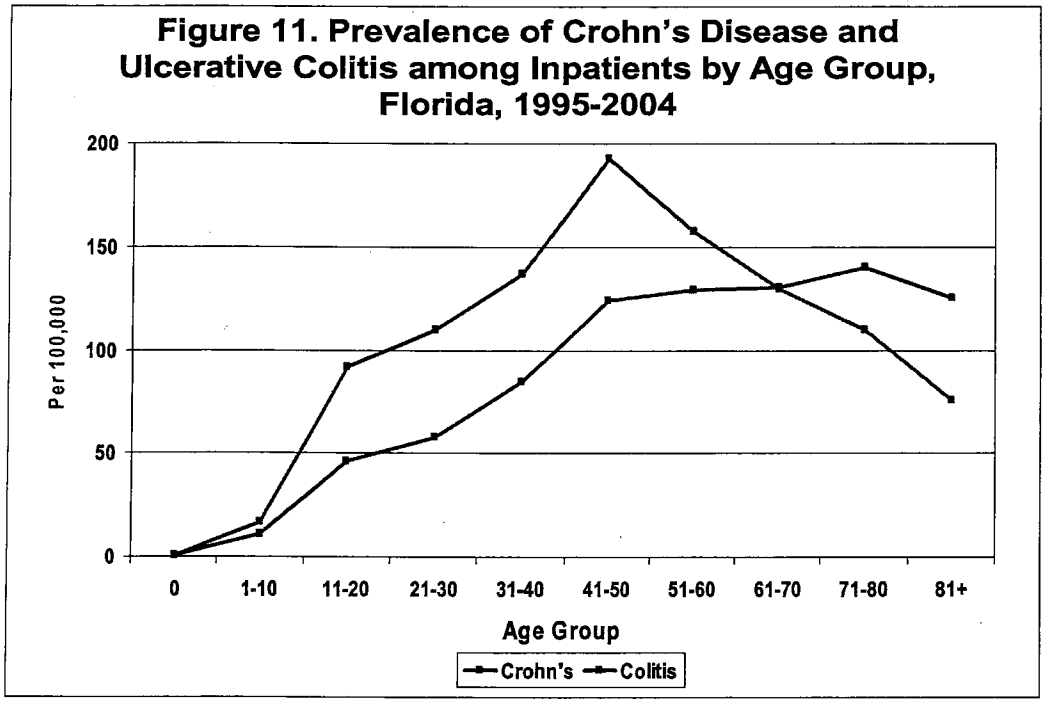
The number of patients with Crohn's disease and ulcerative colitis that were hospitalized increased by 61 percent and 51 percent, respectively, from 1995 to 2004. In 2004, 5,123 Crohn's disease and 3,561 ulcerative colitis patients were hospitalized. (Figure 9)
The 10-year overall prevalence was 120.1 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)



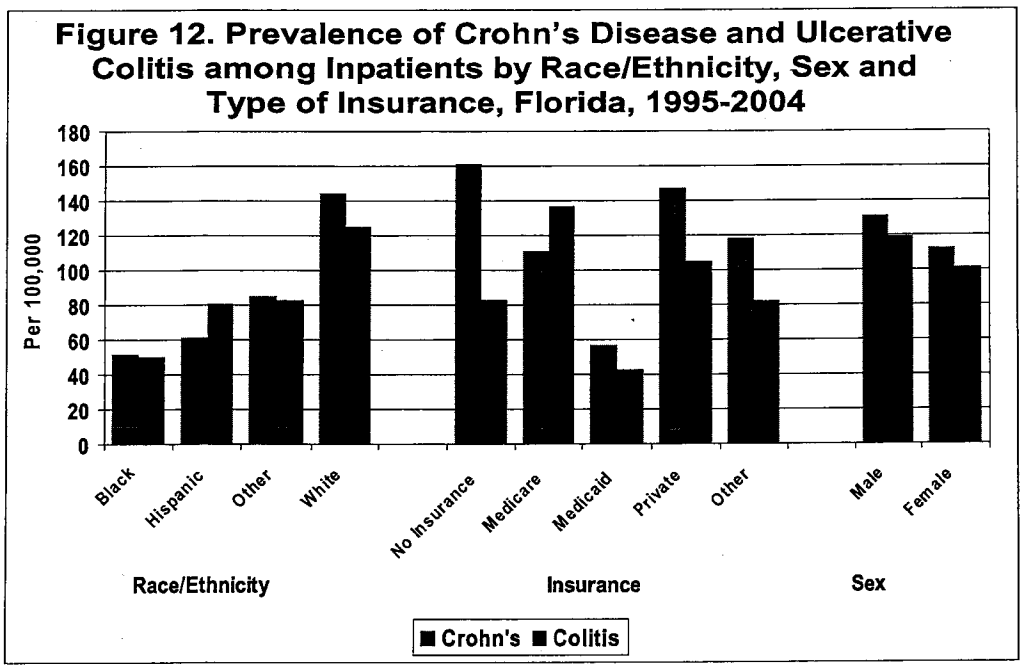
The age-specific prevalence of Crohn's disease increased by age, reached a peak of 193 per 100,000 people among the 41-to-50-year age group, then it decreased to 76 per 100,000 people among people aged 81 years and older. The prevalence of ulcerative colitis also increased by age, reached a peak of 140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

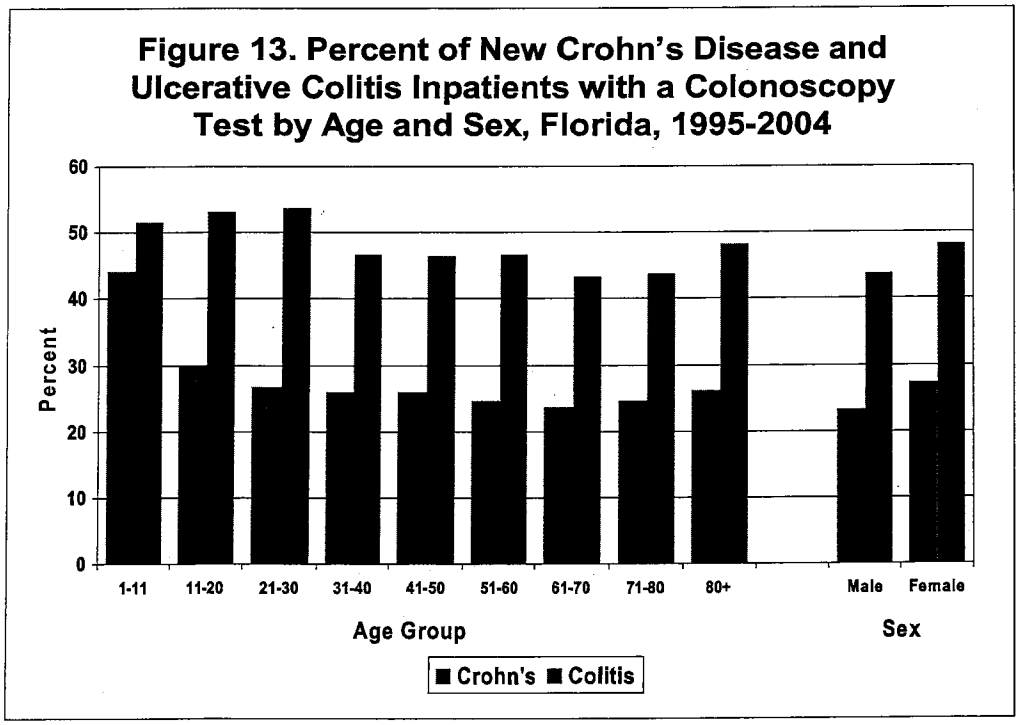
Patients who had a private medical insurance (147 per 100,000 people) and patients without any insurance (162 per 100,000 people) had a higher prevalence for Crohn's disease than their counterparts did. Medicare beneficiaries had the highest prevalence (137 per 100,000 people) of ulcerative colitis.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

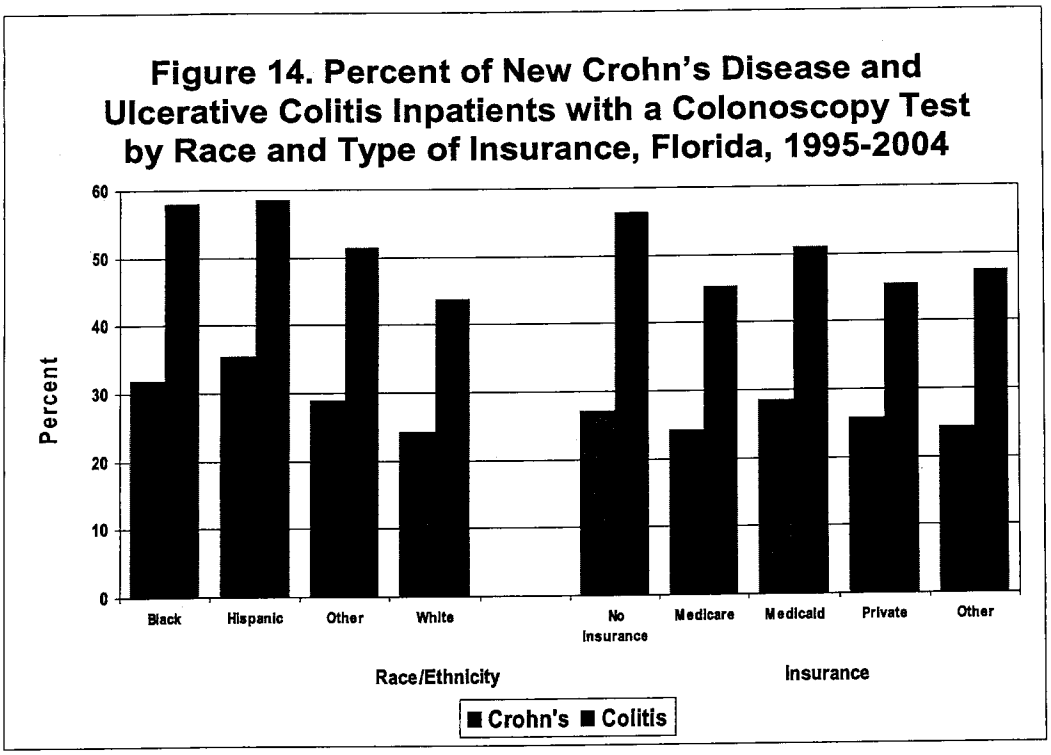


Approximately one quarter (25.5 percent) of new Crohn's disease patients had a colonoscopy. The percent of patients with a colonoscopy was higher among younger patients (under age 20) than among older patients, and higher among females than among males.

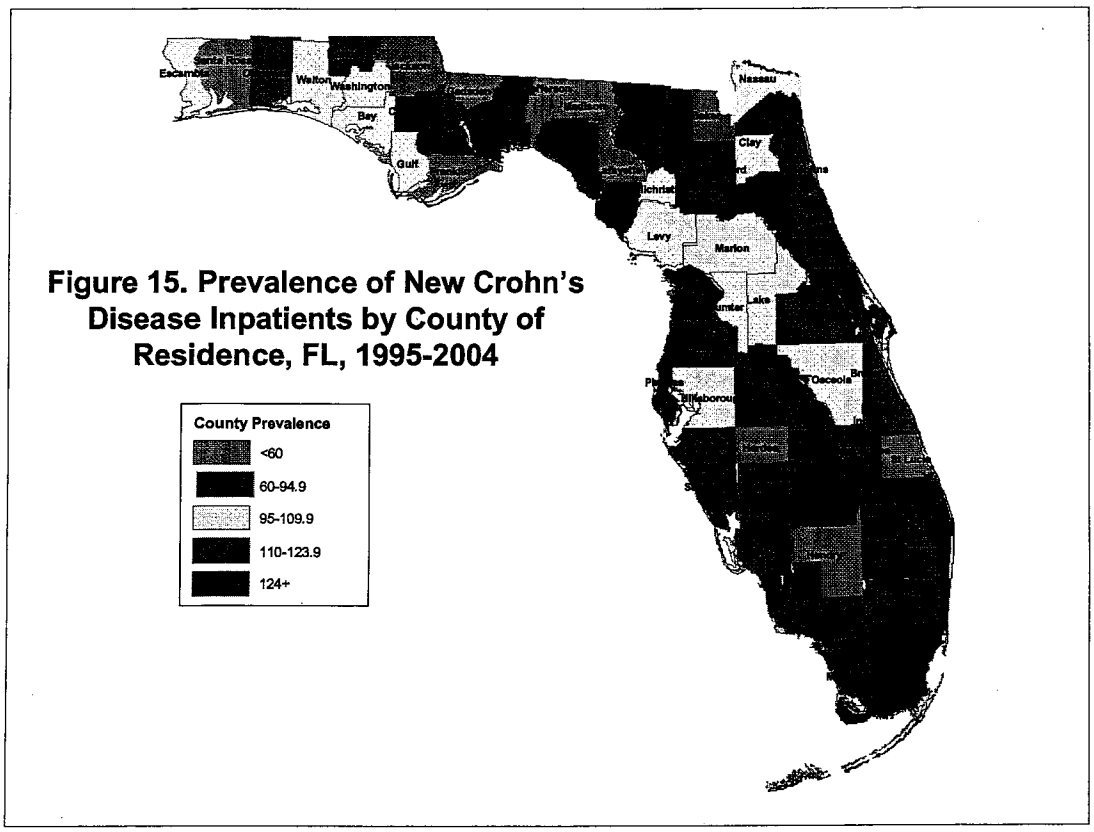
Among new patients with ulcerative colitis, 42.3 percent had a colonoscopy. The percent of patients with a colonoscopy was also higher among patients under age 30 and among females than among their counterparts. (Figure 13)



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)

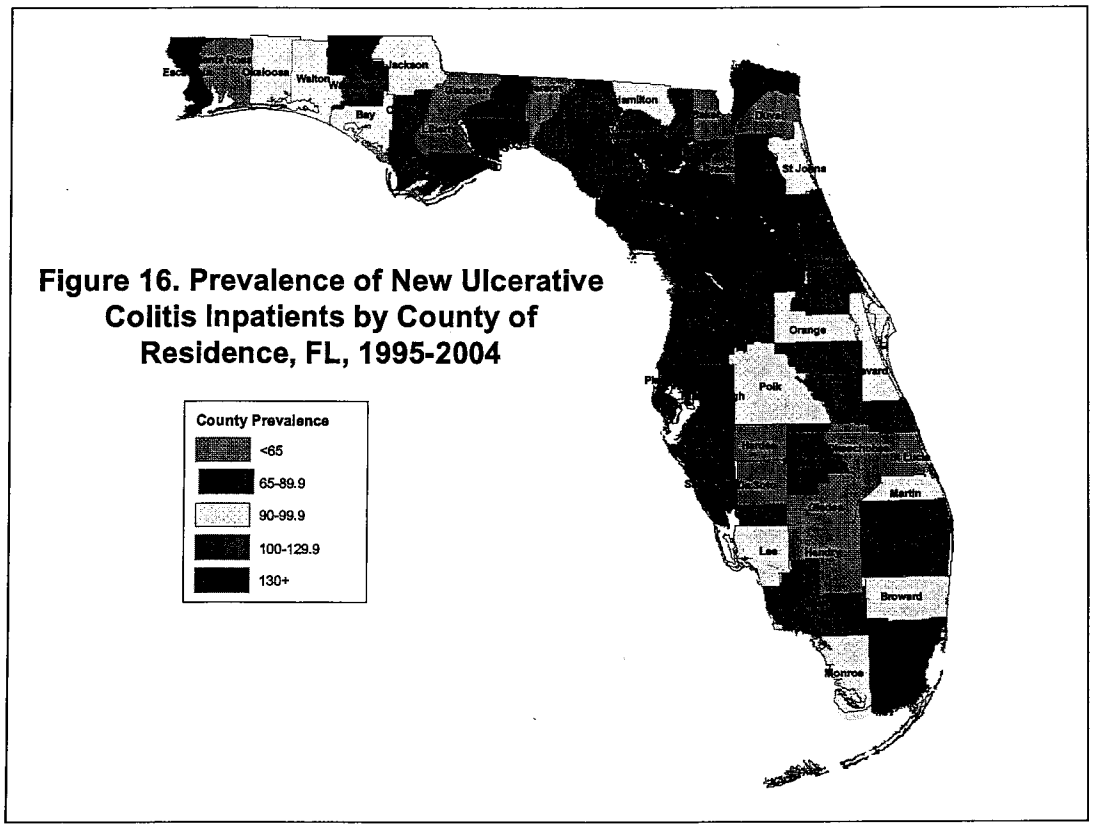


Twelve counties had a 10-year overall prevalence of Crohn's disease of 124 per 100,000 people or greater in Florida. These counties are Holmes, Union, Seminole, Hernando, Pasco, Pinellas, Indian River, Okeechobee, Sarasota, Charlotte, Collier, and Monroe. (Figure 15)



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)

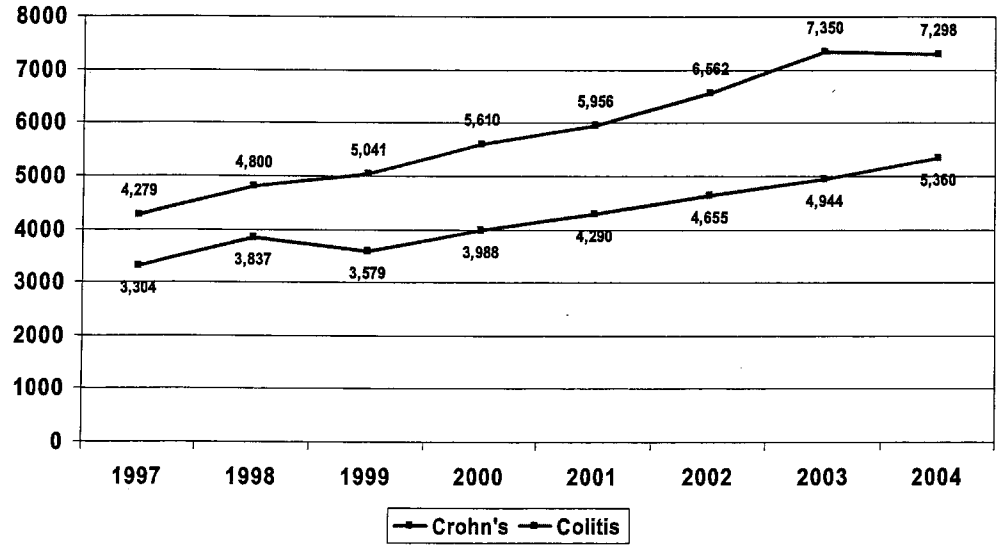
Table 4. Average Number of New Outpatients with IBD per Year, Florida, 1997-2004

	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

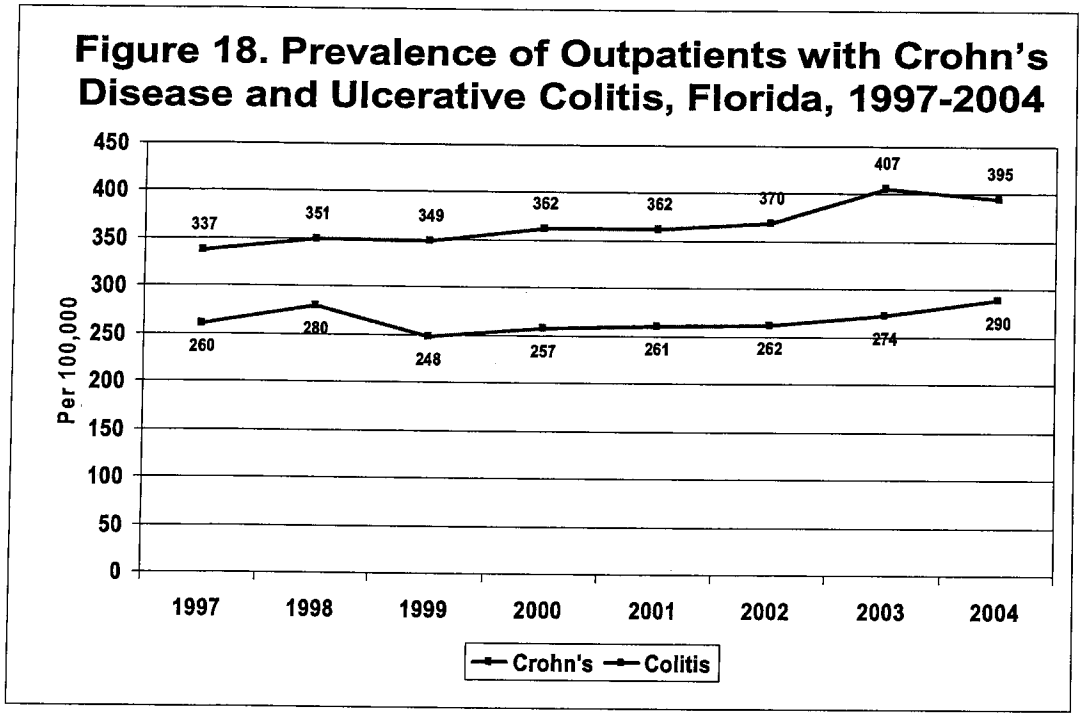
The number of Crohn's disease patients that were treated as ambulatory patients was 3,304 in 1997 and increased by 62 percent to 5,360 in 2004. The number of ulcerative colitis patients increased by 71 percent, from 4,279 in 1997 to 7,298 in 2004. (Figure 17)

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



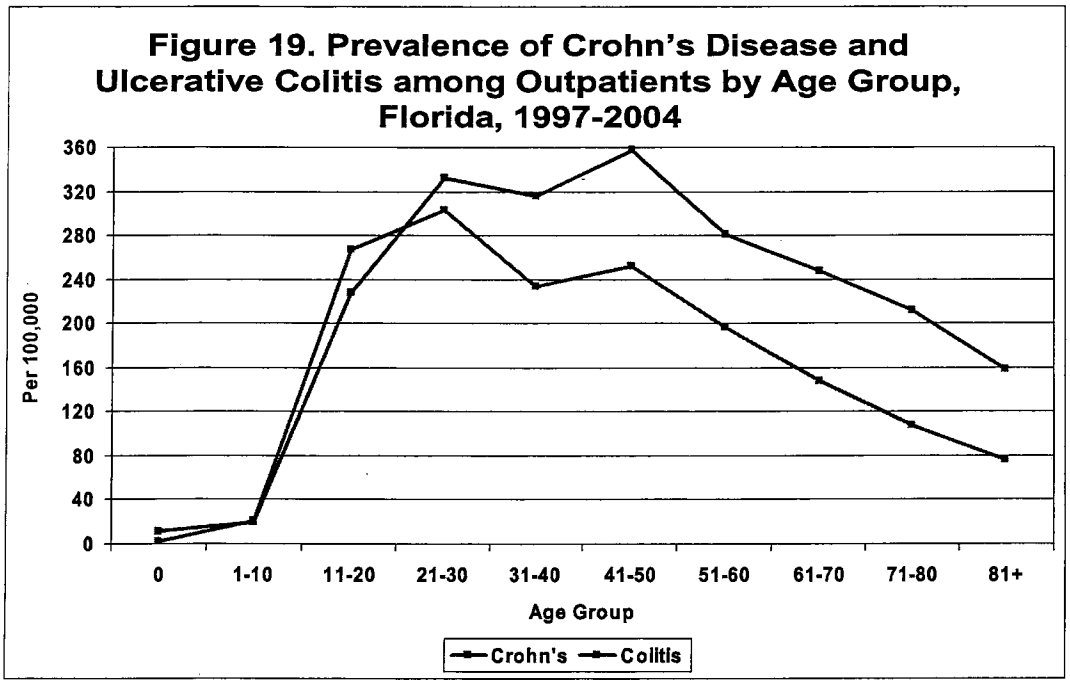
The 8-year overall prevalence (each patient was counted only once) was 173.1 per 100,000 people for Crohn's disease and 256 per 100,000 people for ulcerative colitis during 1997-2004. Some patients were diagnosed with both Crohn's disease and ulcerative colitis. The average prevalence of patients with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

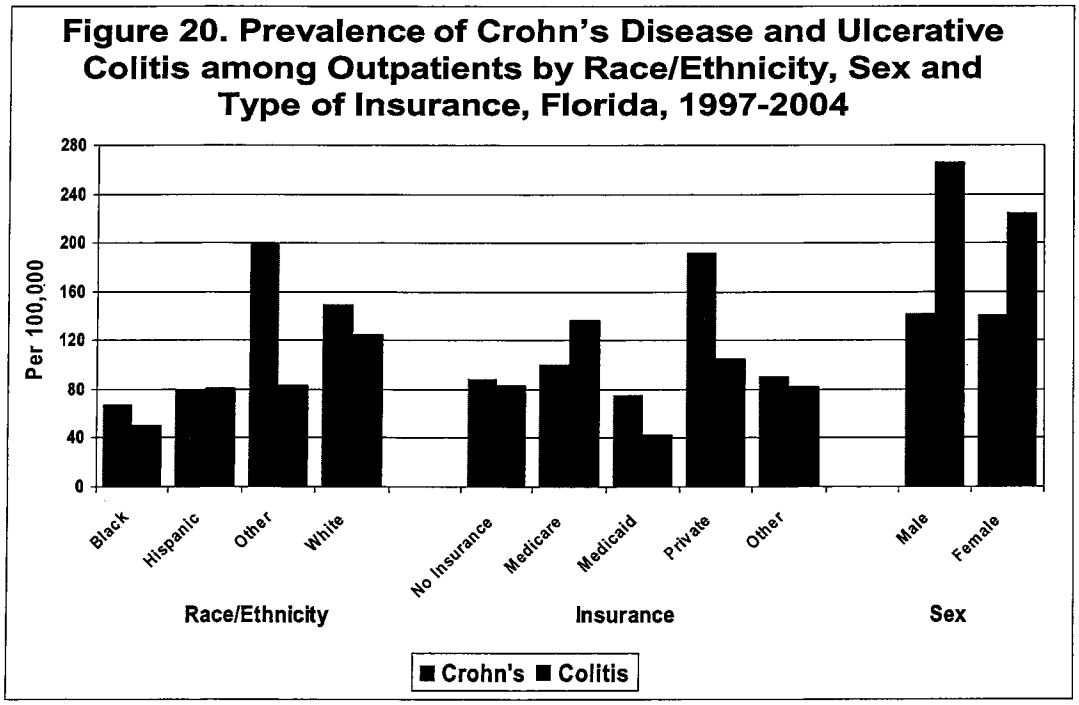


The age-specific prevalence of Crohn's disease increased dramatically in teenagers and peaked in the 21- to 30-year-old age group. Age-specific prevalence decreased among patients aged 30 years and older, with an exception of an increase in the 41- to 50-year-old age group.

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)

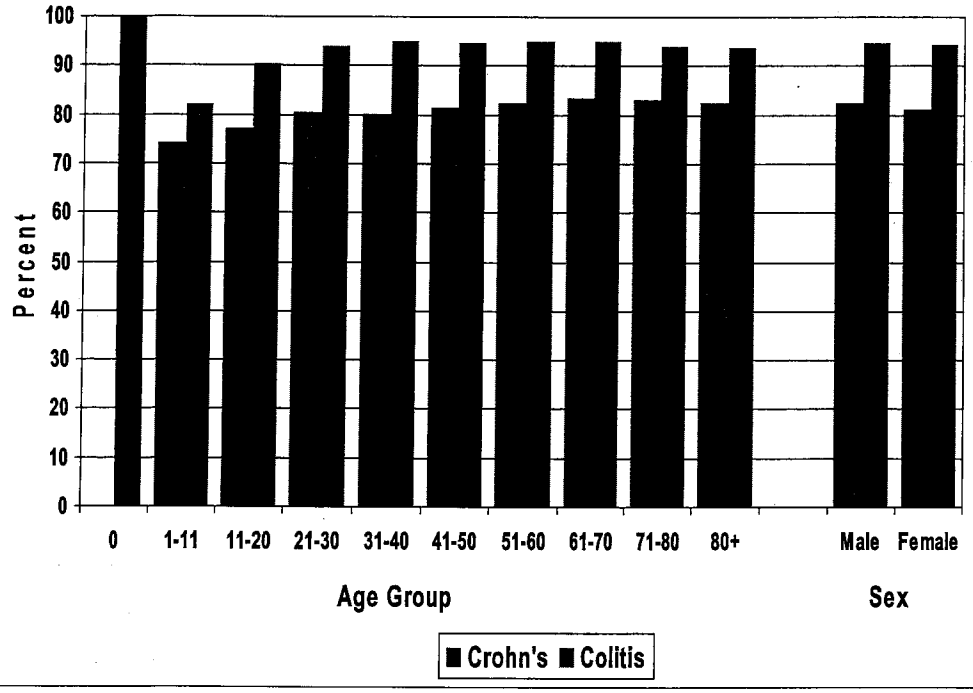


The prevalence of ulcerative colitis was the highest among Whites (125 per 100,000 people), and among Medicare beneficiaries (137 per 100,000 people). The prevalence was the lowest among Medicaid recipients (43 per 100,000 people). Males had a higher prevalence of ulcerative colitis (265 per 100,000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

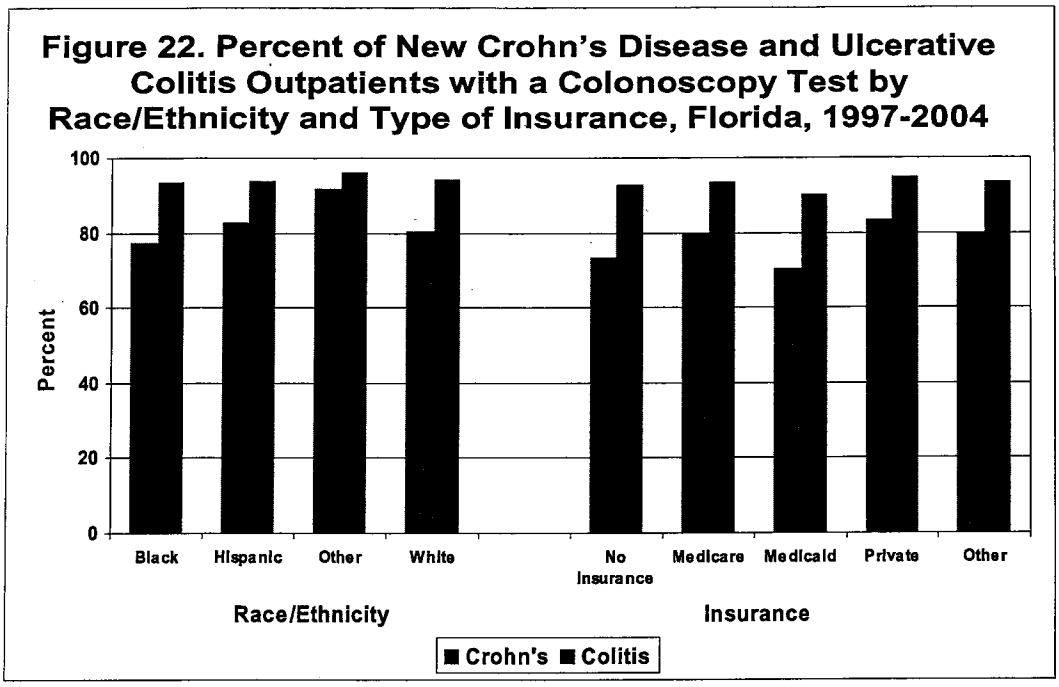
Approximately 82 percent of Crohn's disease patients had a colonoscopy. The percent of Crohn's disease patients with a colonoscopy was lower among patients under age 20 than among older patients. The percent was the same among both males and females.

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)

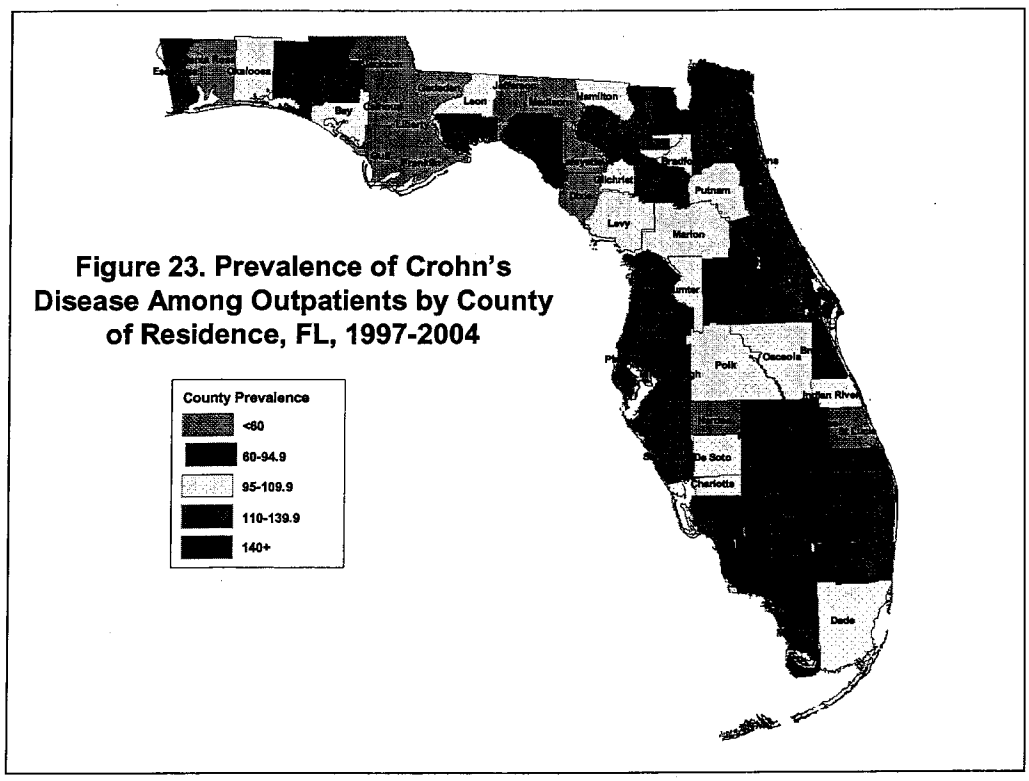
Figure 21. Percent of New Crohn's Disease and Ulcerative Colitis Outpatients with a Colonoscopy Test by Age and Sex, Florida, 1997-2004



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.

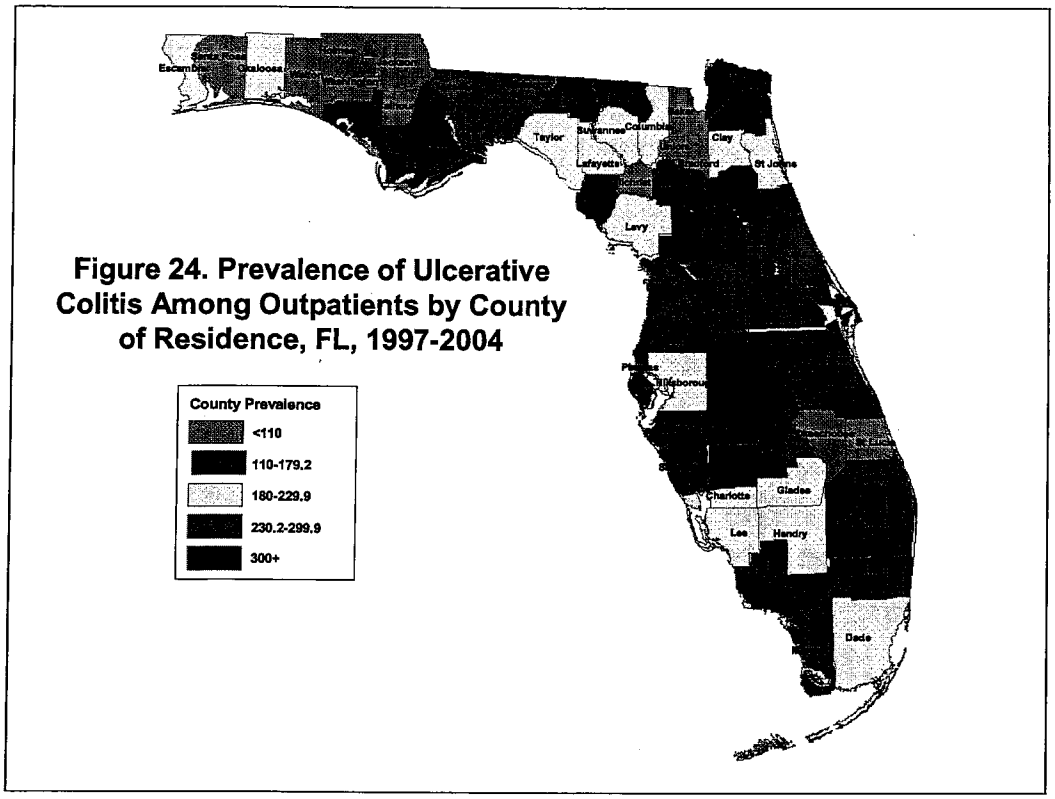


Figure 24. Prevalence of Ulcerative Colitis Among Outpatients by County of Residence, FL, 1997-2004

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

Florida Council for Community
Mental Health

Emergency Psychiatric Care
A Community Crisis

House Health Care Committee

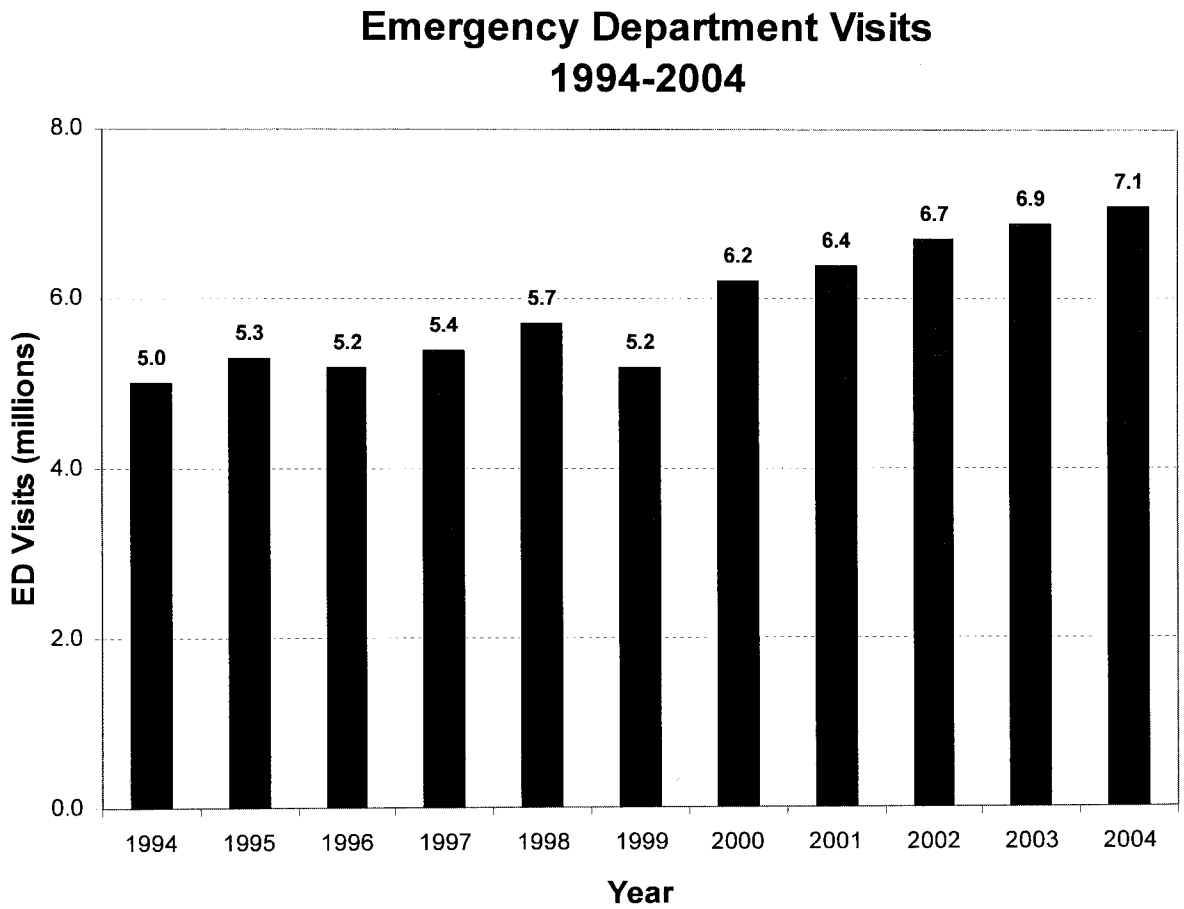
February 22, 2006

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).

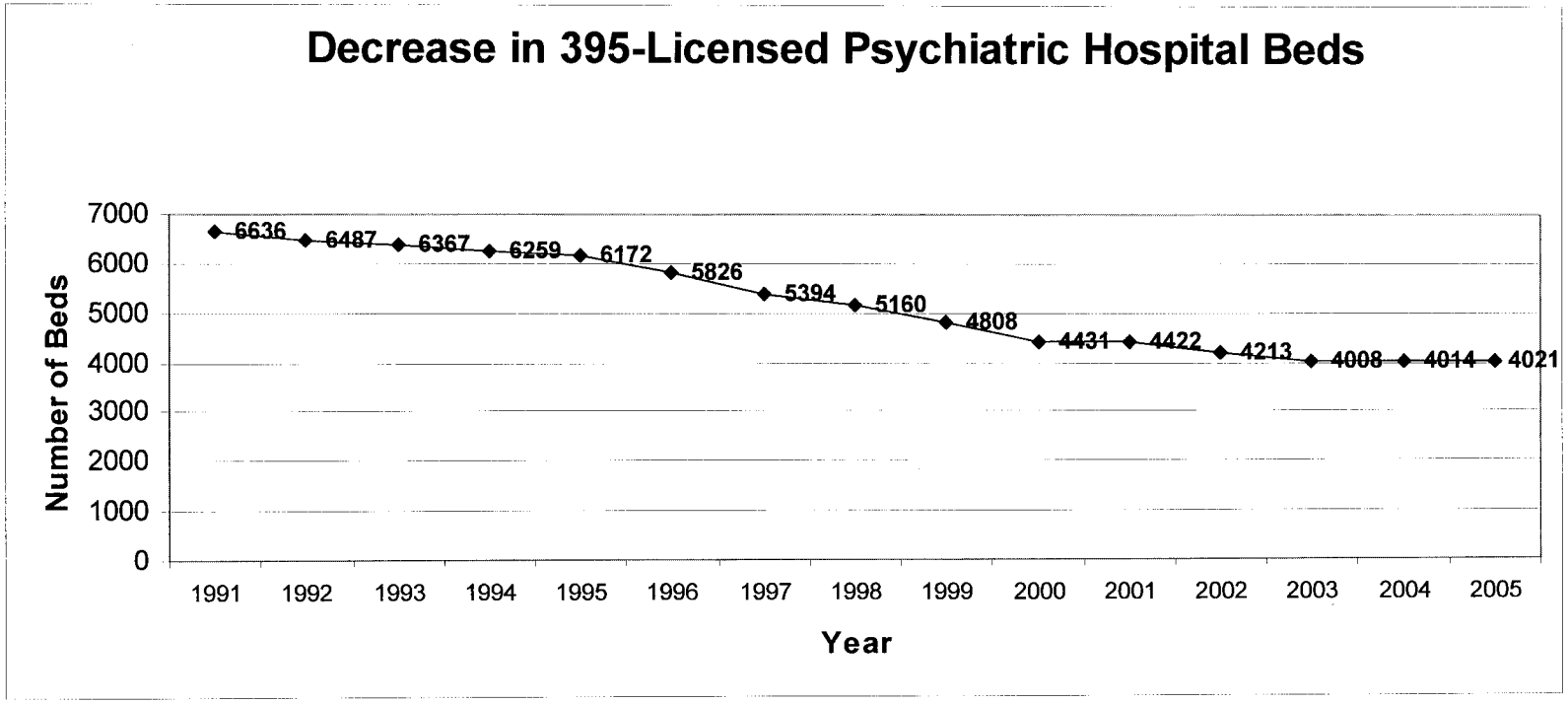
Emergency Department (ED) Use Psychiatric Disorders

- 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.

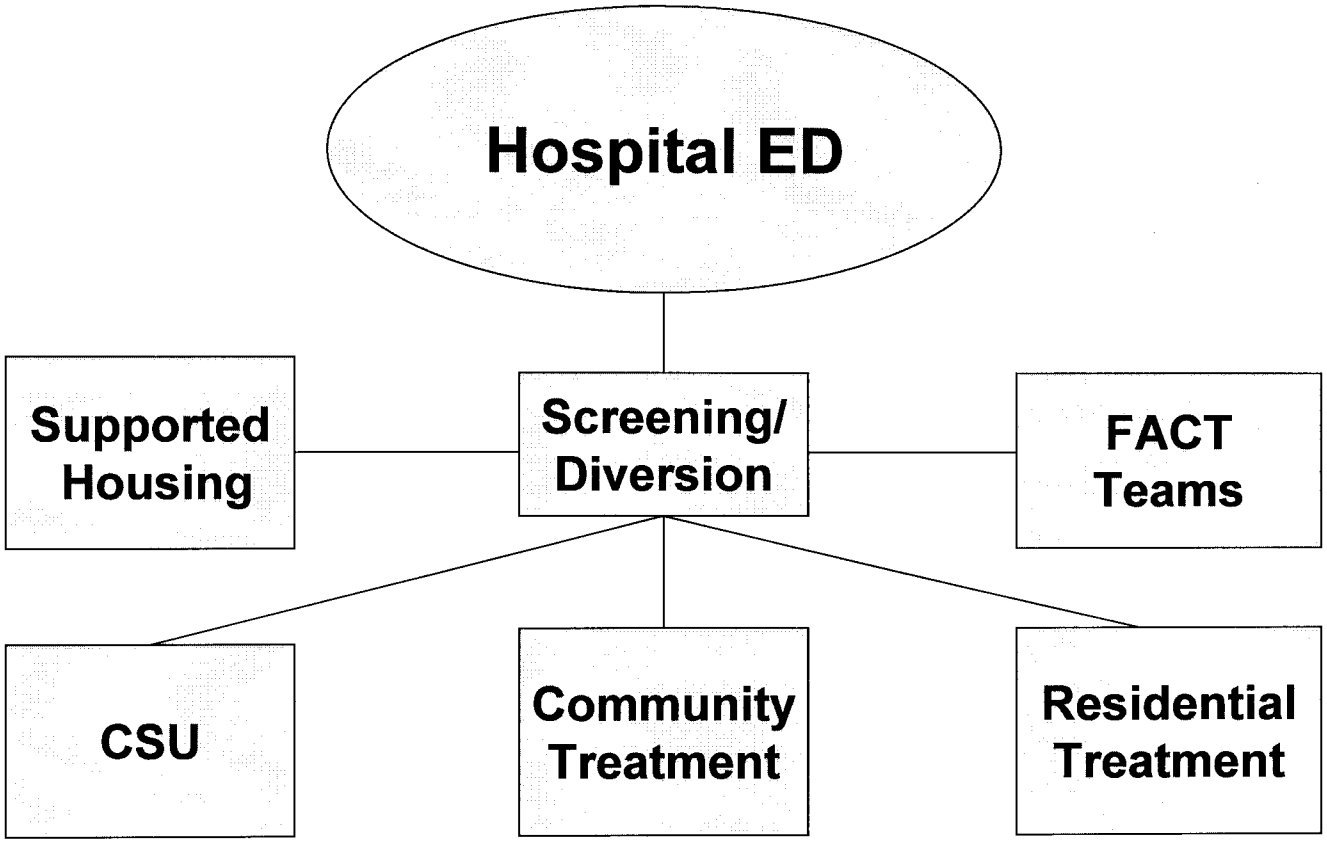
Acute and Emergency Care Issues

- 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, February 22, 2006
10:30 AM – 12:00 PM
306 HOB

COMMITTEE MEETING PACKET

Revised

ADDENDUM "A" (02/22/2006; 8:00 AM)

Allan G. Bense
Speaker

Gayle B. Harrell
Chair

Bill No. **0241**

COUNCIL/COMMITTEE ACTION

ADOPTED	__	(Y/N)
ADOPTED AS AMENDED	__	(Y/N)
ADOPTED W/O OBJECTION	__	(Y/N)
FAILED TO ADOPT	__	(Y/N)
WITHDRAWN	__	(Y/N)
OTHER	____	

---

1 Council/Committee hearing bill: Health Care General Committee
2 Representative(s) Vana offered the following:
3
4 **Amendment (with title amendment)**
5 Remove everything after the enacting clause and insert:
6 Section 1. Subsection (5) of section 409.814, Florida
7 Statutes, is amended to read:
8 409.814 Eligibility.--A child who has not reached 19 years
9 of age whose family income is equal to or below 200 percent of
10 the federal poverty level is eligible for the Florida KidCare
11 program as provided in this section. For enrollment in the
12 Children's Medical Services Network, a complete application
13 includes the medical or behavioral health screening. If,
14 subsequently, an individual is determined to be ineligible for
15 coverage, he or she must immediately be disenrolled from the
16 respective Florida KidCare program component.
17 (5) A child whose family income is above 200 percent of
18 the federal poverty level or a child who is excluded under the
19 provisions of subsection (4) may participate in the Medikids
20 program as provided in s. 409.8132 or, if the child is
21 ineligible for Medikids by reason of age, in the Florida Healthy

22 Kids program, ~~Florida KidCare program, excluding the Medicaid~~
23 ~~program, but is~~ subject to the following provisions:
24 (a) The family is not eligible for premium assistance
25 payments and must pay the full cost of the premium, including
26 any administrative costs.
27 (b) The agency is authorized to place limits on enrollment
28 in Medikids by these children in order to avoid adverse
29 selection. The number of children participating in Medikids
30 whose family income exceeds 200 percent of the federal poverty
31 level must not exceed 10 percent of total enrollees in the
32 Medikids program.
33 (c) The board of directors of the Florida Healthy Kids
34 Corporation is authorized to place limits on enrollment of these
35 children in order to avoid adverse selection. In addition, the
36 board is authorized to offer a reduced benefit package to these
37 children in order to limit program costs for such families. The
38 number of children participating in the Florida Healthy Kids
39 program whose family income exceeds 200 percent of the federal
40 poverty level must not exceed 10 percent of total enrollees in
41 the Florida Healthy Kids program.
42 (d) Children described in this subsection are not counted
43 in the annual enrollment ceiling for the Florida KidCare
44 program.
45 Section 2. The Agency for Health Care Administration shall
46 begin enrollment under s. 409.814(5), Florida Statutes, as
47 amended by this act, by July 1, 2006.
48 Section 3. This act shall take effect July 1, 2006.
49
50 ========== T I T L E A M E N D M E N T ==========
51 Remove the entire title and insert:
52 A bill to be entitled

53 An act relating to the Florida KidCare program; amending
54 s. 409.814, F.S.; providing for certain children who are
55 ineligible to participate in the Florida KidCare program
56 to be eligible for the Medikids program or the Florida
57 Healthy Kids program; requiring that the Agency for Health
58 Care Administration begin enrollment under the revised
59 program criteria by a specified date; providing an
60 effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCB HCG 06-01 Emergency Management
SPONSOR(S): Health Care General Committee
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
Orig. Comm.: Health Care General Committee		Ciccone JC	Brown-Barrios B3
1)			
2)			
3)			
4)			
5)			

SUMMARY ANALYSIS

The proposed committee bill amends various sections of Florida Statutes relating to the planning and operation of special needs emergency shelters in Florida. Specifically, the bill addresses emergency planning and management to enhance the safety and well-being of persons with special needs before, during, and after a disaster. The bill assigns lead responsibility regarding special needs shelter maintenance and operation to certain state agencies, establishes the multiagency special needs shelter discharge planning team and encourages coordination of emergency services among national, state and local agencies and volunteer organizations.

The bill assigns lead agency education, communication and outreach responsibilities to the Department of Community Affairs, expands special needs registration efforts, revises the membership and role of the Special Needs Interagency Committee and amplifies the Department of Health's role in establishing a more coordinated comprehensive emergency plan review of certain facilities and providers with the Department of Elder Affairs and the Agency for Health Care Administration.

The bill provides procedures to address the needs of families of special needs shelter residents, provides facility and provider reimbursement when rendering services during a disaster, authorizes certain facilities to exceed their licensed capacity during an evacuation situation, and requires the Agency for Health Care Administration to monitor and assist nursing homes during a disaster and to publish an emergency phone number for nursing requesting assistance.

The Department of Health estimates the additional responsibilities associated with the increase in comprehensive emergency management plan reviews to require $2.7M in initial funding. The Department of Community Affairs, the Department of Elder Affairs, and the Agency for Health Care Administration, should be able to carry out the provision of the bill within existing resources. Certain provisions of the bill are conditional upon funding.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Promote Personal Responsibility and *Empower Families* – Providing time and appropriate pre- and post-disaster information and improving the availability of services should enable the state's residents to make choices that will enhance the safety and well-being of themselves and their families.

B. EFFECT OF PROPOSED CHANGES:

Current situation

Florida's geographical location makes this state vulnerable to a variety of natural disasters. Various state agencies coordinate with local and federal governments, interstate organizations, and the private sector to prepare residents and visitors before disasters to help protect them during such events and assist with recovery afterward.

Florida's regulatory guidelines regarding disaster response are outlined in several documents. Chapter 252, F.S., mandates the development of the Florida Comprehensive Emergency Management Plan (the Plan). The Plan establishes the framework to ensure that Florida is prepared to deal with the aftermath of any one of several hazards that threaten our communities, businesses, and the environment. The Plan coordinates response and recovery activities with federal, state, local, and volunteer entities and organizations in an attempt to unify the efforts of these groups to ensure a comprehensive approach to reducing and mitigating the effects of an emergency or disaster.

Additionally, laws relating to health care providers, including ancillary services, provide that certain rules be developed and enforced to establish reasonable and consistent quality of care to persons prior, during, and after a disaster.

A significant number of Florida's citizens are considered vulnerable in the event of natural disasters such as hurricanes:

- More than 76% of Florida's total population (12,816,041 persons) resides in the 35 coastal counties.
- Eight percent of the state's total population (1,333,969 persons) resides in mobile homes.
- More than 18% of the state's total population (3,051,453 persons) is 65 years of age or older, with the highest number in Miami-Dade (314,497), Palm Beach (278,868), Broward (315,470), Pinellas (229,763) and Hillsborough (139,341) counties.[1]
- Florida has made significant strides in reducing the deficit of safe hurricane shelter space in the past five years. Approximately 50% of the deficit has been eliminated. However, between 2004 and 2009, the vulnerable population in Florida is projected to increase by nearly 900,000, with as many as 16% possibly seeking safety in public shelters.[2]
- There are 746 nursing homes with 81,986 licensed beds in the state.
- There are an estimated 333,492 citizens that may be considered "frail elderly" (about 2% of the Florida's population).

Special needs shelters provide refuge to persons who because of a health or medical condition require the supervision of a health care professional during a disaster or emergency. These shelters operate and coordinate services with state, local agency and volunteer organizations. The Department of Health is the primary agency under the Emergency Support Function-8 operations to maintain and staff special

[1] *Comprehensive Emergency Management Plan 2004*, February 1, 2004
[2] *State of Florida 2004 Statewide Emergency Shelter Plan*, February 2004.

needs shelters. [3] On September 1, 2004, the Governor issues Executive Order Number 04-192, authorizing the Department of Health to assume responsibility for special needs shelter operations if specifically requested by any county Director of Emergency Management. This order, incorporated in subsequent hurricane executive orders, was prompted by, "(T)he recognition that the system was overwhelmed and that the department was in the best position, under the circumstances to assume expedient responsibility for SpNs operations..."

The Department of Health, in its 2004 Hurricane Season *AFTER ACTION REPORT* documents that changing demographics have resulted in increasing numbers of elderly and disabled individuals receiving in-home services. The reports states, "(D)uring these storms, Florida, with its high proportion of elderly, experienced the effects of these combinations of factors like never before. Individuals, who functioned well in their homes during normal times, many with support services from home health care agencies, were unable to maintain that level of functionality during and after the storms. Storm-related disruptions to communications, transportation, power supplies, and lack of continuity of in-home support services as well as structural damage to their homes, forced many seniors out of their independent living status and into SpNS, at least temporarily. In some areas, those who had not evacuated prior to the storm found they could not safely remain in their homes after the storm due to these disruptions resulting in a 'second wave' of evacuees entering special needs shelters."[4]

The department's report highlights a number of issues and lessons learned including:

- County health departments were not always involved with other government entities in selecting SpNS.
- Many eligible persons were not aware of the Special Needs Registry and many of those registered did not actually choose to shelter in SpNS.
- Many eligible persons asked to be added to the registry just prior to storm landfall and many registry lists were not updated.
- Better asset assignment was needed, including staff with current specialty skill sets and specialized equipment such as heavy patient lift devices or able-bodied staff, respiratory therapists, oxygen concentrators and other medical support equipment.
- Lack of air conditioning and marginal food and water supplies created stressful shelter conditions.
- Need for more coordinated discharge planning.

Further, during the 2005 hurricane season, additional analysis revealed that physically impaired individuals who decided to shelter at home in multi-story buildings became "trapped" when elevators were rendered inoperable due to power outages. These individuals represent a substantial group that may also seek SpNS services in the future.

Proposed changes

The bill amends certain sections of chapter 252, F. S., and other chapters addressing pre- and post-disaster planning to address services to persons with special needs before, during, and after disasters. The bill assigns lead responsibility for certain functions to specific state agencies and establishes a multiagency emergency special needs shelter discharge planning team to assist local areas impacted by natural or manmade disasters that require the use of special needs shelters. The bill also provides certain pre- and post disaster facility use and licensure flexibility. The effect of these provisions should be to provide increased coordination among federal, state and local entities and to facility the timely and appropriate use of facilities to serve the special needs population.

The bill:

- Includes individuals with cognitive impairments among persons considered to have special needs.

[3] The Florida House of Representatives, Interim Project Report, Health Care General Committee, November 2005
[4] Florida Department of Health, 2004 Hurricane Season *AFTER ACTION REPORT*, March 4, 2005.

- Expands the communication and outreach efforts regarding special needs registration.
- Requires year-round maintenance of the special needs registry.
- Designates the Department of Community Affairs as the lead agency responsible for community education and outreach and requires the department to coordinate with certain other entities in those efforts.
- Provides that a special needs shelter is considered a public facility when activated for a disaster and as such must allow people with disabilities to bring their service animals into the facility.
- Provides that the Department of Agriculture and Consumer Services as the lead agency responsible for pet and animal sheltering during a disaster.
- Designates Children's Medical Services as the lead agency for coordinating local medical and health care providers for the staffing and management of pediatric special needs shelters.
- Provides that the Agency for Health Care Administration monitor nursing homes during emergencies to determine if assistance is needed and that the agency publishes an emergency telephone number for nursing homes to use.
- Specifies that the Division of Emergency Management include special needs shelter assessment, location, estimated need, and other information in its statewide emergency shelter plan.
- Provides that the Department of Health assist the Division of Emergency Management in determining the estimated need for special needs shelter space and the adequacy of the facility to meet shelterees' needs.
- Provides that the local emergency management agency shall inspect a facility to determine its readiness prior to activating such facility.
- Assigns the county health departments, in conjunction with the local emergency management agencies, the lead responsibility to coordinate and recruit health care practitioners to staff local special needs shelters, and encourages coordination of non-medical staffing and operating of special needs shelters.
- Provides that local emergency management agencies are responsible for the designation and operation and closure of facilities and that services are coordinated with county health departments.
- Establishes state employee roles under certain circumstances in a disaster response.
- Establishes a multiagency emergency special needs shelter discharge planning team.
- Directs the Department of Elder Affairs to convene the multiagency special needs shelter discharge planning team as necessary to assist local areas impacted by emergency or disaster.
- Allows certain practitioners, hospitals, nursing homes or receiving facilities to request reimbursement for sheltering persons with special needs.
- Provides protections against duplication of reimbursements to receiving facilities.
- Revises the duties and membership of the Special Needs Shelter Interagency Committee and expands the committee to include the Florida Association of Aging Services Providers, the Florida Renal Coalition and AARP.
- Requires the Department of Health to adopt rules.
- Requires emergency management plans to address home health agency, nurse registry, hospice, and home medical equipment provider's functional staffing plan for shelters to ensure continuity of care and services for clients.
- Provides that home health agencies, nurse registries, hospice and home medical equipment providers include a continuity of care component in its respective comprehensive emergency management plans, encourages these entities to establish links to emergency operations centers to determine a mechanism to approach disaster areas in order to reach clients, provides for a more coordinated review of such plans by the county health departments and allows sanctioning capability by the Agency for Health Care Administration under certain circumstances.
- Provides licensure and use flexibility to allow nursing homes, assisted living facilities, and other residential care facilities to exceed their licensed bed capacity to act as a receiving facility in accordance with emergency operations plans.

C. SECTION DIRECTORY:

Section 1. Amends s. 252.355, F.S., regarding public shelter space and special needs registration.

Section 2. Amends s. 252.3568, F. S., to create s. 252.3568, F.S., regarding emergency pet sheltering.

Section 3. Amends s. 381.0303, F.S., regarding operation, maintenance and closure of special needs shelters; assignment and coordination of local and state agency lead responsibilities; coordination of medical and non-medical staffing in special needs shelters; designation, operation and infrastructure of special needs shelters; state employees' disaster response roles; the Department of Elder Affairs' convening of the multiagency special needs shelter discharge planning team; health care practitioner and other emergency personnel reimbursement; hospitals, nursing and other facilities reimbursement for disaster-incurred expenses; special needs shelter interagency committee membership and responsibilities; the Department of Health's rule-making authority; pre-event planning activities, and home health agency, nurse registry, hospice and home medical equipment provider emergency management plan review.

Section 4. Amends s. 252.385, F.S., regarding public shelter space, statewide shelter survey and need information included in the statewide emergency shelter plan, space allocation within a shelter, shelter location, adequacy of facilities, pet friendly shelters, inspection, shelter readiness and coordination of shelter services.

Section 5. Amends, s. 400.492, F.S., regarding home health agencies and the provision of services during an emergency; provides that home health agencies may establish links to local emergency operations centers and provides sanctioning ability by the Agency for Health Care Administration.

Section 6. Amends s. 400.497, F.S., regarding rules establishing minimum standards; establishes county health department procedures regarding the review of home health agencies comprehensive emergency plans, provides for notification of plan approval or deficiency, and provides that the Agency for Health Care Administration may impose a fine under certain circumstances.

Section 7. Amends s. 400.506, F.S., regarding nurse registries and the provision of services during an emergency; provides that nurse registries may establish links to local emergency operations centers; establishes county health department procedures regarding review of nurse registries comprehensive emergency plans, provides for notification of plan approval or deficiency; and provides that the Agency for Health Care Administration may impose a fine under certain circumstances.

Section 8. Amends s. 400.610, F.S, regarding hospice facilities and the provision of services during an emergency; provides that hospice facilities may establish links to local emergency operations centers; establishes county health department procedures regarding the review of hospice facilities comprehensive emergency plans; provides for notification of plan approval or deficiency; and provides sanctioning ability by Agency for Health Care Administration.

Section 9. Amends s. 400.925, F.S., providing the definition of life-supporting or life-sustaining equipment.

Section 10. Amends s. 400.934, F.S., regarding home medical equipment providers and the provision of services during an emergency; provides that home medical equipments providers may establish links to local emergency operations centers; establishes county health department procedures regarding review of home medical equipment providers comprehensive emergency plans; provides for notification of plan approval or deficiency; and provides that the Agency for Health Care Administration may impose a fine under certain circumstances.

Section 11. Amends s. 400.935, F.S., providing rules establishing minimum standards.

Section 12. Amends s. 408.831, F.S., regarding facility licensure and the provision of certain licensure and facility use pre and post disaster.

Section 13. Creates s. 252.357, F.S., regarding monitoring of nursing homes during a disaster.

Section 14. Provides an effective date of July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

The Department of Health estimates that the increase in the coordination and number of comprehensive emergency management plan reviews would require the following budget:

	2005/06	2006/07
Salaries:		
36 Full time Equivalent (FTE)		
Special Needs Shelter Specialists (4 per region)		
Pay grade 20 @ $55,000	$1,980,000	$2,534,400
4 Admin. Assist. Pay grade 418 @ $39,000	156,000	199,680
Other Personnel Services	15,720	15,720
Expenses:		
40 FTE @Std. DOH professional package W/travel @$13,117	524,680	658,400
Other Capital Outlay:		
40 FTE @Std. DOH professional package @1,900	76,000	
	$2,752,400	$3,408,200

1. Revenues:

   None

2. Expenditures:

   None

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None

2. Expenditures:

   None

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None

D. FISCAL COMMENTS:

The Department of Health estimates the additional responsibilities associated with the increase in comprehensive emergency management plan reviews to require $2.7M in initial funding. The Department of Community Affairs, the Department of Elder Affairs, and the Agency for Health Care Administration, should be able to carry out the provision of the bill within existing resources. Certain provisions of the bill are conditional upon funding.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Counties are already involved in emergency management activities, and the bill does not appear to impose significant new responsibilities upon them. The fiscal impact, if any, on counties is nonexistent or insignificant. The bill does not appear to require a municipality to expend funds or to take actions requiring the expenditure of funds.

2. Other:

   None

B. RULE-MAKING AUTHORITY:

The Department of Health is required to promulgate certain rules.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Technical changes, primarily relating to reordering and renumbering sections, and clarifying existing content are included in the amendment to the proposed committee bill.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

EMERGENCY PREPAREDNESS AMENDMENT
TO THE PROPOSED COMMITTEE BILL

- Includes individuals with cognitive impairments among persons considered to have special needs.

- Expands communication and outreach efforts regarding special needs registration.

- Requires year-round maintenance of the special needs registry.

- Designates the Department of Community Affairs as the lead agency responsible for community education and outreach and requires the department to coordinate with other entities in those efforts.

- Provides that a special needs shelter is considered a public facility when activated for a disaster and as such must allow people with disabilities to bring their service animals into the facility.

- Designates Children's Medical Services as the lead agency for coordinating local medical and health care providers for the staffing and management of pediatric special needs shelters.

- Provides that the Agency for Health Care Administration monitor nursing homes during emergencies to determine if assistance is needed and that the agency publishes an emergency telephone number for nursing homes to use.

- Specifies that the Division of Emergency Management include special needs shelter assessment, location, estimated need, and other information in its statewide emergency shelter plan.

- Provides that the Department of Health assist the Division of Emergency Management in determining the estimated *need* for special needs shelter space and the *adequacy* of the facility to meet shelterees' needs.

- Provides that the Division of Emergency Management include information regarding the availability pet friendly shelters in the statewide emergency shelter plan.

- Provides that the local emergency management agency shall inspect a facility to determine its readiness prior to activating such facility.

- Assigns the county health departments, in conjunction with the local emergency management agencies, the lead responsibility to coordinate and recruit health care practitioners to staff local special needs shelters, and encourages coordination of non-medical staffing and operating of special needs shelters.

- Provides that local emergency management agencies are responsible for the designation, operation, infrastructure and closure of facilities, and that these services and activities are coordinated with county health departments.

- Establishes state employee roles under certain circumstances in a disaster response.

- Establishes a multiagency emergency special needs shelter discharge planning team.

- Directs the Department of Elder Affairs to convene the multiagency special needs shelter discharge planning team as necessary to assist local areas impacted by emergency or disaster.

- Allows certain practitioners, hospitals, nursing homes or receiving facilities to request reimbursement for sheltering persons with special needs.

- Provides protections against duplication of reimbursements to receiving facilities.

- Revises the duties and membership of the Special Needs Shelter Interagency Committee and expands the committee to include the Florida Association of Aging Services Providers, the Florida Renal Coalition and AARP.

- Requires the Department of Health to adopt rules regarding; the definition of a special needs person, eligibility criteria, services, practitioner and facility reimbursement, staffing, supplies and equipment, compliance with animal service laws, registration process, special needs families, and authorizes the Department of health to solicit pre-planning event participation--includes dialysis centers to participate in pre-planning event participation.

- Requires emergency management plans to address home health agency, nurse registry, hospice, and home medical equipment provider's functional staffing plan for shelters to ensure continuity of care and services for clients.

- Provides that home health agencies, nurse registries, hospice and home medical equipment providers include a continuity of care component in its respective comprehensive emergency management plans, encourages these entities to establish links to emergency operations centers to determine a mechanism to approach disaster areas in order to reach clients, provides for a more coordinated review of such plans by the county health departments and allows sanctioning capability by the Agency for Health Care Administration under certain circumstances.

- Provides licensure and use flexibility to allow nursing homes, assisted living facilities, and other residential care facilities to exceed their licensed bed capacity to act as a receiving facility in accordance with emergency operations plans.

Fiscal Note:

The Department of Health estimates based on the increased number and coordination of comprehensive emergency management reviews, a first year cost of $2.7m.
The Department of Community Affairs, the Department of Elder Affairs, and the Agency for Health Care Administration, although directed to enhance and increase emergency management preparedness efforts, should be able to carry out the provisions of the bill within existing resources.
Certain provisions of the bill are conditional upon receipt of funds.

Hurricane Preparedness Issues
HB 89 (workshopped bill) vs. amendment to PCB HCG 06-01
02-22-06

Page/ Line	HB 89	Page/ Line	PCB 06-01
Sec. 1 5/134	Section 252.355, F.S. Include cognitive impairment in special needs criteria	**Sec. 1** 1/11	***No change*** – Section 252.355, F.S. Include cognitive impairment in special needs criteria
6/141-142	Include home health agencies, hospices, nurse registries and home medical equipment providers in list of persons who can identify special needs persons.	1/18-19	***No change*** - Include home health agencies, hospices, nurse registries and home medical equipment providers in list of persons who can identify special needs persons.
6/144-154	Include Department of Education and Agency for Persons with Disabilities; remove Department of Labor and Employment Security in list of entities that may identify special needs persons, add reference to people with disabilities or special needs who receive services. Maintain special needs registry year round.	1/21-2/27	***No change*** - Include Department of Education and Agency for Persons with Disabilities; remove Department of Labor and Employment Security in list of entities that may identify special needs persons, add reference to people with disabilities or special needs who receive services. Maintain special needs registry year round.
6/155-7/179	Clarify the Department of Community Affairs as the community education and outreach lead agency. Provide that people with disabilities can bring their service animals into shelter facilities. Provides that the Department of Agriculture and Consumer Services shall be the lead agency responsible for pet and animal sheltering during a disaster.	2/32	***No change*** - Clarify the Department of Community Affairs as the community education and outreach lead agency. Provide that people with disabilities can bring their service animals into shelter facilities. Delete reference to pet-friendly shelter. Create new section 2 regarding pet shelters.
7/180-181	Require electric utilities to notify residential customers at least quarterly each year beginning January 1st, regarding the registration process.	3/58-72	***Revised*** – Require electric utilities to notify residential customers 1) upon initiation of service and one time each year between January 1 and May 31, or 2) two times between January 1 and May 31changed quarterly to twice a year.
7/191-194	Maintain client privileged information.	3/79-80	***No change*** - Maintain client privileged information
8/197-206	Include home health care providers, hospices, nurse registries, and home medical equipment providers in the list of entities that can identify special needs persons. Include cognitive impairment in special needs criteria	3/83-84	***No change*** - Include home health care providers, hospices, nurse registries, and home medical equipment providers in the list of entities that can identify special needs persons. Include cognitive impairment in special needs criteria

Page/ Line	HB 89	Page/ Line	PCB 06-01
N/A		**Sec. 2** 4/96-102	***Revised*** - New language – creates s. 252.3568(1), F.S. requires the Division of Emergency Management to address evacuation of persons with pets in the shelter component of the state emergency management plan. Requires the Department of Agriculture and Consumer Services to assist the division in determining strategies regarding evacuation of persons with pets.
Sec.12 32/887-897	Section 252.357, F.S. Monitor nursing homes during a disaster. Publish an internet emergency telephone number for nursing home assistance.	**Sec. 3** 4/105-115	***No change*** - Section 252.357, F.S. Monitor nursing homes during a disaster. Publish an internet emergency telephone number for nursing home assistance.
		Sec. 4 5/132-146 6/153-156	***Revised*** – New language s. 252.385 (2) is created to require the division of emergency management to include information regarding the availability of pet-friendly shelters in the statewide emergency shelter plan; revise the statewide emergency shelter plan to include special needs shelter projection and facility adequacy. Including facility adequacy information in the shelter plan will help to address matching shelterees to appropriate facilities. . Requires the local emergency management agency to inspect a facility to determine readiness prior to activating the facility.
Sec. 2 8/211-213	Section 381.0303, F.S. Clarify purpose of special needs shelter section regarding operating, maintaining and closing shelters	**Sec. 5** 7/187-189	***No change*** - Clarify purpose of special needs shelter section regarding operating, maintaining and closing shelters
9/229-236	Clarify the local Children's Medical Services lead responsibility.	7/207-8/212	***No change*** - Clarify the local Children's Medical Services lead responsibility.
9/242-255	Clarify county health department lead responsibility. County assistance regarding staffing and operating special needs shelters. .	8/215-233	***No change*** - Clarify county health department lead responsibility. County assistance regarding staffing and operating special needs shelters.

Page/ Line	HB 89	Page/ Line	PCB 06-01
10/258-259	Clarify that the local emergency management agency is responsible for the designation and closure of facilities following an emergency or disaster.	8/234-9/248	***Revised*** - to add that the local emergency management agencies shall be responsible for the designation, operation and infrastructure of special needs shelters and that the emergency management agency and the local health department shall coordinate these efforts to ensure appropriate designation, operation and infrastructure.
10/263-268	Require state employee's service during a disaster, unless they have other mandated response activities that preclude participation.	9/249-254	***No change*** - Require state employee's service during a disaster, unless they have other mandated response activities that preclude participation.
10/269-11/303	Revise the multiagency special needs shelter *response* team to the multiagency special needs shelter *discharge planning* team to more clearly describe DoE's role.	9/255-10/289	***No change*** - Revise the multiagency special needs shelter *response* team to the multiagency special needs shelter *discharge planning* team to more clearly describe DoE's role.
12/318-319	Include that national or state recognized data sources may be used to determine health care practitioner reimbursements.	11/305-306	***No change*** - Include that national or state recognized data sources may be used to determine health care practitioner reimbursements.
12/323-13/347	Provide that hospitals, assisted living facilities, hospices and skilled nursing facilities that are used to shelter special needs clients may submit invoices for reimbursement.	11/309-327	**Revised** – Clarify that health care facilities such as hospitals, nursing homes, assisted living facilities, and community residential homes that may be used to shelter special needs clients may submit invoices for reimbursement.
12/348-362	Reimbursement to of eligible expenditures, prohibiting reimbursement if services are covered in other state-funded programs or sources.	12/336-344	***No change*** - Reimbursement to of eligible expenditures, prohibiting reimbursement if services are covered in other state-funded programs or sources.
14/367	Use health care practitioner registry to assist with disaster related activities.	12/349	***No change*** - Use health care practitioner registry to assist with disaster related activities.
14/370-15/409	Clarify SpNS committee membership, roles and responsibilities	12/351-14-394	**Revised –** Expand the SpNS committee to Include the Florida Renal Coalition.
15/410-16/453	Clarify rule making authority regarding specific areas including special needs shelter staff levels, definition of special needs supplies and equipment, definition of special needs person, compliance with animal shelter laws, special needs shelter registration, special needs shelter persons and their families, pre-event disaster planning..	14/395-15/426	***No change*** - Clarify rule making authority regarding specific areas including special needs shelter staff levels, definition of special needs supplies and equipment, definition of special needs person, compliance with animal shelter laws, special needs shelter registration, special needs shelter persons and their families, pre-event disaster planning.

Page/ Line	HB 89	Page/ Line	PCB 06-01
17/455-468	Clarify continuity of care regarding home health agencies, nurse registries, hospice and home medical equipment providers in emergency management plans	15/427-437	***Revised*** – reword no change in content Clarify continuity of care regarding home health agencies, nurse registries, hospice and home medical equipment providers in emergency management plans
17/468 7-478	Delete language regarding funds appropriated to support medical services disaster coordinator positions in county health department.	15/442-448	***Revised*** – reinserted language regarding comprehensive emergency plan reviews of home health agencies, nurse registries, hospices, or home medical equipment providers conditional upon appropriation.
18/495-19/515	Section 252.385, F.S. Revise the statewide emergency shelter plan to include special needs shelter projection need and facility adequacy. Including facility adequacy information in the shelter plan will help to address matching shelterees to appropriate facilities. Clarify designation and readiness inspection of shelters.	5/116	See Sec. 4
Sec.4 20/541-22/599	Section 400.492, F.S. Clarify continuity of care/ require that the plan include how a home health agency will continue to provide services to patients who evacuate to special needs shelters; Provide for links to local emergency operations, provides penalties if a good faith effort is not made and clients are dropped off at a shelter without staff.	**Sec. 6** 16/458-17/513	***No Change*** - Section 400.492, F.S. Clarify continuity of care/ require that the plan include how a home health agency will continue to provide services to patients who evacuate to special needs shelters; Provide for links to local emergency operations, provides penalties if a good faith effort is not made and clients are dropped off at a shelter without staff. Provide clarification of a good faith effort.
Sec.5 23/622-624	Provides rule making authority regarding emergency management plan reviews. Requires that reviewing agencies should forward findings to the county health department within 30 days.	**Sec. 7** 18/518-19/565	***Revised*** – Section 400.497, F.S. . Requires the Agency for Health Care Administration to adopt, publish and enforce rules regarding home health provider disaster preparedness criteria. . Requires the county health departments to include state and local health and medical stakeholders in its comprehensive emergency plan review where necessary to ensure a coordinated review and approval process. . Encourages the health department to advise the home health provider of any plan submissions or revisions. . Requires the health department to notify Agency for Health Care Administration if the home health provider has not submitted or remedied the plan, and provides that the agency may impose a fine of $5,000 if plan submissions or corrections are not made.

Page/ Line	HB 89	Page/ Line	PCB 06-01
Sec. 6 24/646-25/677	Section 400.506, F.S. Require that the plan include how a nurse registry will continue to provide services to patients who evacuate to special needs shelters. Provide that nurse registries may establish links with local emergency operations. Clarify that presenting a nurse registry client without making a good faith effort to provide service will constitute abandonment and subject to sanctions. . Requires coordination of agency reviews and forwarding of findings to county health departments within 30 days of receipt of the plan.	**Sec. 8** 19/573-21/626	***Revised –*** Section 400.506, F.S. . Requires the county health departments to include state and local health and medical stakeholders in its plan review where necessary to ensure a coordinated review and approval process. . Encourages the health department to advise the nurse registries of any plan submissions or revisions. . Requires the health department to notify Agency for Health Care Administration if the nurse registry provider has not submitted or remedied the plan, and provides that the agency may impose a fine of $5,000 if plan submissions or corrections are not made.
Sec. 7 25/693-26/716	Section 400.610, F.S., Hospice Requires hospice to include in their comprehensive emergency management plan how hospice will continue provide staff to perform the same type and quantity of services to patients who evacuate to a special needs shelter. Provide that hospice may establish links with local emergency operations. Clarify that presenting a hospice client without making a good faith effort to provide service will constitute abandonment and subject to sanctions.	**Sec. 9** 22/641-23/679	***Revised -*** Section 400.610, F.S. . Requires the county health departments to include state and local health and medical stakeholders in its plan review where necessary to ensure a coordinated review and approval process. . Encourages the health department to advise the hospice provider of any plan submissions or revisions. . Requires the health department to notify Department of Elder Affairs if the hospice provider has not submitted or remedied the plan, and provides sanction ability.
Sec. 8 26/776 – 27/740	Section 400.925, Home medical equipment Provides a definition of life-supporting or life-sustaining equipment.	**Sec. 10** 23/686-695	***No change –*** Section 400.925, F.S. Provides a definition of life-supporting or life-sustaining equipment.

Page/ Line	HB 89	Page/ Line	PCB 06-01
Sec.9 27/746- 29/789	Section 400.934, Home medical equipment Requires home medical equipment providers to include in their comprehensive emergency management plan how the provider will continue provide staff to perform the same type and quantity of services to patients who evacuate to a special needs shelter. Provide that home medical equipment providers may establish links with local emergency operations. Clarify that presenting a home medical equipment patient without making a good faith effort to provide service will constitute abandonment and subject to sanctions.	**Sec. 11** 23/696- 25/760	***Revised*** – Section 400.934, F.S. . Requires the county health departments to include state and local health and medical stakeholders in its comprehensive emergency plan review where necessary to ensure a coordinated review and approval process. . Encourages the health department to advise the home medical equipment providers of any plan submissions or revisions. . Requires the health department to notify Agency for Health Care Administration if the home medical equipment provider has not submitted or remedied the plan, and provides that the agency may impose a fine of $5,000 if plan submissions or corrections are not made.
Sec.10 29/790- 806	Section 400.935, F.S. Provides rule making authority regarding home medical equipment	**Sec. 12** 26/769- 776	***No change*** – Section 400.935, F.S. Provides rule making authority regarding home medical equipment
Sec.11 30/837 32/878	Section 408.831, F.S. Provides licensed capacity flexibility	**Sec. 13** 27/806- 28-847	***Revised*** - reword - no change in content Section 408.831, F.S. Provides licensed capacity flexibility
Sec.13 33/897	Provides July 1, 2006 effective date.	**Sec. 14** 29/854	No change Provides July 1, 2006 effective date