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Justification Review

Health Care Regulation Program
Agency for Health Care Administration

Report No. 01-24 May 2001



*Office of Program Policy Analysis
and Government Accountability*

an office of the Florida Legislature

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John W. Turcotte, OPPAGA Director*



The Florida Legislature

OFFICE OF PROGRAM POLICY ANALYSIS AND GOVERNMENT ACCOUNTABILITY



John W. Turcotte, Director

May 2001

The President of the Senate,
the Speaker of the House of Representatives,
and the Joint Legislative Auditing Committee

I have directed that a program evaluation and justification review be made of the Health Care Regulation Program administered by the Agency for Health Care Administration. The results of this review are presented to you in this report. This review was made as a part of a series of justification reviews to be conducted by OPPAGA under the Government Performance and Accountability Act of 1994. This review was conducted by Cynthia Cline, Mary Alice Nye, and Rebecca Urbanczyk under the supervision of Tom Roth.

We wish to express our appreciation to the staff of the Agency for Health Care Administration for their assistance.

Sincerely,

John W. Turcotte
Director

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Justification Review of the Health Care Regulation Program

Purpose

This report presents the results of OPPAGA's program evaluation and justification review of the Agency for Health Care Administration's Health Care Regulation Program. State law directs OPPAGA to conduct a justification of each program that is operating under a performance-based program budget. OPPAGA is to review each program's performance and identify alternatives for improving services and reducing costs.

Background

The Health Care Regulation Program is intended to ensure that Floridians have access to quality health care and services through the licensure, monitoring, and regulation of facilities, services, and practitioners. Program activities are divided into four major service categories.

- ***Licensure and regulation of health care facilities and services.*** Program staff inspect and license health care facilities, including hospitals, nursing homes, assisted living facilities, ambulatory surgical centers, adult day care centers, home health care, and laboratory testing facilities to ensure that the public's health care is provided in facilities that, at a minimum, meet federal and state standards.
- ***Health facilities planning and construction review.*** Program staff are responsible for projecting the need for additional health services and controlling the quantity of services provided through the Certificate of Need Program. In addition, program staff review new construction, additions, and renovations of all hospitals, and monitor and approve the construction of nursing homes.
- ***State regulation of health care practitioners.*** Program staff provide support services to regulatory boards and councils of various health care professions administratively housed within the Department of Health. Program staff perform activities such as processing complaints, investigating health care practitioners, and prosecuting practitioners in cases in which an investigation shows there is probable cause to believe the person has violated professional

standards. The regulatory boards in the Department of Health make the final decisions in these cases.

- ***Oversight and monitoring of health maintenance organizations.*** Program staff oversee and monitor commercial and Medicaid managed health care plans, workers' compensation arrangements, and consumer choice counseling initiatives. The program also provides the final appeals process for consumers in grievances against commercial and Medicaid HMOs.

The program is administered by the Agency for Health Care Administration's Division of Managed Care and Health Quality through the division's office in Tallahassee and 11 area field offices throughout the state.

The Health Care Regulation Program receives funding from several sources, including the Health Care Trust Fund (71%), state general revenue (14%), and other trust funds (15%). Sources of revenue for the Health Care Trust Fund include license fees and fines assessed against health care practitioners and facilities. In Fiscal Year 2000-01, the program was appropriated \$73,100,784.

Program Benefit, Placement, and Performance

Florida's program to regulate health care practitioners and to license and regulate health care facilities and services is vital to ensure that Floridians have access to quality health care. The program is needed to provide adequate safeguards against practitioners who might practice while impaired and health care facilities and providers that endanger public health and well-being by providing substandard care.

The program offers limited opportunities for further privatization. Some regulatory functions, such as investigating complaints, do not lend themselves to privatization. However, the program has taken steps to privatize activities where possible.

Florida's Auditor General recently completed a study that recommends that the Legislature authorize additional study to determine the feasibility of having one department perform all state medical quality assurance functions. OPPAGA is scheduled to conduct a comprehensive justification review of the Department of Health's Medical Quality Assurance program and will address these and other organizational issues in that report, which will be published prior to the 2002 legislative session.

Improved Enforcement Needed to Reduce Risk to Consumers

AHCA needs to improve its performance in taking action concerning serious complaints against practitioners and facilities. While the agency is responding faster to serious facility complaints, it has not met its legislative performance standard for taking emergency actions against facilities. Further, the risk to consumers from practitioners who have made serious, harmful medical mistakes is greater than available data appear to indicate. Nearly one in seven hospitals failed to report serious harmful incidents in Fiscal Year 1999-2000 as required by law. However, program staff said that the data on non-reporting by hospitals do not accurately reflect the extent of the failures by hospitals to report adverse incidents. Instead, they represent only those cases in which program staff learned of unreported incidents when conducting regulatory activities. We also have concerns about the validity and reliability of some of the performance data that we reviewed for Fiscal Year 1999-2000 and Fiscal Year 2000-01.

The Legislature should consider revising the law to increase the consequences to hospitals from failing to report adverse incidents to the Agency for Health Care Administration. One action the Legislature should consider is removing the statutory protection of confidentiality from records of adverse incidents that facilities have failed to appropriately report to the state. A hospital's failure to report an adverse incident would make that information a public record that could be used in civil proceedings. As long as hospitals follow the law, the records will be protected; if they choose not to follow the law, the protection will not apply. Failing to follow the law will open the records to discovery in a civil action. We believe this recommendation would be self-executing and involve no additional cost to the state or extra work for program staff.

The agency should

- ensure the accuracy of data entered into its complaint database; steps must be taken to insure the data accuracy since many of the program's performance measures rely on data extracted directly from the database, such as the average number of days to take emergency action on Priority I complaints;
- establish procedures requiring its staff to maintain documentation needed to verify its reported performance figures; and
- exclude from its performance measure on the new Medicaid recipients voluntarily selecting to participate in managed care those cases in which a recipient switched from one form of managed care to another, such as from a Medicaid HMO to MediPass. Including these cases distorts the accuracy of the agency's measure.

The AHCA/DOH joint committee should seek ways to improve access to state attorney information regarding complaints in which the states attorneys' offices are pursuing criminal cases against practitioners and the complaints involve an immediate threat to consumers.

Consumer Access and Outcomes ---

AHCA has taken steps to improve consumer access to Health Care Regulation Program services by outsourcing the program's complaint call center. However, the call center was not used to handle complaints regarding the agency's action to cancel the Medicaid contracts of six nursing homes in October 2000. Further, the agency does not collect data that would allow it to assess its effectiveness in providing non-English-speaking consumers access to the complaint investigation process.

Currently, only a small percentage of the complaints involving allegations of standard of care violations result in a disciplinary action being taken against a practitioner. By using alternative resolution methods such as mediation and issuing citations, the program would be able to improve complaint outcomes and reduce the cost of the complaint resolution process.

The agency should monitor the frequency with which it decides to use its own staff to handle complaints over the next year, rather than allow the complaints to be handled by the privatized call center. If there is a trend for agency staff to handle complaints regarding sensitive matters, such as the nursing home contract cancellations in October 2000, the agency either should ensure it maintains sufficient internal resources and expertise to handle such incidents or review its contract with the private company operating its call center and determine whether the contract should be modified so as to ensure that the center can handle calls of this nature. The agency should collect data that will enable it to assess whether non-English-speaking consumers are having difficulty accessing the complaint investigation process.

The Legislature should direct the Agency for Health Care Administration and Department of Health to develop proposals to increase the use of mediation and citations as means to resolve complaints against practitioners. Increased use of these approaches should allow the agency and the department's professional boards to more cost-effectively use their resources and provide an annual cost savings of \$1.6 million.

Medicaid Managed Care

In order to make effective policy decisions concerning Medicaid managed care, legislators and consumers need information comparing MediPass and Medicaid HMOs on measures of consumer satisfaction, health outcomes, and complaints. AHCA has been working to develop a system; however, it cannot currently assess the relative effectiveness of the different Medicaid managed care delivery systems. In addition, the information that is available raises serious quality of care concerns about access and services available through Medicaid HMOs.

The Legislature created the Medicaid Options Program to ensure that Medicaid participants had information about their health plan choices, to increase voluntary enrollment in managed care, and to eliminate unscrupulous enrollment practices by HMOs. The program is administered by Benova, a private enrollment broker, under a three-year contract with AHCA that expires in June 2001. During Fiscal Year 1999-2000, Benova staff received 742,000 telephone calls, mailed an average of 40,000 new eligible packets per month, and processed an average of 15,000 plan changes per month. Benova was paid \$14,150,000 during that fiscal year. The agency's Long Range Program Plan and the Governor's budget propose reducing the contract's cost from \$14.2 million to \$1 million. While we support agency efforts to reduce the costs of state programs, we note that the program's Long Range Program Plan does not describe how Medicaid enrollment functions would be performed if the program's funding were cut from \$14.2 million to \$1 million.

The agency should develop a system to provide ongoing comparative information on health outcomes and consumer complaints for Medicaid HMOs, MediPass, and the new Provider Service Network.

The agency also should ensure that HMOs are providing quality care to all Medicaid participants and consumers. It also should assess the extent to which Medicaid HMO consumers are opting out of HMOs after the lock-in period because of quality of care concerns.

At a minimum, the agency should restructure the current outreach activities performed under the Medicaid Options Program. This should save approximately \$1.7 million to \$2.2 million annually. AHCA also should consider adopting alternative methods for informing consumers about their health plan choices, such as providing only printed materials, or providing choice counseling materials when the consumer applies for services such as is done in Oregon. Finally, it should explore further the costs associated with the various enrollment services currently provided by Benova and the effect on consumers of eliminating the Benova call center.

Regulation of Facilities

The Certificate of Need (CON) Program can be eliminated. Due to changes in federal law, the state's Medicaid payments for nursing homes residents are now made on a per diem basis, and no longer cover building construction costs. Consequently, there is no longer a need to control the number of unused facility beds in order to contain Medicaid costs. If the CON Program were abolished, the agency could reduce its costs by \$836,525 and eliminate 18 positions.

If the program were abolished, the state would need to develop alternatives for addressing several issues, such as ensuring that facilities that undertake certain medical procedures can respond to emergency situations; providing a means for ensuring that the "unprofitably" ill, such as persons with acute needs such as AIDS/HIV patients or the elderly, have access to long term care; and addressing the financial problems associated with the state's large urban teaching hospitals. These hospitals attempt to help cover the costs of providing health care services to the poor and providing training facilities for medical schools by performing profitable medical procedures. The CON Program limited the competition in these profit centers to promote indigent care, training, and technology. Elimination of CON may impair the ability of the urban teaching hospitals to fund and provide less profitable services.

AHCA took action in October 2000 to cancel the Medicaid contracts of six chronically under-performing homes. AHCA managers stressed that this was a contract action taken by the Medicaid Program and was not a disciplinary action taken under the authority of the Health Care Regulation Program. They also said that the facilities' Medicaid contracts could be cancelled with 30 days notice to the provider and without having to offer due process, as would be the case if disciplinary action was taken against a facility. Three nursing homes owned by one company agreed to create quality assurance departments within the company as well as monitor quality in the facilities. Of the remaining three facilities, one has closed, the second experienced a change of ownership and reopened, and the third has adopted the monitoring agreement noted above.

However, we identified several concerns with the agency's approach of addressing problems with the quality of care offered by facilities through a contract action, including AHCA not taking strong disciplinary action against the homes prior to October 2000 and the due process issues noted by the federal district court. While the agency's desire to improve the quality of care offered by homes is laudable, the use of a contract action to address facility quality of care problems raises concerns regarding the efficacy of its use of available statutory disciplinary remedies. All of the six facilities that had their Medicaid contracts cancelled in October 2000 had numerous violations over the two-year period preceding the contract

cancellations. However, AHCA did not take action to suspend or revoke the license of any of the six substandard nursing homes in the two-year period preceding the action to cancel their Medicaid contracts.

AHCA needs to improve its systems for informing consumers about the quality of care provided in nursing homes. The agency's nursing home watch list, which is published quarterly and is available both in print and on the Internet, has several limitations that reduce its usefulness. For example, the list does not provide quantitative data on the frequency with which listed deficiencies occurred in a facility. Consequently, citizens cannot tell whether a deficiency was an isolated case or whether it was widespread.

AHCA staff indicated that their plan to provide consumers with a watch list is to be supplemented by a new scorecard system. However, the scorecard is seriously limited as a means for providing consumers with useful information on a nursing home's condition. For example, consumers viewing the scorecard's ratings cannot readily discern the frequency and seriousness of deficiencies among facilities. Further, the scorecard provides no information on when a violation occurred and when a corrective action was taken.

The Legislature should amend the law to eliminate the Certificate of Need Program. If the CON Program is eliminated, AHCA should develop guidelines requiring hospitals that perform certain types of procedures to have the necessary facilities to provide quality care. In order to provide a means for ensuring that the "unprofitably" ill, such as persons with acute needs such as AIDS/HIV patients or the elderly, have access to long term care, AHCA could make acceptance of these patients a condition for issuing a license to a facility. Also, to help ensure that elimination of the CON Program does not impair the ability of the urban, teaching hospitals to fund and provide less profitable services, AHCA can control the medical procedures offered by surrounding hospitals through licensing.

We recommend that AHCA take strong disciplinary actions under its statutory enforcement authority to address the problem of chronically under-performing facilities. In taking such actions, AHCA should be mindful of providing facility owners due process and an opportunity to be heard. AHCA should ensure that the operators of substandard facilities understand that initial, less serious enforcement actions will be followed by more severe enforcement actions based upon the facilities' prior records.

The agency should improve its system for informing consumers about the quality of care provided in nursing homes by incorporating quantitative data as well as more detail into their reports on the records of nursing facilities.

Agency Response

The Secretary of the Agency for Health Care Administration provided a written response to our preliminary and tentative findings and recommendations. (See Appendix C, page 45.)

Introduction

Purpose

This report presents the results of OPPAGA's program evaluation and justification review of the Agency for Health Care Administration's Health Care Regulation Program. State law directs OPPAGA to complete a justification review of each state agency program that is operating under a performance-based program budget. OPPAGA is to review each program's performance and identify alternatives for improving services and reducing costs.

This report analyzes the services provided by the Health Care Regulation Program and identifies alternatives to improve these services. Appendix A summarizes our conclusions regarding each of the nine areas the law directs OPPAGA to consider in a program evaluation and justification review.

Background

Program mission

The goal of the Health Care Regulation Program is to ensure access to quality health care services through

- licensing and certifying facilities and services and
- responding to consumer complaints about facilities, services, and practitioners.

Program services

The purpose of the Health Care Regulation Program is to help ensure that Floridians have access to quality health care and services through the licensure, monitoring, and regulation of facilities, services and practitioners. Program activities are divided into four major service categories.

Licensure and regulation of health care facilities and services. This service category includes such activities as inspecting and licensing various health care facilities. The program regulates the following types of health care facilities and service providers:

- ***inpatient or residential facilities*** such as hospitals, nursing homes, and assisted living facilities;
- ***outpatient or ambulatory facilities*** such as ambulatory surgical centers, adult day care centers, and end stage renal disease facilities; and
- ***services*** such as home health care, laboratory testing, and rehabilitation therapy.

Program staff inspect and license these entities to ensure that the public's health care is provided in facilities that, at a minimum, meet federal and state standards. Depending on the type of care provided, regulatory standards address such areas as staff qualifications and staffing levels, financial stability, internal quality assurance programs, patient or resident rights, and life safety.

When facilities and service providers fail to meet state and federal regulatory standards, the program may impose sanctions such as denial, suspension, or revocation of the facility's license. The program may also levy administrative fines or impose a moratorium on new admissions to the facility. The program may also recommend federal decertification of facilities participating in the Medicare and/or Medicaid programs. The agency considers cases involving license denials, moratoriums, and fines of \$5,000 or more to be significant administrative actions.

Health facilities plans and construction review. This service category includes such activities as conducting construction plan reviews and on-site surveys. Program staff are responsible for reviewing and surveying (inspecting) new construction, additions, and renovations of all hospitals, nursing homes, and ambulatory surgical centers after the issuance of a Certificate of Need and prior to licensure and occupancy. The intent of these reviews and surveys is to achieve and maintain consistent statewide minimum design and construction standards to assure the safety and well-being of those who use these facilities. Program staff inspect facilities during construction to ensure they will meet minimum design, building code, and life-safety standards.

State regulation of health care practitioners. This service category includes staff and support services to regulatory boards and councils of various health care professions administratively housed within the Department of Health. Activities within this service category include processing complaints about health care practitioners, investigating health care practitioners who are the subject of complaints, and prosecuting practitioners in cases where an investigation shows there is probable cause to believe the person has violated professional standards. The regulatory boards in the Department of Health make the final decisions in these cases. If necessary, the agency can initiate emergency action, such as suspending or restricting a practitioner's license, subject to approval by the Secretary of the Department of Health. Program staff also provide consumers with information about specific practitioners, including

disciplinary actions against a practitioner and the status of the practitioner's license.

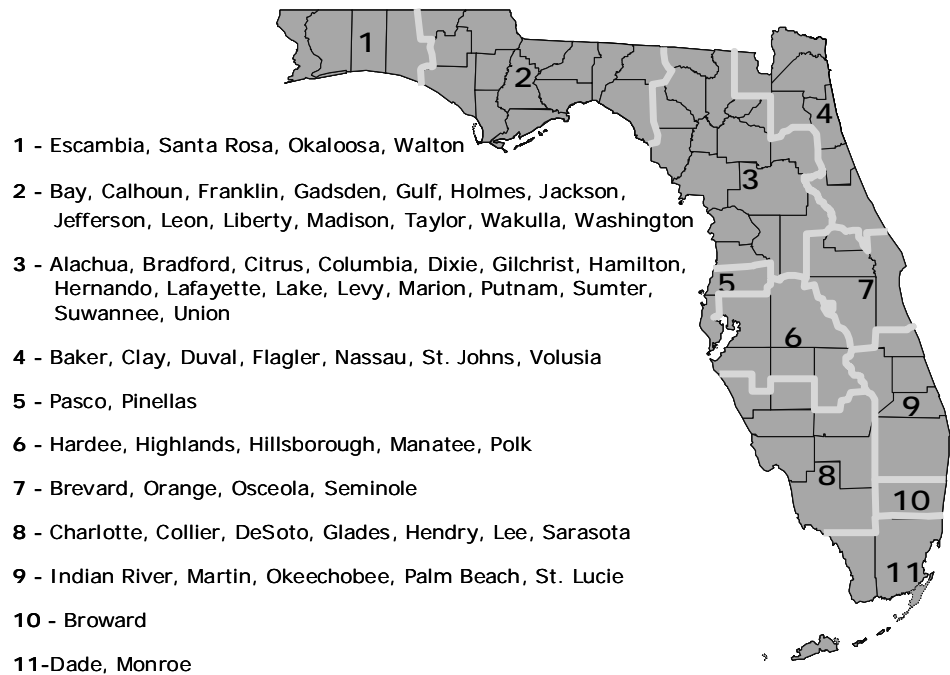
Oversight and monitoring of health maintenance organizations. This service category includes oversight and monitoring of commercial and Medicaid managed health care plans, workers' compensation arrangements, and the consumer choice counseling initiatives. The program also provides the final appeals process for consumers in grievances against commercial and Medicaid HMOs through the Statewide Provider and Subscriber Assistance Program.

Program organization

The program is administered by the Agency for Health Care Administration, Division of Managed Care and Health Quality, through the division office in Tallahassee and 11 area field offices throughout the state.

Exhibit 1

Health Care Regulation Program Districts



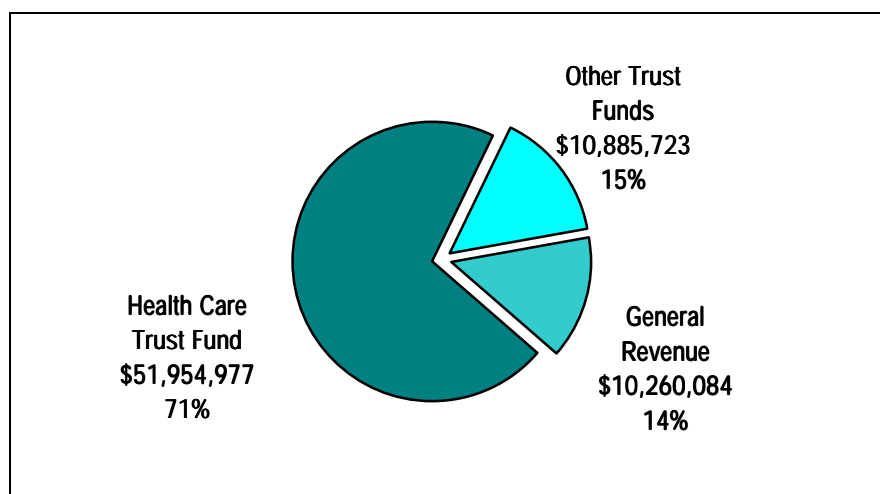
Source: Agency for Health Care Administration.

Program resources

The Health Care Regulation Program receives funding from several sources, including the Health Care Trust Fund (71%), state general revenue (14%) and other trust funds (15%). Sources of revenue for the Health Care Trust Fund include license fees and fines assessed against health care practitioners and facilities. As shown in Exhibit 2, Fiscal Year 2000-01 appropriations for the Health Care Regulation Program totaled \$73,100,784.

Exhibit 2

Health Care Regulation Program Was Appropriated \$73,100,784 in Fiscal Year 2000-01



Source: Chapter 2000-166, *Laws of Florida*.

Program Benefit and Placement

Introduction

The Agency for Health Care Administration's (AHCA) Health Care Regulation Program began operating under a performance-based program budget in Fiscal Year 1997-98. The program regulates health care practitioners and licenses and regulates health care facilities and services. The regulation of health care practitioners is conducted under an inter-agency agreement with the Department of Health. AHCA staff receive practitioner complaints, conduct investigations, and prepare recommendations for the disposition of complaints to practitioner boards located in the Department of Health. AHCA field office staff inspect nursing homes, assisted living facilities, and many other facilities.

Activities benefit the state and should be continued

Florida's program to regulate health care practitioners and to license and regulate health care facilities and services is vital to ensure that Floridians have access to quality health care. The program is needed to provide adequate safeguards against practitioners who might practice while impaired and health care facilities and providers that endanger public health and well-being by providing substandard care.

Potential for further privatization appears limited

The Health Care Regulation Program offers limited opportunities for further privatization. Some regulatory functions, like investigating complaints, are not good candidates for privatization because they involve the state's police power and require the exercise of discretion in applying the state's authority and making value judgments in reaching regulatory decisions.¹

¹ See [Assessing Privatization In State Agency Programs](#), OPPAGA Report No. 98-64, February 1999, and [Privatization: Lessons Learned by State and Local Governments](#), U.S. General Accounting Office Report GAO/GGD 97-48, March 1997.

General Conclusions and Recommendations

However, the program has taken steps to privatize activities where possible.

- In July 2000, the agency privatized its complaint call center. Prior to privatizing the center, AHCA operated a total of four separate call centers. These in-house call centers were limited in several ways, such as being unable to track how long consumers had to wait for services. For more information on the program's privatized call center, see Chapter 4, pages 18-19.
- In 1998, AHCA privatized the Medicaid Choice Counseling Program that provides enrollment, outreach, and education to Medicaid consumers about their health plan options. The choice counseling function is carried out by Benova, a private company, that operates the call center, a mail center, and outreach and education programs. For more information on the Choice Counseling Program, see Chapter 5, pages 25 and 26.

Organizational placement

Florida's Auditor General recently completed a study that recommends that the Legislature authorize additional study to determine the feasibility of having one department perform all state medical quality assurance functions.² OPPAGA is scheduled to conduct a comprehensive justification review of the Department of Health's Medical Quality Assurance program and will address these and other organizational issues in that report, which will be published prior to the 2002 legislative session.

² *Operational Audit of Medical Quality Assurance Administered by the Florida Department of Health*, Auditor General Report No. 01-063, November 2000.

Improved Enforcement Needed to Reduce Risk to Consumers

The Legislature requires a swift response to serious situations that might endanger the public's health, safety, and well-being. AHCA can initiate emergency action in situations that represent an immediate threat to consumers. For an individual practitioner, the emergency action might be a temporary suspension of a license to practice. For a facility, an emergency action might be a suspension of new admissions. In addition, the Legislature requires hospitals and other facilities to report events that resulted in harm to patients even though an immediate threat has passed. AHCA staff review reports of these events and conduct investigations of practitioners and facilities when appropriate.

We concluded that the program's immediate response to serious facility complaints has improved. However, the program's response to serious complaints against health care practitioners is not meeting legislative standards and needs improvement. We identified three areas of concern that are discussed more fully in the report.

- The agency is responding faster to serious facility complaints, but the number of emergency actions against facilities has declined. In addition, the program is not meeting legislative performance standards for taking emergency actions against practitioners, and the length of time required to take emergency actions against practitioners has increased.
- The risk to consumers from practitioners who have made serious, harmful medical mistakes may be greater than available data provided by hospitals appear to indicate. Nearly one in seven hospitals failed to report one or more adverse incidents in Fiscal Year 1999-2000³.
- The accuracy of some program performance data and the validity of some performance measures need improvement.

³ Adverse incidents are defined in s. 395.0197, *F.S.* Examples of adverse incidents might be cases that resulted in the death of a patient, a permanent spinal cord injury, and occasions in which the wrong surgery was performed or in which additional surgery was needed to correct a medical error.

Regulation of health care facilities has improved, but practitioner regulation falls short of legislative standards

Program more timely in responding to serious complaints against facilities

The program's performance in responding to serious complaints against health care facilities improved in Fiscal Year 1999-2000. For example, the program improved its timeliness in responding to Priority I facility complaints.⁴ During Fiscal Year 1999-2000, 4,630 complaints were filed against health care facilities in Florida, of which 305 (7%) were Priority I complaints. As shown in Appendix B, the program reported its staff investigated 95.7% of the Priority I complaints within 48 hours, up from 62% in Fiscal Year 1998-99. However, its performance still did not meet the standard of 100% established by the Legislature. Program staff attributed the improvement to personnel changes in certain area offices and improved data collection methods and record keeping practices. The program has an internal performance standard of responding to a Priority I complaint within 24 hours of its receipt. Program documents we reviewed indicate that of 115 Priority I facility complaints investigated from July 1, 2000, through October 6, 2000, 95.7% (all but five) were investigated in 24 hours or less.

Most common facility sanction is a moratorium on new admissions

Along with an immediate response to a serious situation, the Legislature wants AHCA to initiate emergency actions against facilities to prevent further harm to consumers. The agency may seek an order immediately suspending or revoking a facility's license when it determines that any condition in the facility presents a danger to the health, safety, or welfare of its patients or residents. AHCA most frequently sanctions facilities by issuing moratoriums on new admissions or through denial of payment for new admissions.

Facility emergency actions declined by 47%

The Legislature has established performance standards to increase the number of emergency actions taken against facilities. The program did not meet its legislative standard for taking emergency actions against facilities (43 compared to a standard of 51) in Fiscal Year 1999-2000, and the number of emergency actions against facilities was 47% lower than the number taken in the preceding year. Program officials believe that enhanced quality assurance efforts combined with a get-tough approach to problem facilities resulted in the need for fewer emergency orders against facilities in Fiscal Year 1999-2000. Chapter 6 presents our findings and recommendations regarding the program's performance in assuring

⁴ A Priority I complaint is one in which the incident represents a serious threat to public safety and welfare. Examples of Priority I complaints include impairment of a practitioner due to drugs, alcohol, mental or physical illness, sexual misconduct, or fraud, and complaints against facilities involving serious injury or death of a resident, and complaints of abuse, neglect, or exploitation.

*Improved Enforcement Needed to
Reduce Risk to Consumers*

the quality of nursing home care and AHCA's ability to adequately enforce facility standards.

*Response to serious complaints against practitioners
needs improvement in meeting standards*

The program did not meet its legislative standards for regulating practitioners in Fiscal Year 1999-2000.

- Thirteen percent of priority I complaints against practitioners in Fiscal Year 1999-2000 resulted in emergency action compared to the 39% standard set by the Legislature for Fiscal Year 1999-2000 (see Exhibit 3).⁵ Further, while the rate of 13% is higher than the prior year's performance (3%), we believe that the difference may be explained by a narrowing of the definition of what constitutes a priority I complaint.⁶ The 2000 Legislature set the standard at 25% in the General Appropriations Act for Fiscal Year 2001-02.
- The average number of days to take emergency action (124 days) exceeded the standard of 60 days (see Exhibit 4).⁷ The program's performance also did not meet the legislative standard in previous Fiscal Years 1997-98 (98 days) and 1998-99 (76 days).

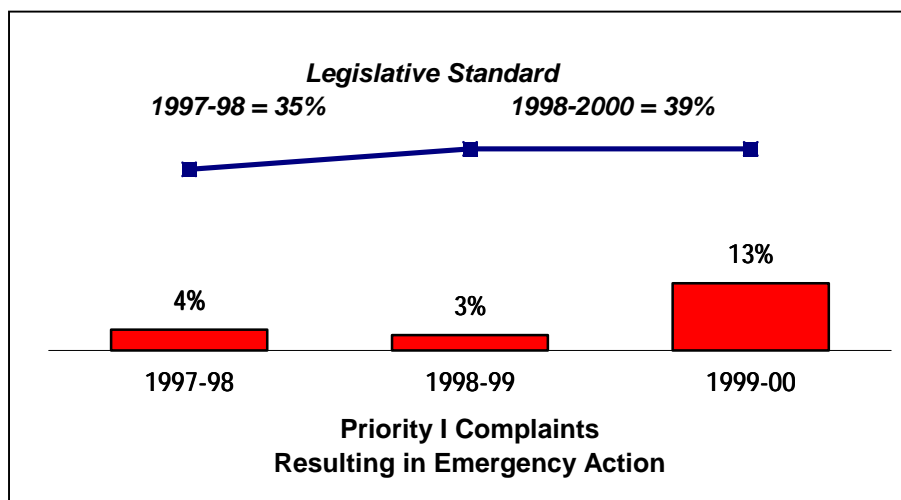
⁵ The Governor's Office changed the standard to 16% after consultation with legislative staff.

⁶ The program developed guidelines that make certain complaints mandatory priority I, while other complaints may be designated priority I at the discretion of AHCA staff.

⁷ The Governor's Office, in a letter to legislative committees, changed the standard for Fiscal Year 1999-2000 from 60 to 80 days.

*Improved Enforcement Needed to
Reduce Risk to Consumers*

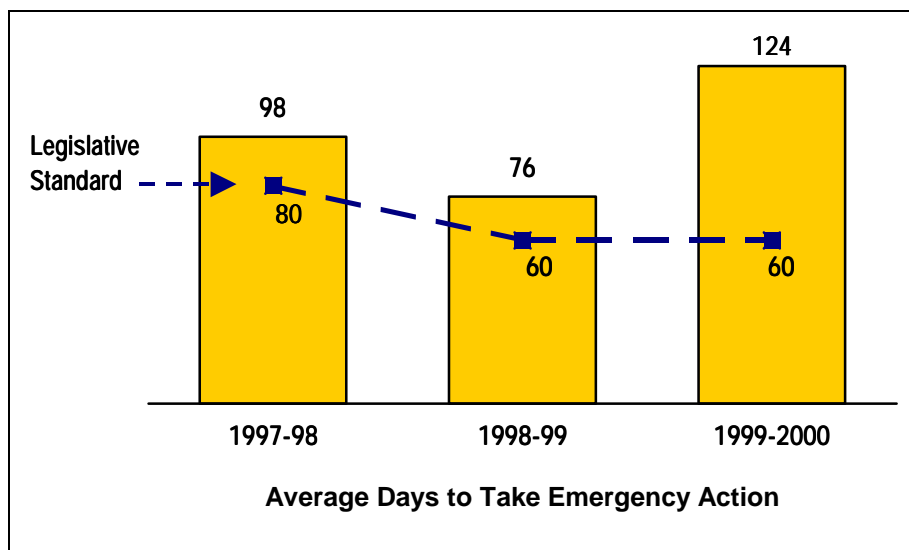
Exhibit 3
**Percentage of Priority I Complaints Resulting in Emergency Actions Has
Not Met the Legislative Standard¹**



¹The Governor's Office, in a letter to legislative committees, changed the standard from 39% to 16% for 1999-2000.

Source: General Appropriation Acts, Agency for Health Care Administration data.

Exhibit 4
**Average Number of Days to Take Emergency Actions Against Practitioners
Has Not Met Legislative Standard and Has Increased¹**



¹The Governor's Office, in letter to legislative committees, changed the standard for Fiscal Year 1999-2000 from 60 to 80 days.

Source: General Appropriation Acts, Agency for Health Care Administration data.

*Improved Enforcement Needed to
Reduce Risk to Consumers*

Agency officials indicated that a factor contributing to the program's failing to meet both standards is an institutional role conflict between AHCA legal staff and state attorneys' offices. They said that state attorneys may be reluctant to disclose evidence they believe might compromise their criminal investigations. In some instances, AHCA staff's inability to get access to evidence might preclude their ability to get an emergency suspension order against the practitioner.⁸ AHCA and the Department of Health (DOH) have a joint committee that reviews health care performance and monitoring issues. The AHCA/DOH joint committee should seek ways to improve access to state attorney case information and thereby help improve performance in meeting legislative standards.

Hospitals' failure to report adverse incidents puts public at risk

Nationally, there is growing concern about the number of serious medical errors occurring in the U.S. An Institute of Medicine study estimated the number of deaths nationwide from medical errors as being between 44,000 and 98,000 annually.⁹

To help protect Florida consumers, the Legislature requires the agency to compile data on practitioners who are involved in adverse incidents or who are subject to peer review discipline at their hospitals and other facilities. Facilities are required to report within 24 hours incidents in which serious injury or death to a patient occurs. Exhibit 5 shows the number of adverse incidents at hospitals and surgical centers reported to the agency increased from 1995 to 1997, but decreased in 1998 and 1999. The decline in the number of adverse incidents coincides with a narrowing of the definition of what constitutes an adverse incident.

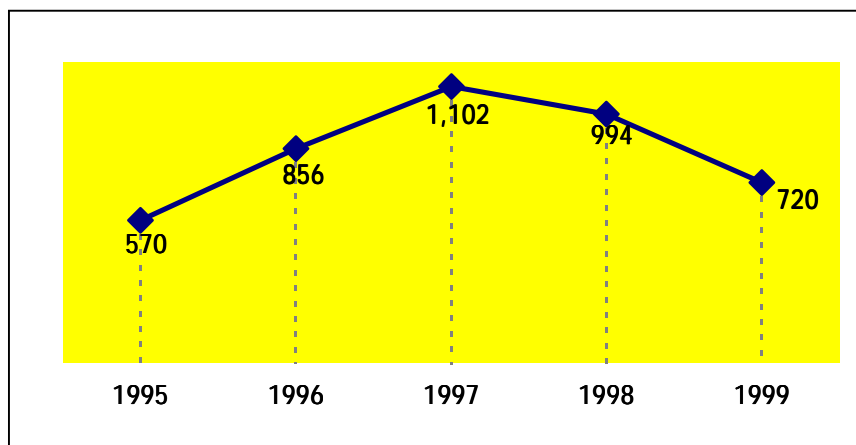
⁸ Rule 3.220 of the Rules of Criminal Procedure requires disclosure of evidence to the defendant by the state attorney within 15 days of the defendant's request. Requests can be made after arraignment. When answering, the state must disclose witness lists, statements of witnesses and others, admissions by the defendant, tangible evidence, any results from electronic surveillance, and expert reports. This information would become a matter of public record after the disclosure is made and would be available to AHCA.

⁹ Institute of Medicine 1999. *To Err is Human: Building a Safer Health System*, Linda Kohn, Janet Corrigan, and Molla Donaldson, eds. (National Academy Press: Washington, D.C.).

*Improved Enforcement Needed to
Reduce Risk to Consumers*

Exhibit 5

**Adverse Incidents Reported by Hospitals Increased from 1995 to 1997,
But Decreased in 1998 and 1999 ¹**



¹ Data for 2000 is due to the Agency in March 2001 and compilation and analysis of the 2000 data will not be available until late in 2001.

Source: AHCA Risk Management Report.

However, we are concerned for several reasons that the data reported by hospitals to the agency are incomplete and may not accurately portray the risk faced by Florida consumers. First, the agency's legislative performance measures represent only the number of adverse incidents self-reported by the hospitals. As a result of court rulings, the agency does not have access to hospital discipline review committee records that could be used to compile data on serious incidents.

*One in seven hospitals
failed to report serious
harm to a patient*

Second, it appears that a significant percentage of hospitals are failing to report adverse incidents to the agency. For example, program data for Fiscal Year 1999-2000 indicate that 14% of the hospitals surveyed failed to report one or more adverse incidents (in contrast to the legislative standard for Fiscal Year 2000-01 that no more than 5% of hospitals fail to report). ¹⁰ In other words, one in seven hospitals that were surveyed failed to report an adverse incident as required.

The problem of non-reporting by hospitals may be even greater than these data appear to indicate. Program staff said that the data on non-reporting by hospitals do not accurately reflect the extent of the failures by hospitals to report adverse incidents. Instead, they represent only those cases in which program staff learned of unreported incidents when conducting regulatory activities. For instance, staff might learn of an unreported incident when they receive notification of a lawsuit against a practitioner or as a result of a survey conducted at the facility.

¹⁰ Of 215 hospitals surveyed, 30 failed to report one or more adverse incidents.

Improved Enforcement Needed to Reduce Risk to Consumers

Legislature should consider increasing sanctions to reduce non-reporting

To provide Florida consumers with more accurate information, the Legislature may wish to amend the law to increase the consequences to hospitals for failing to report adverse incidents. Presently, when the agency identifies a hospital that has failed to report an adverse incident, it can take action to cite the facility for noncompliance and impose fines. In Fiscal Year 1999-2000, the program sanctioned seven facilities for various risk management violations including failure to report adverse incidents and imposed fines totaling \$379,000, with fines for individual facilities ranging from \$6,000 to \$190,500.

One way the Legislature could strengthen the consequences of non-reporting is to amend the statutes to make public the records of adverse incidents that facilities have failed to appropriately report to the state. Under current law, information concerning adverse incidents is not a public record and is not discoverable or admissible in a civil or administrative action. The public record exemption was granted, in part, to encourage hospitals to report adverse incidents to AHCA, thereby enabling program officials to oversee corrective action.

The recommended statutory change would mean that a hospital's failure to report an adverse incident makes that information a public record that could be used in civil proceedings. So long as the hospital follows the statute and reports any adverse incident, the public record exemption and protection applies. However, a failure by a hospital or other facility to report would then open the facility to civil action. We believe this recommendation would be self-executing and involve no additional cost to the state or extra work for program staff. The costs would accrue to the facilities that failed to abide by the law and report adverse incidents.

Accuracy of performance data and validity of some measures need improvement

We generally relied on the inspector general's reviews in examining the validity and reliability of the agency's legislative performance measures. AHCA's inspector general reviewed the program's performance measures in 1998 and reported that additional steps were needed to document measures and data sources, and ensure the accuracy and consistency of performance data.¹¹ The inspector general also conducted follow-up reviews after six months to track the program's progress in making recommended improvements. The inspector general is also planning to further review the program's performance measures in Fiscal Year 2000-01 and Fiscal Year 2001-02.

¹¹ See AHCA OIG Report 98-04, *Audit of the Bureau of Consumer and Investigative Services Performance-Based Program Budgeting/Performance Measures; Division of Health Quality Assurance* and AHCA OIG Report 98-05, *Review of Performance Measures; Division of Health Quality Assurance State Licensure and Federal Certification of Health Care Facilities*.

Improved Enforcement Needed to Reduce Risk to Consumers

During our review, we identified several additional areas in which the accuracy and integrity of the program's performance data could be improved.

AHCA complaint database contains errors and missing data

- We found errors and missing data in the program's complaint database. Our review of a database containing practitioner complaints determined that of 3,620 complaints received concerning four professions (dentistry, medicine, nursing, and pharmacy) in Fiscal Year 1999-2000, 2% of complaints had no priority code, 3% had no allegation code, and 5% appeared to have missing or incorrectly entered dates for key events. The agency cannot accurately calculate its performance in responding to Priority I complaints if records do not include the priority of the complaint or the dates for key events, such as the date a complaint was referred for board action.

Some performance data cannot be verified

- Program staff did not maintain records or documentation that we could use to verify the accuracy of some performance data reported to the Legislature. For example, program staff indicated that they did not maintain hard copies of reports generated from the practitioner database that were used as data sources for the program's performance in practitioner regulation in Fiscal Year 1999-2000. They also indicated that since the database is continually updated, they were unable to recreate the reported data.
- Data reported on a new measure for Fiscal Year 2000-01 (the percentage of new Medicaid recipients voluntarily selecting to participate in managed care) appears to include Medicaid participants who are already in the program and who switch their plan from a Medicaid HMO to MediPass or from MediPass to a Medicaid HMO. However, since MediPass is considered managed care, this means the measure includes individuals who switch from one managed care system to another. Including these cases distorts the extent to which new Medicaid recipients are selecting managed care.
- The agency reported a decrease in the percentage of accredited hospitals and ambulatory surgical centers cited for deficiencies in life safety, licensure, or emergency access standards (31% in Fiscal Year 1998-99 compared to 6.5% in Fiscal Year 1999-2000). Program officials stated that the reported decrease was actually the result of improvements in data collection procedures.

Conclusions and recommendations

In conclusion, AHCA is responding faster to serious facility complaints. However, it has not met its legislative performance standard for taking emergency actions against facilities. Further, the risk to consumers from practitioners who have made serious, harmful medical mistakes is greater than available data appear to indicate. Nearly one in seven hospitals failed to report adverse incidents in Fiscal Year 1999-2000 as required by

*Improved Enforcement Needed to
Reduce Risk to Consumers*

law. Program staff indicated that they learned of unreported incidents through conducting regulatory activities. We also identified some instances in which the validity and reliability of some of the performance data that we reviewed for Fiscal Years 1999-2000 and 2000-01 need improvement.

We recommend that the Legislature consider amending s. 395.0198, *Florida Statutes*, to increase the adverse consequences to hospitals from failing to report adverse incidents to the agency. One action the Legislature should consider is amending the statutes to make public the records of adverse incidents that facilities have failed to appropriately report to the state. Under current law, information concerning adverse incidents is not a public record and is not discoverable or admissible in a civil or administrative action. The statutory change would mean that a hospital's failure to report an adverse incident makes that information a public record that could be used in civil proceedings. So long as the hospital follows the statute and reports any adverse incident the public record exemption and protection applies. However, a failure by a hospital or other facility to report would then open the facility to civil action. We believe this recommendation would be self-executing and involve no additional cost to the state or extra work for program staff. The costs would accrue to the facilities that failed to abide by the law and report adverse incidents.

We recommend that the agency

- ensure the accuracy of data entered into its complaint database;
- establish procedures requiring its staff to maintain documentation needed to verify its reported performance figures; and
- exclude from its performance measure on the new Medicaid recipients voluntarily selecting to participate in managed care those cases in which a recipient switched from one form of managed care to another, such as from a Medicaid HMO to MediPass. Including these cases distorts the accuracy of the agency's measure.

We recommend that the AHCA/DOH joint committee seek ways to improve access to state attorney information regarding complaints in which the states attorneys' offices are pursuing criminal cases against practitioners and the complaints involve an immediate threat to consumers.

Finally, we recommend that the agency report within six months to the Legislature the status of its progress in carrying out these recommendations.

Consumer Access and Outcomes

Introduction

The Health Care Regulation Program has taken steps to improve consumer access to its complaint services, specifically by centralizing and outsourcing complaint call centers. However, as discussed more fully in the report, we identified several concerns impeding the program's ability to more effectively serve consumers and resolve consumer complaints.

The contracted call center has improved consumer access, but its performance could be further enhanced

Prior to July 2000, program staff operated four separate call centers through which consumers gained access to public documents and submitted complaints against health maintenance organizations (HMOs), health care facilities, and practitioners. Program officials said that the centers were using outdated computer systems that did not allow for accurate tracking and monitoring of consumer phone calls and were unable to provide adequate service to non-English speaking consumers.

To address these concerns, program officials decided to outsource the call center function to a private contractor. After reviewing four proposals, the agency awarded a three-year, \$2.9-million contract to HISPACC, Inc., a Miami-based firm. The contractor was expected to improve the call center's technology, handle an increased number of complaints, improve the monitoring of calls through the use of detailed management reports, and employ bi- or tri-lingual staff at the call center to increase access for non-English speaking consumers.

Outsourcing call center improved program's ability to serve consumers, but concerns remain

Outsourcing the call center appears to have improved the program's ability to serve consumers. However, the agency did not use the call center to handle calls regarding the agency's action in October 2000 to cancel the Medicaid contracts of six nursing homes. Following this action, the agency announced it was setting up a temporary hotline staffed by agency personnel to which the public could call with any questions or complaints related to nursing home care or concerns about possible nursing home closures. All calls received by HISPACC regarding the nursing home contract cancellations were forwarded directly to the agency hotline. Program managers said that a decision was made to directly handle calls and complaints related to this action because call

center staff read from a written script and are not trained to answer questions regarding AHCA policy decisions.

One of AHCA's goals for outsourcing the call center was to improve access to non-English speaking consumers. Program managers said AHCA's attempts to hire bilingual staff for the Tallahassee call centers had previously failed, and the centers lacked the technology to accurately track certain characteristics of the calls, including the number of calls received from non-English speaking consumers. They said they intended that the contract with HISPACC, Inc., would increase access and ensure the participation of non-English speaking consumers in the complaint process.

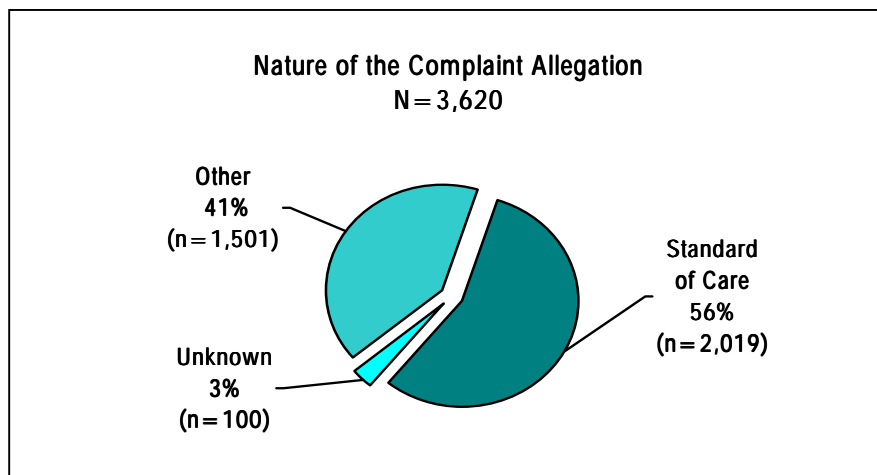
However, the agency is not collecting data that would allow it to evaluate whether non-English speaking consumers are experiencing difficulty accessing the complaint investigation process. Although the contracted call center employs staff that can speak with consumers in Spanish or Haitian-Creole, complaints against practitioners must be made in writing by the consumer on a required form and submitted to the program's office in Tallahassee. Since the complaint forms are provided only in English, non-English speaking consumers may be less likely to complete and forward the forms to the agency's central office in Tallahassee. To determine whether non-English speaking consumers are effectively accessing the complaint investigation process, the agency should collect data indicating the number of complaint forms requested by non-English speaking consumers and the number of forms actually submitted over the next year. Comparative data should also be collected on complaints made by English speakers.

Use of mediation and citations should be increased

The purpose of the Health Care Regulation Program is to help ensure that Floridians have access to quality health care and services through the licensure, monitoring, and regulation of facilities, services, and practitioners. To improve the outcome of complaints against practitioners, we believe that the Health Care Regulation Program should increase its use of alternative methods, such as mediation and issuing citations. Mediation is an informal and non-adversarial process in which a neutral third person or mediator helps disputing parties reach a mutually acceptable and voluntary agreement. A citation is a notice of noncompliance for an initial offense of a minor violation, the penalty for which is a fine or some condition being placed against a practitioner's license. Since 1994, the Legislature has provided for mediation as a method of resolving cases. However, the Health Care Regulation Program was authorized to mediate only one of the 3,620 complaints in the agency database reviewed.

Exhibit 6

Standard of Care Allegations Account for 56% of Investigated Complaints



Source: OPPAGA analysis of data from the Agency for Health Care Administration.

As shown in Exhibit 6, 56% of all complaints in the database are standard of care complaints.¹² Program managers said that standard of care complaints involve subjective determinations of deficient care, and, although they warrant some form of attention, they seldom result in disciplinary action against the practitioner by the Department of Health's professional boards. Also, officials expressed concerns that while significant agency resources are used to follow up on these complaints, consumers, who generate many of these complaints, do not achieve the satisfaction of being heard and are frustrated by having no or little effect on improving patient care.

Program managers also said using mediation to address standard of care complaints would more appropriately serve consumers by providing an opportunity to correct misunderstandings between the parties. Such misunderstandings can be exemplified by a case in which a consumer filed a complaint against a physician for failure to diagnose an ear infection. Although the infection was treated upon a return visit by the patient and no permanent harm was done, the practitioner failed to explain why no action was taken at the initial visit. The consumer then filed a formal complaint, which was reviewed by AHCA investigators and legal staff. AHCA legal staff subsequently recommended that no disciplinary action was warranted. In this type of case, mediation could be used to bring the parties together and facilitate communication regarding the dispute.

¹² For our analysis, standard of care allegations were defined as complaints that alleged gross negligence, gross or repeated malpractice, and failure to practice within standards. Allegations of discipline violations represented all other cases where the nature of the allegation variable was identified in the agency's database. The dataset of 3,620 complaints is a sample of complaints received in Fiscal Year 1999-2000 and includes 100 cases in which the nature of the allegation was unknown.

*Increased use of
mediation would
improve use of
program resources and
reduce costs*

In addition, increasing the use of mediation would conserve agency resources, thereby reducing the overall cost of the complaint resolution process. The agency estimated that its cost to investigate and legally review a complaint averaged \$924 in calendar year 2000. Based on this cost, we estimated that the agency expended \$4.2 million per year investigating and reviewing complaints that result in no recommendation for disciplinary action against practitioners in Fiscal Year 1999-2000. Our analysis of agency data found that only 12% of closed standard of care complaints resulted in a recommendation for disciplinary action against the practitioner.¹³

Mediation is frequently used as an alternative means for resolving complaints by other governmental entities, such as the Florida circuit court system. In 1999, 40% of all civil complaint cases referred for mediation succeeded in reaching an agreement between the parties involved. If AHCA's preliminary investigation indicates that the evidence is not sufficient to bring about a formal sanction, the agency's consumer services unit could refer the complaint for mediation. If the agency achieved a similar success rate to circuit court mediation programs, we estimate that increased use of mediation in resolving complaints regarding health care practitioners would save AHCA \$1.6 million annually.¹⁴ The Department of Health's professional boards would also likely incur a cost savings due to a reduction in the number of complaints reviewed by its probable cause panels.

In addition, program officials said that if they were authorized to do so by Department of Health professional boards, they could increase the use of citations to resolve minor disciplinary violations and further reduce the expense required to investigate and review complaints. Currently, professional boards within the Department of Health designate the specific types of minor violations for which AHCA may issue citations. A minor violation is a first-time offense by a practitioner that does not pose an immediate threat to public safety. For example, failure to report a change of address and pre-signing laboratory work order forms are designated by various professional boards as minor violations. Although the Department of Health's professional boards designate a total of 51 offenses as minor violations, the boards grant authority to AHCA to issue citations for only 28 offenses. Agency officials indicated that the boards are reluctant to authorize agency use of these options. Increasing the use of citations for violations that do not pose an immediate threat to public safety would allow the agency to expedite the complaint process and

¹³ The database reviewed included 2,019 complaints identified as standard of care type allegations; 575 of these complaints were active at the time of our review and, therefore, were not included in this figure.

¹⁴ Annual cost savings of \$1.6 million is based on the cost of 6,318 legally sufficient complaints in Fiscal Year 1999-2000 at an average cost per complaint of \$924 compared with the cost that would be incurred if 40% of these complaints were resolved through mediation, at an average cost per mediated complaint of \$300. Estimates for mediation costs are based on an average hourly rate provided by the Florida Dispute Resolution Center, Florida Mediation and Arbitration Programs.

better focus its investigative and legal resources on complaints involving more serious violations.

Conclusions and recommendations

AHCA has taken steps to improve consumer access to Health Care Regulation Program services by outsourcing the program's complaint call center. However, the call center was not used to handle complaints regarding the agency's action to cancel the Medicaid contracts of six nursing homes in October 2000. Further, the agency does not collect data that would allow it to assess its effectiveness in providing non-English speaking consumers access to the complaint investigation process.

We recommend that the Agency for Health Care Administration monitor the frequency with which it decides to use its own staff to handle complaints over the next year, rather than allow the complaints to be handled by the privatized call center. If there is a trend for agency staff to handle complaints regarding sensitive matters, such as the nursing home contract cancellations in October 2000, the agency either should ensure that it maintains sufficient internal resources and expertise to handle such incidents or review its contract with the private company operating its call center and determine whether the contract should be modified so as to ensure that the center can handle calls of this nature. We also recommend that the agency collect data over the next year that will enable it to assess whether non-English-speaking consumers are having difficulty accessing the complaint investigation process.

Currently, only a small percentage of the complaints involving allegations of standard of care violations result in a disciplinary action being taken against a practitioner. By using alternative resolution methods such as mediation and issuing citations, the program would be able to improve complaint outcomes and reduce the cost of the complaint resolution process.

We recommend that the Legislature direct the Agency for Health Care Administration and Department of Health to develop proposals to increase the use of mediation and citations as a means to resolve complaints against practitioners. Increased use of these approaches should allow the agency and the department's professional boards to more cost-effectively use their resources and provide an annual cost savings of \$1.6 million.

We recommend that the agency report within six months to the Legislature the status of its progress in carrying out these recommendations.

Medicaid Managed Care

To reduce the costs of the state's large expenditures for Medicaid (\$8.75 billion in Fiscal Year 2000-01), the Governor's Office has proposed changes that would make Medicaid HMOs the only choice for health care services for most of the state's 1.1 million Medicaid managed care participants.¹⁵ Along with reducing costs, however, the program must ensure the quality of care provided to consumers, which requires accurate and reliable information about the quality and effectiveness of Medicaid managed care services. While AHCA has been working to develop a system to compare MediPass and Medicaid HMOs, it cannot currently assess the relative effectiveness of its different Medicaid managed care delivery systems.¹⁶

In a 1997 report on Medicaid managed care, OPPAGA encouraged AHCA to seek additional strategies to provide useful information to the Legislature about the quality of Medicaid managed care services and to compare the relative performance of pre-paid health plans and Medicaid managed care.¹⁷ We identified three areas of concern discussed more fully in the report:

- AHCA cannot effectively evaluate the quality of care provided to Medicaid managed care participants by different service delivery systems on an ongoing basis;
- limited information from available studies raises concerns about the quality of Medicaid managed care and participants' access to preventative care; and
- agency officials plan to reduce the state's choice counseling program's funding from \$14.2 million to \$1 million, which may not be sufficient to cover enrollment services also currently provided by the program.

¹⁵ Current proposals would eliminate MediPass for two-thirds of consumers who reside in Florida counties with two or more Medicaid HMOs. While we requested documents or plans detailing these proposed changes, the agency was unable to provide details for our review.

¹⁶ Two recent studies that compared HMO consumer outcomes and MediPass consumer outcomes in Florida both found mixed results. One study, which was conducted by KMPG and released in November 2000, was privately commissioned by Florida's HMO industry. The second study, which was conducted by the Lawton and Rhea Chiles Center for Healthy Mothers and Babies at the University of South Florida and was released in February 2001, focused on comparing pregnancy-related outcomes.

¹⁷ *Follow-up Report on Medicaid Managed Care Options*, OPPAGA [Report No. 97-11](#), October 1997.

As of December 2000, 1.1 million persons were participating in Medicaid managed care,¹⁸ including 632,000 in MediPass,¹⁹ 501,000 in Medicaid HMOs,²⁰ and 23,000 in Provider Service Networks.²¹ In addition, beginning in November 1999, participants are locked into a health plan for 8 to 11 months after their enrollment and may only change plans once a year during an open enrollment period except for good cause.

Needed MediPass and Medicaid HMO quality of care information is not available

To make effective decisions, legislators and consumers need to be able to compare the performance of MediPass, Medicaid HMOs, and the provider service networks in terms of health outcomes, consumer satisfaction, and consumer complaints. However, AHCA has not put in place a system to provide ongoing information needed by legislators and consumers to compare the quality of MediPass and Medicaid HMOs. AHCA has HMO consumer satisfaction and health outcome data for 1998 and 1999, but comparable data on MediPass is not readily available. Legislators need to know whether the health outcomes for Medicaid HMO participants are better, the same, or worse than MediPass participants, as well as how satisfied consumers are who are served by the service delivery systems. Without such information, lawmakers face making policy decisions in an atmosphere of uncertainty.

The lack of comparable performance data on the quality of MediPass and Medicaid HMOs reflects the fragmentation of data collection responsibilities among various agency units, each of which compiles data for its specific purposes. For example, AHCA's Health Care Regulation Program oversees quality of care and consumer complaints about HMOs, and compiles data on HMO accreditation and market penetration. The agency's Medicaid Services Program oversees actual program services including MediPass and compiles data on consumer health outcome measures. The agency's State Center for Health Care Statistics compiles data on health care services, providers, and consumers and produces a report card on HMO performance. These data are not combined in a manner that would allow the agency to perform a comparative evaluation

¹⁸ There are 1.1 million managed care recipients out of a total of 1.7 million Medicaid participants in Florida.

¹⁹ Medicaid Provider Access System (MediPass). Under MediPass, primary care physicians act as "gatekeepers" and control access to specialized treatment and care. Services provided under MediPass are reimbursed on a fee-for-service basis.

²⁰ Medicaid Health Maintenance Organizations (HMOs). The state contracts with HMOs to provide prepaid Medicaid services. The HMO receives a set fee for each participant regardless of the care provided.

²¹ Provider service networks (PSNs). PSNs are integrated health care delivery system owned and operated by Florida hospitals and physicians groups. Like MediPass, PSNs are reimbursed on a fee-for-service basis.

of the quality of services provided by various Medicaid managed care systems.

Although Medicaid participants report being satisfied with managed care, access to quality care and preventative services is a concern

Managed care is intended not only to help control the cost of health care services, but to provide quality care and emphasize preventative services that contribute to improved consumer health. Survey results show Medicaid participants generally are satisfied with Medicaid managed care. A University of Florida's Bureau of Economic and Business Research survey published in May 2000 reported that Medicaid HMO members were more satisfied with services than commercial HMO members,

However, a November 1999 study made for the agency by Florida Medical Quality Assurance, Inc., raised a number of concerns regarding the quality of care received by MediPass participants, such as referrals to specialists and patient teaching. The report cited access to specialists by MediPass participants as a "significant concern." In many cases, consumers who should have been referred to specialists did not receive referrals. The report recommended "renewed emphasis on the importance of prevention in practice for MediPass providers."²²

Medicaid HMO consumers had lower levels of preventative services

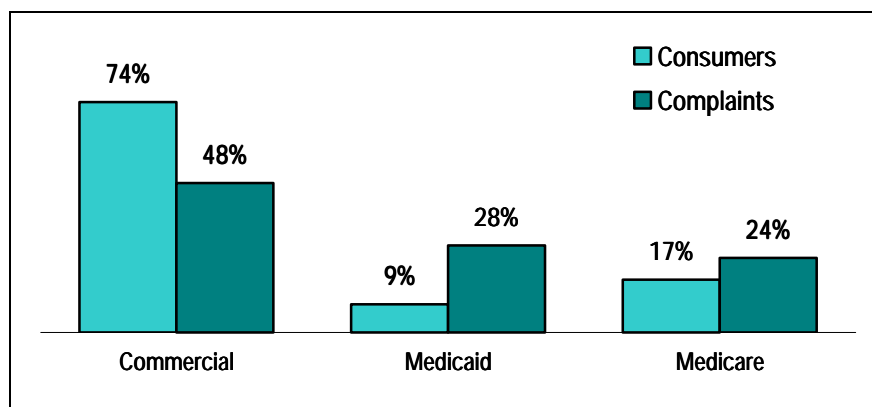
HMO outcome data included in the HMO report card study shows that Medicaid HMO consumers had lower levels of preventative care than commercial HMO members. For example, the percentage of eligible participants who received cervical cancer screenings ranged from 18% to 60% for Medicaid HMOs compared with 42% to 82% for commercial HMOs. Further, the percentage of eligible participants who received prenatal care in the first trimester of their pregnancies ranged from 5% to 62% for Medicaid HMOs compared with 35% to 96% for commercial HMOs. Such services also varied between Medicaid and commercial HMO members served by the same providers. To illustrate, 45% of one HMO's (United Health Care of Florida) eligible Medicaid HMO clients received cervical cancer screening compared to nearly 70% of eligible commercial members.^{23, 24}

²² See Florida Medical Quality Assurance, Inc., *MediPass Final Report (July 1, 1998-June 30, 1999)*, pages 9-10.

²³ Results for Medicaid and commercial consumers served by the same HMO should be comparable, since HMOs are required to certify that their outcome data have been subject to verification by an independent audit.

²⁴ Experts agree that factors other than quality of service may explain the differences in the services received by persons enrolled in Medicaid and commercial HMOs, such as ethnic or racial differences in the use of medical services. For discussion of caveats and other limitations to quality of care data, such as the length of enrollment, see Ross, Nancy and Glenn Mitchell, "Plan Comparisons for Consumers: Premature for Medicaid," *The Florida Health Care Journal*, January 2000.

Exhibit 7
Medicaid Participants Have the Highest Rate of Complaints



Source: Call center reports provided by AHCA, August-November 2000.

Further, our analysis of the HMO complaint data presented in Exhibit 7 found that while Medicaid HMO consumers represented 9% of Florida's total HMO population, they filed 28% of the total number of complaints filed against HMOs.

If the agency had more data on Medicaid participants, it could use this information to assess whether they are leaving their HMOs due to quality of care concerns. Agency data indicates that although the number of Medicaid HMO enrollees increased from 443,418 in July 1999 to 501,302 in December 2000, the percentage of Medicaid participants enrolled in HMOs decreased from 48% to 44% over the same period. Medicaid clients have 30 days from the date of their enrollment to make a voluntary selection or otherwise be automatically assigned to either MediPass or a Medicaid HMO. Participants then have 90 days to make a plan change. Including their enrollment period, whether voluntary or automatic, participants are locked into their plans for 8 to 11 months, except for good cause changes. Because overall the number of HMO consumers has risen, but the percentage has declined, it seems likely that a number of consumers are changing to MediPass after being in a Medicaid HMO. Further study would be needed to determine if they are leaving due to quality of care concerns.

New study may provide limited quality of care comparison

AHCA's Medicaid Services Division has recently entered into a contract with the University of Florida to evaluate the state's new Provider Service Network and to compare the quality of services provided and consumer satisfaction with MediPass and Medicaid HMOs.²⁵ AHCA expects the

²⁵ As of January 2001, only one PSN was operating in the state, the South Florida Community Care Network. South Florida Community Care currently serves 23,000 consumers and operates in a manner very similar to MediPass in that doctors receive a monthly fee for each member and services are billed on a fee-for-service basis.

project to be completed in mid-2001. However, this evaluation is not a substitute for the agency establishing an ongoing system for evaluating the quality of care provided by various Medicaid managed care systems.

Alternatives to choice counseling for Medicaid managed care recipients

The Legislature created the Medicaid Options Program to ensure that Medicaid participants had information about their health plan choices, to increase voluntary enrollment in managed care, and to eliminate unscrupulous enrollment practices by HMOs. The program is administered by Benova, a private enrollment broker, under a three-year contract with AHCA that expires in June 2001. Benova operates a call center that answers consumer questions and processes plan changes, a mail distribution program that distributes consumer information packets, and community outreach and education. During Fiscal Year 1999-2000, Benova staff received 742,000 telephone calls, mailed an average of 40,000 new eligible packets per month, and processed an average of 15,000 plan changes per month. Benova was paid \$14,150,000 during that fiscal year.

Long-range plans calls for elimination of choice counseling

We noted that the agency's Long Range Program Plan and the Governor's budget propose reducing the contract's cost from \$14.2 million to \$1 million. While we support agency efforts to reduce the costs of state programs, we note that the program's Long Range Program Plan does not describe how Medicaid enrollment functions would be performed if the program's funding were cut from \$14.2 to \$1 million. Accordingly, we sought to identify alternatives for reducing the costs of the Medicaid Options Program.²⁶

Alternatives include reducing community outreach and education

One alternative is to eliminate or reduce the contractor's community outreach activities. The agency's contract with Benova requires the company to provide monthly outreach meetings in each of the 40 counties where an HMO provider operates. Benova officials reported their employees conducted an average of 1,130 outreach sessions per month in Fiscal Year 1999-2000 at an average total monthly cost of \$150,000.²⁷ They also reported an average attendance of three participants per session. Benova officials estimate that eliminating outreach, consumer education and other program changes would save \$2.2 million per year. The consequences of eliminating all outreach activities are not readily measured; however, it might reduce the number of persons voluntarily enrolling in managed care, as more persons would

²⁶ The proposals to eliminate choice counseling coincide with agency proposals to eliminate MediPass for two-thirds of consumers who reside in Florida counties with two or more Medicaid HMOs. While we requested documents or plans detailing these proposed changes, the agency was unable to provide details for our review.

²⁷ As reported by Benova, average monthly cost of \$150,000 for the period December 1999 through September 2000.

*Oregon has point of
entry choice by
consumers*

have less information for making choices. Reducing outreach activities to one session per month per county would reduce costs to \$60,000 annually and produce an estimated cost savings of \$1.7 million annually.²⁸

Another alternative would be to eliminate choice counseling altogether. Oregon presently requires Medicaid recipients to make a choice of health plans at the point of entry into the system, that is, when they are completing their initial application for social welfare support. Oregon's program refuses to process applications of persons who fail to make a choice of health plans. In contrast, Florida consumers have 30 days to make a health plan choice once they are notified of enrollment and 90 days to change plans if they are unhappy with their plan. In addition, Florida's choice counseling program was used to establish the Medicaid lock-in that requires consumers to continue in their health plans for 8 to 11 months after enrollment. Agency officials were uncertain about how eliminating choice counseling would affect the lock-in.

Conclusions and recommendations

In order to make effective policy decisions, Medicaid managed care, legislators, and consumers need information comparing MediPass and Medicaid HMO on measures of consumer satisfaction, health outcomes, and complaints. Although a study is underway to assess the new Medicaid provider service networks, AHCA has not developed a system to allow ongoing comparison of the different delivery systems. In addition, the information that is available raises concerns regarding the quality of care and level of preventative services received by Medicaid HMO participants.

We recommend that the Agency for Health Care Administration develop a system to provide ongoing comparative information on health outcomes and consumer complaints for Medicaid HMO, MediPass, and the new provider service network participants.

We recommend that the agency assess the extent to which Medicaid HMO consumers are opting out of HMOs after the lock-in period because of quality of care concerns.

We recommend that, at a minimum, the agency restructure the current outreach activities performed under the Medicaid Options Program. This should save approximately \$1.7 million to \$2.2 million annually. AHCA should also consider adopting alternative methods for informing consumers about their health plan choices, such as providing only printed materials, or providing choice counseling materials when the consumer applies for services such as is done in Oregon. Finally, the agency should further explore the costs associated with the various enrollment services

²⁸ The \$60,000 is based on Benova's reported per session cost of \$121.41 from December 1999 through September 2000.

currently provided by Benova and the effect on consumers of eliminating the Benova call center.

We recommend that the agency report within six months to the Legislature the status of its progress in carrying out these recommendations.

Regulation of Facilities

The Health Care Regulation Program has several major responsibilities relating to health care facilities.

- Determine the number of new health care beds built in Florida. The Certificate of Need Program establishes the number, type, and size of facility construction for most types of health care facilities through a comparative review process. Biannually, providers seeking to create additional beds in certain facilities, such as hospitals, nursing homes, and hospices, must apply for approval to build based upon the number of additional beds AHCA has predetermined will be needed during the year.
- Approve plans for new construction and the monitoring of construction of facilities.
- License facilities once they are built.
- Inspect facilities once they are licensed. AHCA staff inspects facilities for compliance with state and federal Health Care Finance Agency (hereinafter HCFA) requirement.
- Enforce facility regulations. Deficiencies identified by AHCA surveyors are reported to both AHCA and HCFA. After being provided notice, the facilities must provide the AHCA with a plan of correction that details the steps the facility will take to correct deficiencies within a specified time period. If the deficiencies are not corrected, AHCA may take enforcement action against the facility.

Based on our research and analysis of AHCA data, we reached several conclusions.

- The Certificate of Need (CON) Program can be eliminated.
- AHCA recently took action to cancel the Medicaid contracts of six nursing homes that had chronic problems in providing quality care. This action resulted in the owner of three facilities implementing at an earlier date a federal agreement to improve monitoring and quality control. One of the other three facilities also implemented this the agreement, while one changed owners and one closed. While the agency's desire to improve the quality of care offered by homes is laudable, the use of a contract action to address facility quality of care problems raises concerns regarding the efficacy of its use of available statutory disciplinary remedies. ACHA did not use strong, available statutory disciplinary remedies, such as suspending or revoking the facilities' licenses, to address quality of care problems.

- AHCA has not developed an effective system for informing consumers about the quality of care provided in nursing homes.

Certificate of Need Program no longer needed

In the early 1970s, medical costs began to rapidly rise, increasing the cost of state and federal health programs. In response to these increasing costs, the Florida Legislature created the CON Program in 1973. The primary purpose of the program was to help contain health care costs by controlling the supply of health care facility beds. The prevailing concern at the time of the program's creation was that the supply of beds would outstrip the demand for services. This would result in excess capacity and further increase health care costs because facilities would have to spread their fixed costs over fewer individuals. In addition to limiting the supply of beds, the CON Program was designed to help ensure underserved populations had access to quality health care.

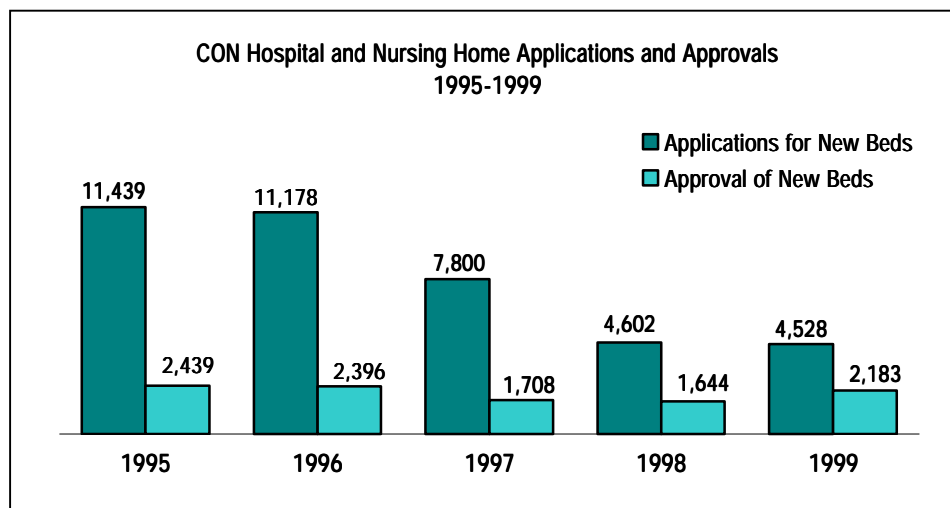
During the period from 1974 to 1986, all states were required by federal law to operate a CON program as a condition for receiving financial assistance for health planning. This requirement was eliminated in 1986. However, most states, including Florida, continued to operate their CON programs. A major reason why Florida continued the program after 1986 was that another provision of federal law known as the Boren Amendment required states to reimburse nursing home providers for Medicaid patients with rates that covered the facilities' costs, including building and construction costs.²⁹ Since the CON Program limited both the number of new facilities and unused nursing home beds, it was seen as a means to help control the increase in Medicaid nursing home costs resulting from this requirement.

The goals of Florida's present Certificate of Need Program include controlling the supply of health care facilities, increasing facility use, and reducing facility costs. Under the CON Program, individuals wishing to construct or expand certain health care facilities, such as hospitals and nursing homes, must receive a certificate of need from the state.³⁰ Before issuing a certificate of need, AHCA staff estimate the number of facility beds that will be needed to meet future demand and use these estimates to limit the number of new beds that will be approved for construction. In making their assessments, AHCA staff considers factors such as the provision of services, the needs of the indigent and Medicaid populations, and the protection of teaching hospitals from competition. Between 1995 and 1999, AHCA staff reviewed 1,395 CON applications for 39,547 beds and approved 26% of these beds (see Exhibit 8).

²⁹ 42 USC Section 1396(a)(13)(A).

³⁰ The Florida Legislature removed assisted living facilities from the purview of CON regulations in 1999.

Exhibit 8
Applications for New Hospital and Nursing Home Beds
Decreased by 6,900 Over the Last Five Years



Source: Agency For Health Care Administration, Certificate of Need Program, *Annual Report 1999*, pp. 36-37.

Based on our research and review of AHCA data, we concluded that the CON Program is unnecessary and could be abolished by the Legislature. It is no longer needed because the conditions that led to the program's creation and contributed to its continuation have changed.

Specifically, the Boren Amendment was repealed in 1997. As a result, the state's Medicaid payments for nursing homes residents now are made on a per diem basis and no longer cover building construction costs. Consequently, there is no longer a need to control the number of unused facility beds in order to contain Medicaid costs. With the elimination of the CON Program, market forces would be allowed to determine the number of beds that are needed.

Financial problems within the nursing home industry have already reduced applications to build new facilities. As shown in Exhibit 8, applications for hospital and nursing home beds decreased from 11,439 in 1995 to 4,528 in 1999.

If the CON Program were abolished, the agency could reduce its costs by \$836,525 and eliminate 18 positions. However, if the program were abolished, the state would need to develop alternatives for addressing several issues, such as those discussed below.

- The state would need to ensure that facilities that undertake certain medical procedures can respond to emergency situations. For example, Pennsylvania, which abolished its Certificate of Need Program, required hospitals that performed cardiac catheterizations to have facilities capable of performing open-heart surgery. AHCA program managers suggested that this could be accomplished by

developing guidelines similar to those created for pediatric care. These guidelines require hospitals that perform certain types of services for children to have the necessary facilities to provide quality care.

- The state would need to provide a means for ensuring that the “unprofitably” ill, such as persons with acute needs such as AIDS/HIV patients or the elderly, have access to long term care. In 1999, for example, 97.2% of the conditions AHCA placed on Certificates of Need for nursing homes required the facilities to accept Medicaid patients. If these populations cannot access long-term care facilities, they may spend more time in more expensive acute care facilities, thus raising Medicaid costs. This issue can be addressed by making the acceptance of these patients a condition of the facility’s license.

Also, eliminating the CON Program may have consequences for the state’s large urban teaching hospitals that often provide health care services to the poor and provide training facilities for medical schools. These hospitals attempt to help cover the costs of these functions by performing profitable medical procedures. The CON Program limited the competition in these profit centers to promote indigent care, training, and technology. Elimination of CON may impair the ability of the urban teaching hospitals to fund and provide less profitable services. This problem can be addressed by controlling the medical procedures offered by surrounding hospitals through licensing. Thus, rather than controlling the number of beds, AHCA will be regulating the types of services offered.

Program should take strong disciplinary action against nursing home facilities that have chronic problems meeting quality of care standards

The Legislature has given AHCA the responsibility for ensuring the safety and well-being of the vulnerable population of nursing home residents. The law provides the Health Care Regulation Program with strong disciplinary remedies, including license suspension and revocation, to deal with problematic facilities and owners.

AHCA took action in October 2000 to cancel the Medicaid contracts of six chronically under-performing homes. AHCA managers stressed that this was a contract action taken by the Medicaid Program and was not a disciplinary action taken under the authority of the Health Care Regulation Program. They also said that the facilities’ Medicaid contracts could be cancelled with 30 days notice to the provider and without having to offer due process, as would be the case if disciplinary action was taken against a facility.

Subsequent to AHCA’s termination of the Medicaid contracts, a company that owned three of the affected facilities filed suit against the agency.

This company requested and received a temporary restraining order against AHCA's action from the federal district court in Tampa. The federal district court held that AHCA had failed to make a preliminary showing that its actions were consistent with a contract cancellation rather than a disciplinary action. The court further held that AHCA's actions not only violated the due process provisions in the Medicaid law, but also ran afoul of the Fourteenth Amendment requirement of notice and opportunity to be heard.

AHCA reached a settlement with this company shortly thereafter. Under the settlement, the nursing homes owned by the company would create quality assurance departments within the company as well as monitor quality in the facilities. The terms of the settlement were modeled on an agreement into which the company had already entered with the inspector general of the U.S. Department of Health and Human Services in August 2000 that allowed the entity to continue to receive Medicaid funds, but provided for increased monitoring and evaluation of its facilities. AHCA was not aware of the agreement when it initiated its own action.

Of the remaining three facilities, one has closed, the second experienced a change of ownership and reopened, and the third has adopted the monitoring plan noted above. Consequently, as a result of the agency's contract action, the facilities entered into agreements to address problems, changed owners or closed.

However, we identified several concerns with the agency's approach of using contract actions to address quality of care problems, including not taking strong disciplinary action against the homes prior to October 2000 and the due process issues noted by the federal district court.

Program needs to effectively employ available statutory disciplinary remedies

While the agency's desire to improve the quality of care offered by homes is laudable, the use of a contract action to address facility quality of care problems raises concerns regarding the efficacy of its use of available statutory disciplinary remedies. Enforcement actions that do not pose the realistic threat of serious disciplinary sanctions at the time infractions occur will not compel good conduct.

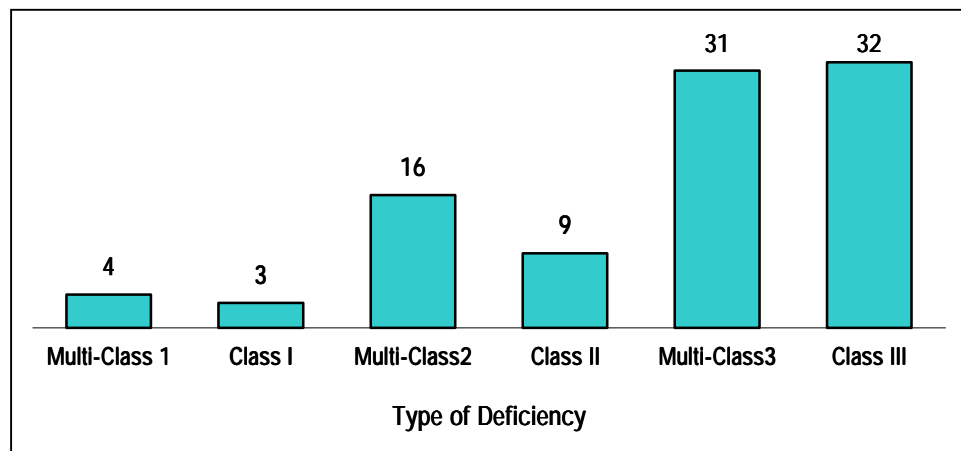
AHCA has the authority to impose increasingly more severe sanctions on problematic nursing homes. The agency has the power to make the license of a nursing home conditional, deny payment for new admissions, impose a moratorium on new admissions, levy fines, and suspend or revoke the facility's license.

All of the six facilities that had their Medicaid contracts cancelled in October 2000 had numerous violations over the two-year period preceding the contract cancellations.

AHCA data indicates that the six nursing homes that AHCA identified for cancellation of their Medicaid contracts had a total of 95 deficiencies during the period from August 8, 1998, to September 15, 2000 (see Exhibit 9). Deficiencies are categorized by the severity of the offense and the jeopardy in which the patient is placed. There may be multiple deficiencies in each class. Class 1 violations are the most serious; Class 3 are the least serious.

Exhibit 9

Nursing Homes With Cancelled Medicaid Contracts Had a History of Deficiencies That Threatened Patient Health, Safety, and Quality of Life During the Period from August 8, 1998, to September 15, 2000¹



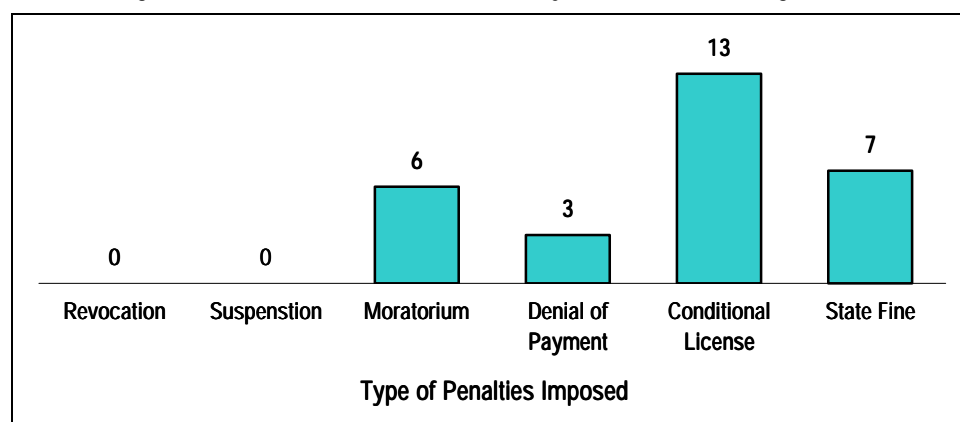
¹ Deficiencies are categorized by the severity of the offense and the jeopardy in which the patient is placed. There may be multiple deficiencies in each class (Class 1 violations are the most serious; Class 3 the least serious).

Source: Agency for Health Care Administration.

However, as shown in Exhibit 10, AHCA did not take action to suspend or revoke the license of any of the six substandard nursing homes in the period preceding the action to cancel their Medicaid contracts.

Exhibit 10

AHCA Did Not Use the Most Serious Sanctions Available Against the Six Nursing Homes Deemed to Be Chronically Under-Performing



Source: Agency for Health Care Administration.

According to Florida law, AHCA would have a basis for taking such strong enforcement action. Section 400.121(4)(b), *Florida Statutes*, provides the agency authority to suspend the license of a facility and its management company if a moratorium has been imposed twice in seven years. Although one of the six facilities had two moratoriums within three months, AHCA did not seek to suspend the facility's license. A recent U.S. General Accounting Office report on nursing home regulation concluded that lax enforcement practices might send a signal to noncompliant facilities that a pattern of repeated noncompliance carries few consequences.³¹

In our opinion, AHCA should use its available disciplinary remedies, such as suspending or revoking licenses, in taking action against facilities that demonstrate a repeated pattern of failing to provide adequate quality of care. Further, if AHCA had sought to take strong disciplinary actions against the facilities, it would have avoided concerns about the lack of due process resulting from its action to cancel the facilities' Medicaid contracts. AHCA's argument that the contract cancellations did not require due process was rejected by the federal district court. While AHCA disagrees with the court, we believe that the agency needs to act with fundamental fairness to providers and residents when its policies are changed. This could be accomplished by taking disciplinary action through the Health Care Regulation Program since such actions are subject to hearings and administrative appeals.

Moreover, by taking strong disciplinary action, AHCA would remedy issues related to giving advanced notice of its policy change. AHCA's policy on which it based its action to cancel the Medicaid contracts was

³¹ *Nursing Homes: Additional Steps Needed to Strengthen Enforcement of Federal Quality Standards*. U.S. General Accounting Office report, GAO/ HEHS 99-46, March 1999.

never reduced to writing or distributed in writing to the nursing home owners prior to the announcement of the intended action on October 2, 2000. AHCA managers indicated that the owners were verbally informed about the agency's policy at industry meetings and immediately prior to the agency's announcement of the contract cancellations. However, we believe it is insufficient for the agency to verbally warn providers that it intends to change policies without informing them in writing when and how the policy will change. In this case, the scoring mechanism used by agency staff to target and identify the facilities whose contracts were cancelled was not made available until after the cancellations took place. The federal district court noted that both the Medicaid regulations and the Fourteenth Amendment to the United States Constitution require advanced notice of an enforcement action. Integral to such a notice would be the knowledge by the provider of the policy upon which the enforcement action was being taken.

AHCA needs to improve its system for informing consumers about nursing home quality of care

As a part of its regulatory and enforcement function, AHCA publishes a nursing home guide referred to as the watch list to assist consumers in evaluating the quality of nursing home care in Florida and alert them of potential problems with facilities. The list, which is published quarterly and is available both in print and on the Internet, provides a summary of findings from AHCA's surveys for certain nursing home facilities. Contained in the list are the actual conditions that resulted in the findings of deficiencies.

The current watch list lacks quantitative information that would make it useful to consumers

However, the watch list as currently designed has several limitations that reduce its usefulness. For example, the list does not provide quantitative data on the frequency with which listed deficiencies occurred in a facility. Consequently, citizens cannot tell whether a deficiency was an isolated case or whether it was widespread. Providing such quantitative information would increase consumer awareness of facility conditions in the home.

The proposed scorecard lacks basic information for consumers

AHCA staff indicated that they also plan to provide consumers with information from the new scorecard system that was used to identify the six facilities that the agency announced would have their Medicaid contracts cancelled in October 2000.³² Staff indicated they planned to make this information available on the Internet in 2001 and believed the scorecard would provide more information to consumers than the watch list alone. However, the scorecard is limited as a means for providing consumers with useful information on a nursing home's condition. For

³² The proposed scorecard was the subject of agency rule making and was adopted on February 15, 2001, Ch. 59A-4.165, *Florida Administrative Code*.

example, consumers viewing the scorecard's ratings cannot readily discern the frequency and seriousness of deficiencies among facilities. Further, the scorecard provides no information on when a violation occurred and when a corrective action was taken.

In our opinion, the agency should be providing consumers with more information about nursing home conditions. Information should be provided that identifies for each provider the types and seriousness of deficiencies identified; the percentage of patients who were affected by the deficiencies; and the dates the deficiencies were discovered and number of days it took to correct the problem or the number of days the problems have remained unresolved. Other states, such as Illinois and Utah, have produced consumer reports that cover each of these areas.

Recommendations

We recommend that the agency and the Legislature take the actions described below.

- The Legislature should amend the Health Facilities and Services Development Act, s. 408.031 *Florida Statutes, et seq.*, to eliminate the Certificate of Need Program.
- If the CON Program is eliminated, AHCA needs to ensure that certain goals that are presently addressed through the CON process be addressed through its facility licensing function. To ensure that facilities that undertake certain medical procedures can respond to emergency situations, AHCA should develop guidelines requiring hospitals that perform certain types of services to have the necessary facilities to provide quality care. To provide a means for ensuring the “unprofitably” ill, such as persons with acute needs such as AIDS/HIV patients or the elderly, have access to long term care, AHCA could make acceptance of these patients a condition for issuing a license to a facility. Also, to help ensure elimination of the CON Program does not impair the ability of the urban teaching hospitals to fund and provide less profitable services, AHCA can control the medical procedures offered by surrounding hospitals through licensing.
- We recommend that AHCA seek to take strong disciplinary actions under its statutory enforcement authority to address the problem of chronically under-performing facilities. AHCA should ensure that the operators of substandard facilities understand that initial, less serious enforcement actions will be followed by more severe enforcement actions based upon the facilities' prior records.
- AHCA should improve its system for informing consumers about the quality of care provided in nursing homes by incorporating quantitative data as well as more detail into their reports on the records of nursing facilities.

- We recommend that the agency report within six months to the Legislature the status of its progress in carrying out these recommendations.

Appendix A

Statutory Requirements for Program Evaluation and Justification Review

Section 11.513, *Florida Statutes*, provides that OPPAGA Program Evaluation and Justification Reviews shall address nine issue areas. Our conclusions on these issues as they relate to the Agency for Health Care Administration's Health Care Regulation Program are summarized in Table A-1.

Table A-1
Summary of the Program Evaluation and Justification Review
of the Health Care Regulation Program

Issue	OPPAGA Conclusion
The identifiable costs of the program	The Health Care Regulation Program receives funding from several sources, including the Health Care Trust Fund (71%), state general revenue (14%) and other trust funds (15%). Sources of revenue for the Health Care Trust Fund include license fees and fines assessed against health care practitioners and facilities. Fiscal Year 2000-01 appropriations for the Health Care Regulation Program totaled \$73,100,784.
The specific purpose of program, as well as the specific public benefit derived therefrom	The purpose of the Health Care Regulation Program is to help ensure that Floridians have access to quality health care and services through the licensure, monitoring, and regulation of facilities, services, and practitioners.
Progress toward achieving the outputs and outcomes associated with the program	<p>The agency is responding faster to serious facility complaints, but the number of emergency actions against facilities has declined. In addition, the program is not meeting performance standards for taking emergency actions against practitioners and the length of time required to take emergency actions against practitioners has worsened.</p> <p>The risk to consumers from practitioners who have made serious harmful medical mistakes may be greater than the agency performance data appear to indicate. Nearly one in seven hospitals failed to report one or more serious harmful incidents in Fiscal Year 1999-2000.</p>
An explanation of circumstances contributing to the department's ability to achieve, not achieve, or exceed its projected outputs and outcomes, as defined in s. 216.011, <i>F.S.</i> , associated with the program	<p>Agency officials attribute the program's performance in not meeting the standards for emergency actions involving practitioners to a lack of cooperation between AHCA legal staff and state attorneys offices and to problems in getting access to evidence that is part of ongoing criminal investigations.</p> <p>Program officials believe that enhanced quality assurance efforts combined with a get-tough approach to problem facilities resulted in the need for fewer emergency orders against facilities in Fiscal Year 1999-2000.</p>

Issue	OPPAGA Conclusion
Alternative courses of action that would result in administering the program more efficiently or effectively	<p>The Legislature should consider amending s. 395.0198, <i>Florida Statutes</i>, to increase the adverse consequences to hospitals from failing to report adverse incidents to the agency. One action the Legislature should consider is amending the statutes to make public the records of adverse incidents that facilities have failed to appropriately report to the state. Under current law, information concerning adverse incidents is not a public record and is not discoverable or admissible in a civil or administrative action. The statutory change would mean that a hospital's failure to report an adverse incident makes that information a public record that could be used in civil proceedings. So long as the hospital follows the statute and reports an adverse incident, the public record exemption and protection applies. However, a failure by a hospital or other facility to report would then open the facility to civil action. We believe this recommendation would be self-executing and involve no additional cost to the state or extra work for program staff. The costs would accrue to the facilities that failed to abide by the law and report adverse incidents.</p> <p>AHCA needs to improve its system for informing consumers about the quality of care provided in nursing homes by incorporating quantitative data as well as more detail into their reports on the records of nursing facilities. AHCA should increase its use of available alternative dispute resolution options, such as mediation to resolve complaints involving less serious offenses, many of which are generated by consumers. Significant resources are currently being used for the investigation and legal review of these complaints, which often result in no disciplinary action being taken.</p> <p>AHCA needs to ensure that HMOs are providing quality care to all Medicaid participants. It should also assess the extent to which Medicaid HMO consumers are opting out of HMOs after the 12-month lock-in period because of quality of care concerns.</p> <p>At a minimum, AHCA should restructure the current outreach activities performed under the Medicaid Options program. This should save approximately \$1.7 to \$2.2 million annually. AHCA should also consider adopting alternative methods for informing consumers about their health plan choices, such as providing only printed materials, or providing choice counseling materials when the consumer applies for services, similar to Oregon's system. Finally, the agency must further explore the costs associated with the various enrollment services currently provided by Benova and the cost to consumers of eliminating the Benova call center.</p> <p>The Legislature should amend the law to eliminate the Certificate of Need Program. Several functions that are presently performed as part of the CON process reassigned to other AHCA program areas.</p> <p>AHCA should take effective enforcement action to address the problem of chronically under-performing facilities. In taking such actions, AHCA should be mindful in providing facility owners due process and an opportunity to be heard. AHCA should take the specific actions noted below.</p> <ul style="list-style-type: none"> ▪ Provide notice of proposed changes in enforcement standards and procedures to stakeholders, including the health care industry, HCFA, patients, families, and advocacy groups, and provide an opportunity for these groups to provide comments. ▪ Ensure the consistency and reliability of surveyor data used for comparing the performance of facilities.

Appendix A

Issue	OPPAGA Conclusion
	<ul style="list-style-type: none"> Ensure that operators of substandard facilities understand that initial, less serious enforcement actions will be followed by more severe enforcement actions based upon the facilities' prior record.
The consequences of discontinuing the program	Florida's program to regulate health care practitioners and to license and regulate health care facilities and services is vital to ensure that Floridians have access to quality health care. The program is needed to provide adequate safeguards against practitioners who might practice while impaired and health care facilities and providers that might endanger the public.
Determination as to public policy; which may include recommendations as to whether it would be sound public policy to continue or discontinue funding the program, either in whole or in part	Based on our research and analysis of health care facilities data, we concluded that the Certificate of Need Program should be eliminated.
Whether the information reported pursuant to s. 216.031(5), <i>F.S.</i> , has relevance and utility for evaluation of the program	<p>Data reported on the percentage of new Medicaid recipients voluntarily selecting to participate in managed care appear to be inaccurate. These figures reported by the agency include Medicaid participants who are already in the program and who switch their plan from a Medicaid HMO to MediPass. However, since MediPass is considered managed care, this means the agency is including individuals who switch from one managed care system to another. Including these cases distorts the accuracy of the agency's measure of the extent to which new Medicaid recipients are selecting managed care.</p> <p>An apparent improvement in the percentage of accredited hospitals and ambulatory surgical centers cited for life safety, licensure, or emergency access standards was due to correction of data errors rather than improved performance. Program officials explained that a significant decrease in the reported percentage of accredited hospitals and ambulatory surgical centers cited for not complying with life safety, licensure or emergency access (31% in Fiscal Year 1998-1999 compared to 6.5% in 1999-2000) resulted from the correction of errors in the earlier data that were made when collection of the data was automated.</p>
Whether state agency management has established control systems sufficient to ensure that performance data are maintained and supported by state agency records and accurately presented in state agency performance reports	AHCA's inspector general reviewed the program's performance measures in 1998, and reported that additional steps were needed to document measures and data sources, and ensure the accuracy and consistency of performance data. ¹ The inspector general also conducted follow-up reviews after six months to track the program's progress in making recommended improvements. The inspector general is also planning to further review the program's performance measures in Fiscal Year 2000-01 and Fiscal Year 2001-02. We relied on the inspector general's reviews in examining the measures' validity and reliability. However, we identified several areas of concern pertaining to the accuracy and integrity of the program's performance data.

¹ See AHCA OIG Report 98-04, *Audit of the Bureau of Consumer and Investigative Services Performance-Based Program Budgeting/Performance Measures*; Division of Health Quality Assurance and AHCA OIG Report 98-05, *Review of Performance Measures*; Division of Health Quality Assurance State Licensure and Federal Certification of Health Care Facilities.

Issue	OPPAGA Conclusion
	<p>We found errors and missing data in the program's complaint database. Our review of the program's practitioner complaint database determined that of the 3,620 complaints received concerning four professions (dentistry, medicine, nursing, and pharmacy) in Fiscal Year 1999-2000, 10% of the complaint records had missing or incorrectly entered data. Critical information missing from the records included the nature and the priority status of some complaints. The agency cannot accurately calculate its performance in responding to Priority I complaints if records do not include the priority of the complaint and the date the complaint was recommended for probable cause.</p> <p>Program staff did not maintain records or documentation needed to verify the accuracy of some performance data reported to the Legislature. Program staff indicated that they did not maintain hard copies of reports generated from the practitioner database that were used as data sources for the program's performance in practitioner regulation in Fiscal Year 1999-2000. They also indicated that since the database is continually updated, they were unable to recreate the reported data. Thus, even though AHCA's inspector general has reviewed the methods used to collect data for performance measures, we were unable to verify the accuracy of actual data reported for performance.</p>

Appendix B

Program Performance in Meeting Performance for Fiscal Year 1999-2000

Measures	Fiscal Year 1998-99 Actual Performance	Fiscal Year 1999-2000 Actual Performance	Fiscal Year 1999-2000 Legislative Performance Standard	Performance Standard Not Met for Fiscal Year 1999-2000
Outcome Measures 1999-2000¹				
Percent of Priority I practitioner Investigations resulting in Emergency Action	3%	13%	39 ^{3%}	X
Average length of time (in days) to take emergency action in Priority I practitioner investigations	76	124	60 ³	X
Percent of cease and desist orders issued to unlicensed practitioners in which another complaint of unlicensed activity is subsequently filed against the same practitioner	18%	0 ¹	7%	Function Transferred to Department of Health
Percent of licensed practitioners involved in adverse incidents (agency identified)	.23%	Not Available	.33%	Measure Eliminated
Percent of licensed practitioners involved in peer review discipline (agency identified)	.11%	Not Available	.02%	Measure Eliminated
Percent of investigations of alleged unlicensed facilities and programs that have been previously issued a cease and desist order, that are confirmed as repeated unlicensed activity	5%	5.7%	7 ^{3%}	
Percent of Priority I consumer complaints about licensed facilities and programs that are investigated within 48 hours	62%	95.7%	100%	X
Percent of accredited hospitals and ambulatory surgical centers cited for not complying with life safety, licensure, or emergency access standards	31%	6.5%	9%	
Percent of accreditation validation surveys that result in findings of licensure deficiencies	67%	66%	66% ²	
Percent of nursing home facilities in which deficiencies are found that pose a serious threat to the health, safety, or welfare of the public	15%	3.5%	5%	
Percent of assisted living facilities in which deficiencies are found that pose a serious threat to the health, safety, or welfare of the public	1%	3.2%	5%	
Percent of home health facilities in which deficiencies are found that pose a serious threat to the health, safety, or welfare of the public	0%	0%	5%	
Percent of clinical laboratories in which deficiencies are found that pose a serious threat to the health, safety, or welfare of the public	0%	0%	5%	

Measures	Fiscal Year 1998-99 Actual Performance	Fiscal Year 1999-2000 Actual Performance	Fiscal Year 1999-2000 Legislative Performance Standard	Performance Standard Not Met for Fiscal Year 1999-2000
Percent of ambulatory surgical centers in which deficiencies are found that pose a serious threat to the health, safety, or welfare of the public	0%	0%	5%	
Percent of hospitals with deficiencies that pose a serious threat to the health, safety, or welfare of the public	0%	0%	5%	
Percent of hospitals that fail to report adverse incidents (agency identified)	In litigation	13.9%	5%	X
Percent of hospitals that fail to report peer review disciplinary actions (agency identified)	In litigation	0%	3%	
Output Measures 1999-2000				
Number of complaints determined legally sufficient	6,200	6,318	7,112	
Number of legally sufficient practitioner complaints resolved by findings of no probable cause (nolle prosequere)	1,072	1,333	680	
Number of legally sufficient practitioner complaints resolved by findings of no probable cause (letters of guidance)	993	1,118	491	
Number of legally sufficient practitioner complaints resolved by findings of no probable cause (notice of noncompliance)	3	9	35	X
Number of legally sufficient practitioner complaints resolved by findings of probable cause (issuance of citation for minor violations)	51	152	34	
Number of legally sufficient practitioner complaints resolved by findings of stipulations or informal hearings	845	1,484	662	
Number of legally sufficient practitioner complaints resolved by findings of formal hearings	31	30	44	X
Percent of investigations completed within time frame:				
Priority I (45 Days)	12%	14.1	100 ³ %	X
Priority II (180 Days)	55%	68.1	100 ³ %	X
Other (180 Days)	73%	67.7	100 ³ %	X
Average number of practitioner complaint investigations per FTE	227	264	87	
Number of inquiries to call center regarding practitioner licensure and disciplinary information	104,517	52,036	113,293 ³	X
Number of facility emergency actions taken	81	43	51	X
Number of nursing home full facility quality of care surveys conducted	646	694	815 ³	X
Number of assisted living full facility quality of care surveys conducted	1,108	1,473	1,282 ³	X
Number of home health agency full facility quality of care surveys conducted	692	1,075	1,600 ³	X

Appendix B

Measures	Fiscal Year 1998-99 Actual Performance	Fiscal Year 1999-2000 Actual Performance	Fiscal Year 1999-2000 Legislative Performance Standard	Performance Standard Not Met for Fiscal Year 1999-2000
Number of clinical laboratory full facility quality of care surveys conducted	1,055	722	1,082 ³	X
Number of hospital full facility quality of a care surveys conducted	33	66	35 ³	
Number of other full facility quality of care surveys conducted	983	1,736	1,357 ³	
Number of hospitals the agency determines have not reported:				
1. Adverse Incidents	39	30	23	X
2. Peer Review Disciplinary Actions	In Litigation	Not Available	2	Not Available
Average processing time (in days) for Statewide Provider and Subscriber Assistance Panel Cases	192	58	259	
Number of nursing home plans and construction reviews performed	637	659	1,200 ³	X
Number of hospital plan and construction reviews performed	2,663	3,037	3,500	X
Number of ambulatory surgical center plans and construction reviews performed	110	228	400	X
Average number of hours for a nursing home plans and construction review	29	77	35	X
Average number of hours for a hospital plans and construction review	33	60	35	X
Average number of hours for an ambulatory surgical center plans and construction review	19	81	35	X
2000-01 New Measures				
Administrative cost as a percent of total program costs	NA	4.5%	6.4%	Not Applicable
Percent of initial investigations and recommendations as to the existence of probable cause completed within 180 days after receipt of complaint	NA	83%	85%	Not Applicable
Percent of new recipients voluntarily selecting managed care	NA	57.4%	71%	Not Applicable
Number of new enrollees provided choice counseling	NA	522,637	191,582	Not Applicable

Not Applicable—measure did not exist for Fiscal Year.

Not Available—not reported for Fiscal Year 1999-2000 due to litigation, see discussion in Chapter Three.

¹ Agency reports that cease and desist orders for practitioners are now under the Department of Health.

² As reported in the Agency's 2000-01 Legislative Budget Request, surveys that are consistent with accreditation surveys.

³ The Executive Office of the Governor, in a letter to legislative committees, lowered the standards for these measures.

Source: Performance data are from AHCA legislative budget requests, AHCA Long Range Program Plan for Fiscal Years 2001-02 through 2005-06, and program documents. Performance standards are from the 1999 General Appropriations Act implementing bill and the 2000 General Appropriations Act implementing bill.

Response from the Agency for Health Care Administration

In accordance with the provisions of s. 11.45(7)(d), *Florida Statutes*, a draft of our report was submitted to the Secretary of the Agency for Health Care Administration for his review and response.

The Secretary's written response is reprinted herein beginning on page 46. The enclosure cited in the written response is not included here, but is available upon request or may be found at OPPAGA's website.



JEB BUSH, GOVERNOR

RUBEN J. KING-SHAW, JR., SECRETARY

April 27, 2001

Mr. John W. Turcotte, Director
Office of Program Policy Analysis
and Government Accountability
111 West Madison Street, Room 312
Claude Pepper Building
Tallahassee, FL 32399-1475

Dear Mr. Turcotte:

Thank you for the opportunity to respond to the preliminary and tentative audit findings and recommendations of your justification review of the Health Care Regulation Program. Our response to the recommendations found in your review is enclosed.

You will note in our response that the Agency has accepted the majority of the report recommendations. However, some of the recommendations, as well as some of the report narrative, contained statements or conclusions that we found to be in need of clarification or explanation. We have included these clarifications and explanations in our response.

If you have any questions regarding this response please contact Rufus Noble at 921-4897 or Kathy Donald at 922-8448.

Sincerely,

/s/

Ruben J. King-Shaw, Jr.

RJKS/kd
Enclosure



**Agency for Health Care Administration
Response to OPPAGA's Justification Review of the
Health Care Regulation Program**

Chapter 3 - Improved Enforcement Needed to Reduce Risk to Consumers

Agency Response to Report Recommendations on Pages 14 and 15

Recommendation:

We recommend that the Legislature consider amending s. 395.0198, Florida Statutes, to increase the adverse consequences to hospitals from failing to report adverse incidents to the agency. One action the Legislature should consider is amending the statutes to make public the records of adverse incidents that facilities have failed to appropriately report to the state.

Agency Response:

The Agency concurs with this recommendation.

Recommendation:

We recommend that the agency:

- *ensure the accuracy of data entered into its complaint database;*

Agency Response:

The Agency agrees with this recommendation. The Department of Health converted to a new licensure and enforcement tracking system during the timeframe encompassed in this audit. Errors were created by the conversion and were not the result of individual input error. Staff is continuing to correct conversion errors as well as data entry errors. Requests have been submitted to the Department of Health for program enhancements to diminish the possibility of data entry errors or omissions. The Agency has been working to ensure the integrity of the enforcement data during and since conversion to the new database. We will continue to work with the Department of Health in identifying and correcting errors and ensuring the integrity of the data.

- *establish procedures requiring its staff to maintain documentation needed to verify its reported performance figures; and*

Agency Response:

The Agency agrees with this recommendation. Programmatic reports that are run to determine performance measures are currently maintained and saved on the Agency's server. Back-up data (listings of complaints considered in the reports) was not originally maintained. Reports were run and verified to obtain aggregate statistics based on the description in the Agency's Performance Measure Validity and Reliability Forms. Subsequent to the first time audit of Performance Based

Budgeting measures by OPPAGA, the Agency agreed to maintain the appropriate back-up data.

- *exclude from its performance measure on the new Medicaid recipients voluntarily selecting to participate in managed care those cases in which a recipient switched from one form of managed care to another, such as from a Medicaid HMO to MediPass. Including these cases distorts the accuracy of the agency's measure.*

Agency Response:

When the Agency entered into a contract with Benova to administer the HMO enrollment of Medicaid recipients, the definition of "new managed care enrollee" was vague and the contract manager at the time believed that "plan changes" should be included in the "voluntary enrollment" rate. The Agency is in the process of implementing systems changes to accurately reflect "voluntary enrollment rates" consistent with the following definition:

The voluntary enrollment rate is calculated by dividing the number of new Medicaid managed care eligibles voluntarily selecting a managed care plan by the total number of new Medicaid managed care eligibles for the specific month. "New Eligible" is defined as a person who has not participated in a managed care plan within the previous 90 days prior to enrollment. This group of persons includes those that would have been mandatorily assigned to a managed care plan and those who chose a managed care plan voluntarily but would not have been mandatorily assigned to a managed care plan (i.e. dually Medicaid eligibles.)

Recommendation:

We recommend that the AHCA/DOH joint committee seek ways to improve access to the state attorney information regarding complaints in which the states attorneys' offices are pursuing criminal cases against practitioners and the complaints involve an immediate threat to consumers.

Agency Response:

The Agency has improved its working relationship with the State Attorney's offices throughout the State and it is a very productive one. This relationship has been developed through years of partnership in investigating complaints with shared jurisdiction. The efficacy of this relationship is illustrated by the success of the Agency's emergency action program. In the past few years, the number of emergency orders has dramatically increased. In fiscal year 1999/2000, there were 102 emergency actions. In the 9 months of fiscal year 2000/2001, the Agency has already issued 127 emergency actions. This dramatic increase can somewhat be attributed to the evolving working relationship between the criminal justice system and the Agency. Frequently, the information shared by the State Attorney's Office is used to support the emergency summary action taken against a licensee. The appropriateness of the Agency's emergency action, which may be challenged at the District Court of Appeals, has routinely been affirmed thus exemplifying the successful exchange of meaningful evidence by the State Attorney's office to the Agency for Health Care Administration.

Unlike the administrative prosecutions, however, one of the challenges for the criminal prosecutors in the release of this vital information to the Agency is the public disclosure of the evidence collected by the criminal authorities. The criminal justice system's rules of procedure are more restrictive than found in administrative law practice. Thus, the State Attorney's office is reluctant to release prematurely the very evidence that would be used to sustain both causes of action, criminal and administrative. Moreover, since the Agency is obligated to have a public due process hearing on the merits of the case within a very short time frame, the release of the criminal evidence is unavoidable thus potentially rendering a detrimental impact on the criminal prosecution. Nevertheless, the cooperative efforts between both public servants whose mission is to protect the health, safety and welfare of the citizens of Florida continues to improve. These efforts are resulting in a relationship of cooperation and exchange of necessary and vital information.

Chapter 4 - Consumer Access and Outcomes

Agency Response to Report Recommendations on Page 20

Recommendation:

We recommend that the Agency for Health Care Administration monitor the frequency with which it decides to use its own staff to handle complaints over the next year, rather than allow the complaints to be handled by the privatized call center. If there is a trend for agency staff to handle complaints regarding sensitive matters, such as the nursing home contract cancellations in October 2000, the agency either should ensure that it maintains sufficient internal resources and expertise to handle such incidents or review its contract with the private company operating its call center and determine whether the contract should be modified so as to ensure that the center can handle calls of this nature. We also recommend that the agency collect data over the next year that will enable it to assess whether non-English-speaking consumers are having difficulty accessing the complaint investigation process.

Agency Response:

The Agency will monitor the frequency with which it decides to use its own staff; however, the decision to use agency staff rather than call center staff will remain discretionary with agency management. The one incident described in the report in which the call center was not used was a special case. The parameters used to make that decision have been fully described in discussions with OPPAGA staff. As previously indicated, handling consumer calls related to the quality purchasing decision associated with Medicaid contract terminations for 6 nursing homes was not a call center issue. The Agency's decision to staff this function internally was a management decision made to ensure that the inquiry lines were staffed 24 hours each day, 7 days a week, for the period immediately following notification of the facilities of their Medicaid contract terminations. Since the contract with HISPACC, Inc. intends that emergency backup will occur in the event of disasters causing inaccessibility to the complaint lines; such as hurricanes or tornadoes, the contract would have required an expensive amendment to

accommodate any potential calls related to the contract terminations. Also as previously discussed with OPPAGA staff, caller inquiries involved responses that could not have been provided by staff not trained in the details of the nursing home issues associated with the contract cancellations. Call center staff were not so trained.

The Agency has collected data regarding the extent to which non-English speaking consumers access the complaint process. For any complaints filed, the Agency can determine the need for a non-English speaking individual. As reported by the HICPACC, Inc., those data indicate that less than 2 percent of the calls received in the call center are received in a language other than English.

COMPLAINT CALLS BY LANGUAGE HMO, PRACTITIONER, FACILITY

Language	7/1/00 to 7/31/00	8/1/00 to 8/31/00	9/1/00 to 9/30/00	10/1/00 to 10/31/00	11/1/00 to 11/30/00	12/1/00 to 12/31/00	Subtotals
English	1307	1619	1325	1372	1230	1015	7868
Spanish	51	39	30	14	14	20	168
Creole	4	2	0	0	1	0	7
Language	1/1/01 to 1/31/01	2/1/01 to 2/28/01				Subtotals	Totals by Language
English	1558	1489				3047	10915
Spanish	14	28				42	210
Creole	0	1				1	8
							11133

Percentage of Non-English Complaints = $218/11,133 = 0.019581$ or approximately 2%

The call center collects data on all complaint calls, regardless of type. If the caller cannot speak English, the agent designates this information on the call screen. At the time of this report, HISPACC could not tell us how many callers initially selected the option of Spanish, Creole or English when they come into the Interactive Voice Response (IVR) system. However, choosing the Spanish/Creole options does not mean that the caller did not speak perfect English; but rather that a language other than English was chosen for the filing of the complaint. Since the issue was raised, HISPACC, Inc. has created a program to allow data collection about access by non-English speaking consumers through the IVR.

The Agency also addressed accessing the practitioner investigation process by describing the procedures used to deal with complaints filed with the Agency in a language other than English and the assignment of investigative staff to those complaints. These

procedures were provided to OPPAGA staff in writing. The Agency has implemented tracking methods to measure the number of complaints received in Spanish to determine appropriate staffing needs.

Effective April 20th, the Agency will implement a method for identifying which practitioner complaints are first received by the call center in a language other than English and subsequently presented in written form to the Consumer Services Unit. Language use will be tracked in the PRAES database for practitioner complaints.

Recommendation:

We recommend that the Legislature direct the Agency for Health Care Administration and Department of Health to develop proposals to increase the use of mediation and citations as a means to resolve complaints against practitioners. Increased use of these approaches should allow the agency and the department's professional boards to more cost-effectively use their resources and provide an annual cost savings of \$1.6 million.

Agency Response:

The Agency is strictly limited in its use of mediations and citations because it is the Board, not the Agency, that designates the violations that can be managed in these alternative programs. The Boards generally have not taken advantage of these alternative programs and have designated few violations to be handled through citation or mediation. As a result, the Agency has taken a very proactive role in recommending the increase in use of mediation and citations programs by the regulatory boards as a means to resolve complaints against practitioners. The Agency recognized very early in its enforcement responsibilities that both alternative processes would add value to an overburdened disciplinary system. Recently, the agency staff recommended draft language to the Commission on Excellence to enhance the mediation and citation programs. This draft language was overwhelmingly supported by the Commission members and they voted to seek legislative action in the 2001 legislative session. Additionally, the agency staff has affirmatively offered the same legislative language to House of Representative staff to include in proposed bills to increase the types of violations that could be handled in the citation program. This recommended language was accepted by a sponsor and continues to move through the legislative process. Finally, it is noteworthy to recognize that the agency prosecutors have, and continue to, solicit the regulatory boards to increase the number and types of violations to be managed by these two programs. However, the decision to enhance the use of these alternative and effective disciplinary programs is strictly within the prerogative of the individual boards and their desire to increase the frequency of its use.

Chapter 5 - Medicaid Managed Care

Agency Response to Report Recommendations on Pages 26 and 27

Recommendation:

We recommend that the Agency for Health Care Administration develop a system to provide ongoing comparative information on health outcomes and consumer complaints for Medicaid HMO, MediPass, and the new Provider Service Network participants.

Agency Response:

The Agency has a system to provide ongoing comparative information on health outcomes and health measures focusing on the degree to which preventative care is provided. In examining these data, it is important to note that comparisons between Medicaid HMOs and programs such as MediPass are difficult to make and may not always be valid given differences in the characteristics of those selecting an HMO or MediPass. In fact, the Agency is in the forefront of states that collect data on their Medicaid program in comparison to any MediPass equivalent program.

Currently systems are in place in Medicaid to collect comparative data between HMOs and MediPass on the following:

1. Rate of hospitalizations for conditions that could be prevented with adequate ambulatory care;
2. A comprehensive array of pregnancy related outcomes including the rate of Cesarean deliveries performed, trimester of entry into prenatal care and adequacy of prenatal care;
3. Well child visits in a year;
4. Cholesterol management after an acute cardiovascular event;
5. Beta blocker treatment after a heart attack;
6. Cervical cancer screening;
7. Breast cancer screening;
8. Three indicators of diabetes care; and
9. Quality of care as assessed by a peer review organization (However, data is not currently available due to the bid protest on selecting a vendor).

Available data was summarized in a report entitled "Medicaid Health Maintenance Organizations and MediPass" issued in February 2001. In addition, in Area 6 where HMOs are responsible for behavioral health care, the Agency annually collects performance data through the Florida Mental Health Institute. Prenatal care data is published annually by HMOs and a model has been developed to compare performance controlling for relevant demographic differences in enrollment by the University of Florida.

The Agency is also working with the Department of Health to expedite development of the Immunization Registry so that it can be used to obtain comparative data on immunization levels by plan in a less burdensome manner. Currently HMOs report on immunization levels, but comparative data is not available for MediPass without a record review due to the way county health units and rural health clinics bill for service.

We disagree with the statement on page 22 that "The lack of comparable performance data on the quality of MediPass and HMOs reflects the fragmentation of data collection responsibilities. . ." Data are collected for various purposes. The responsibility for collection of HEDIS data is the responsibility of the Center for Health Statistics which utilizes this data for the annual HMO report card. The Managed Care Bureau monitors whether or not HMOs meet National Committee for Quality Assurance (NCQA) standards. Medicaid access data is collected by the Medicaid Office. All data can be easily accessed.

The Agency disagrees with the conclusion on pages v and 23 of the report that Medicaid managed care plans have reduced access and raised serious concerns regarding quality of care is speculative at best. Access data is not reported. Utilization is collected; however it is not a reflection of access, which would reflect whether or not a recipient could obtain a needed service. NCQA requires that measures for Medicaid recipients be reported separately from their commercial business; and NCQA recently issued guidance to HMOs to also exclude Title XXI enrollees from their commercial populations, as inclusion negatively affects performance on the indicators. NCQA does not risk adjust measures and many of the measures are affected by the educational level of the population. Measures particularly sensitive to education are utilization of breast cancer screening and cervical cancer screening rates. Thus, although the Agency is taking action to reduce demographic differences in care, the difference in rates of performance between Medicaid HMOs and commercial HMOs may be entirely explained by the difference in demographics between the two groups.

With respect to patient satisfaction, the Florida legislature appropriated funding for a survey of HMO recipients. The Agency sought and obtained Robert Wood Johnson Foundation funding to collect survey and other data for MediPass and Provider Service Networks (PSN) as part of an evaluation of the PSN. The PSN has only recently been operational long enough to meet criteria for sample selection for the survey using NCQA criteria. The first survey will begin in the next few months.

As part of its activities to improve comparative data, the Agency is holding a meeting on April 23, 2001, to develop funding strategies to expand the HMO survey to MediPass and the PSN on an ongoing basis. This meeting, which is being coordinated by Medicaid, includes representatives from the Agency's State Center for Health Statistics and Managed Health Care; the University of Florida, which administers the HMO survey; PSN evaluators, and Title XXI evaluators.

The Agency is committed to measuring and improving quality services. It has been proactive in developing systems and will continue to make improvements.

Recommendation:

We recommend that the agency assess the extent to which Medicaid HMO consumers are opting out of HMOs after the lock-in period because of quality of care concerns.

Agency Response:

A survey of disenrollees from Medicaid, which was part of the annual Title XXI evaluation, found that 5 percent rated the quality of care in the program fair or poor and 93 percent would recommend the program to another family member or friend. Only 4 percent had ever filed a complaint. Eleven percent of disenrollees from Healthy Kids rated the program as fair or poor. Based on your recommendation, the Agency will explore the possibility of surveying disenrollees from HMOs who switch plans at the end of their lock-in period.

Recommendation:

We recommend that, at a minimum, the agency restructure the current outreach activities performed under the Medicaid Options Program. This should save approximately \$1.7 million to \$2.2 million annually. AHCA should also consider adopting alternative methods for informing consumers about their health plan choices, such as providing only printed materials, or providing choice counseling materials when the consumer applies for services such as is done in Oregon. Finally, the agency should further explore the costs associated with the various enrollment services currently provided by Benova and the effect on consumers of eliminating the Benova call center.

Agency Response:

The Agency is in the process of re-bidding the contract for the Choice Counseling Program, most likely at a significantly reduced cost, depending upon legislative funding. In its 2001-2002 legislative budget request, the Agency proposed a significant reduction in the funding of this program. These funding reductions were included in the Governor's recommended budget. As part of the budget request the Agency proposed possibly eliminating the call center or, alternatively, reducing the current outreach activities performed by the program. In addition, the Agency is exploring changes to the enrollment system that should result in significant cost savings.

Florida has considered enrollment and choice counseling programs of various states, including Oregon, in the structure of our program.

Chapter 6 - Regulation of Facilities

Agency Comments on Report Narrative

Issue:

We identified several concerns with the agency's approach of using contract actions to address quality of care problems, including not taking strong disciplinary action against

the homes prior to October 2000 and the due process issues noted by the federal district court.

Agency Comments:

In October 2000, the Agency issued 30-day notices to 6 Florida nursing facilities advising them that their Medicaid provider agreements were being terminated. The notice was pursuant to a contract clause that either party may — on 30 days notice — terminate the contract at will, for no cause. It was also in accordance with the State Medicaid Plan, the Florida Administrative Code and s. 409.913, Florida Statutes, all of which provided clear statutory authority for the terminations without cause. One of the providers was Vencor, who owned three of the nursing homes (and 17 others in the state that were not terminated).

Vencor filed a lawsuit in federal court in Tampa and asked the Judge to delay the Agency's termination of the provider agreements at these facilities. The legal action was anticipated, as was the request for the court to restrain the Agency from implementing the termination. The Agency further anticipated that a Temporary Restraining Order (TRO) would be issued, but expected to prevail in a hearing on the merits. Although the restraining order was issued for a few days, there never was an evidentiary hearing on the merits. The courts of Florida have since disregarded the restraining order language in Vencor as having very little precedential value for that reason (see Federal District Court Judge Ferguson's notation in Sterling v. AHCA attached, where Judge Ferguson stated the value of the Vencor TRO clearly, and refused to consider it as precedent, as there was no evidence taken or presented to support the TRO).

Meanwhile, the Agency had planned to maintain resident care at the nursing homes affected by closure and to facilitate the possible transfer of the residents and reduce the risk of transfer trauma (see Secretary Ruben J. King-Shaw, Jr.'s letter to HCFA, attached).

Because the termination of the provider agreement was not effective for 30 days from the date of notice, the issuance of the temporary restraining order was prospective only. The TRO was granted as a measure to preserve the status quo and not to decide the case. The case was settled between the parties a few days after the TRO was issued. The resident care issues with Vencor were addressed in a settlement agreement that successfully accomplished the Agency's objective to obtain and sustain quality services for Medicaid residents.

The Agency briefed the Vencor court fully on the issues of due process and policy changes, as well as the Medicaid Act and HCFA requirements. This same briefing was used in the Sterling case. The Memorandum of Law is appended and represents the Agency's interpretation of the law on these issues. Judge Ferguson has generally followed this, and there are no other legal interpretations available at this time. In short, the law appears to be very clear and completely contrary to what is stated in this recommendation (see Memorandum of Law attached).

An affidavit of Gary Crayton, former Medicaid Director, which was obtained and filed in Vencor, is instructive on these issues as well, and is the statement of one who administered the Program for many years (see Affidavit of Gary L. Crayton attached). The Secretary of the Agency, Ruben J. King-Shaw, Jr., also corresponded with HCFA on the issues of notice and compliance. Secretary King-Shaw's letter sets out the Agency's position on those issues.

HCFA took another view and its letter concerning the notice given to Vencor and the denial of a pre-termination hearing was a complete departure from its prior statements to the Agency. The letter also conflicted with HCFA's own long-term plan, which outlines the need for the states to engage in "quality purchasing" with Medicaid dollars.

Finally, prior to the Agency's notice of termination, Vencor had entered into an agreement with HHS to resolve compliance issues. However this agreement was to be effective in *the future*, while the Agency's settlement was effective immediately. The Agency settlement has directly resulted in tangible improvements in the standard of care, quality assurance and integrity of the Vencor nursing homes, and had the secondary result in opening a positive dialogue with the Vencor entity since November 2000. The HHS agreement was never made known to the Agency until the federal suit and, it is highly unlikely it would have been voluntarily disclosed before the Agency took its action.

Agency Response to Report Recommendations on Pages 36 and 37

Recommendation:

The Legislature should amend the Health Facilities and Services Development Act, s. 408.031 Florida Statutes, et seq., to eliminate the Certificate of Need Program.

Agency Response:

The Legislature has mandated the convening of a CON Workgroup to evaluate issues pertaining to the certificate-of-need program, including the impact of trends in health care delivery and financing. The Workgroup shall study issues relating to implementation of the certificate-of-need program. Its first meeting is scheduled for April 27th in Orlando. The scope of the Workgroup's charge and the due dates for its reports may be changed as a result of bills before the current Legislature.

Recommendation:

If the CON Program is eliminated, AHCA needs to ensure that certain goals that are presently addressed through the CON process be addressed through its facility licensing function. To ensure that facilities that undertake certain medical procedures can respond to emergency situations, AHCA should develop guidelines requiring hospitals that perform certain types of services to have the necessary facilities to provide quality care. To provide a means for ensuring the "unprofitably" ill, such as persons with acute needs such as AIDS/HIV patients or the elderly, have access to long term care, AHCA could make acceptance of these patients a condition for issuing a license to a facility. Also, to help ensure elimination of the CON Program does not impair the ability of the urban

teaching hospitals to fund and provide less profitable services, AHCA can control the medical procedures offered by surrounding hospitals through licensing.

Agency Response:

On page 30, this report states that elimination of the CON Program could reduce costs to the Agency by \$836,525 and delete the need for 18 positions. However, the discussion goes on to state that if the program were abolished, the state would need to develop alternatives for addressing several issues: ensuring the quality of services provided; ensuring access to care for the underserved or "unprofitably ill" through conditions placed on a facility's license; and controlling the medical procedures offered by hospitals through licensure to assist the urban, teaching hospitals.... "regulating the types of services offered". The report does not acknowledge that this change in regulation would come at a price.

Analyses conducted by the Agency related to a recent legislative proposal to eliminate the CON Program and shift to an expanded quality of care regulation by the state through the licensure process show that the cost of such regulation would exceed the current cost of operation of the CON Program. Additional staff would be required for the processing of licensure applications, the monitoring of compliance with licensure conditions, the surveying of health care facilities and the investigation of complaints. The Agency's estimate projected an initial need to triple staff.

Also when OPPAGA says that, as the result of the elimination of CON, "the state would need to provide a means for ensuring that the unprofitably ill....have access to long term care," it potentially commits the state to an enormous expenditure.

Recommendation:

We recommend that AHCA seek to take strong disciplinary actions under its statutory enforcement authority to address the problem of chronically under-performing facilities. AHCA should ensure that the operators of substandard facilities understand that initial, less serious enforcement actions will be followed by more severe enforcement actions based upon the facilities' prior records.

Agency Response:

The Agency has taken, and does routinely take strong disciplinary action against poor performing facilities. The Agency is supporting proposed legislation to strengthen its enforcement authority.

It is correct that the Agency did not take action to suspend or revoke the license of the six facilities involved in the initiative activities undertaken last October. However, this report itself documents the variety of other licensure actions that were taken.

The decisions involved in the Medicaid Quality Purchasing Initiative were not a substitute for licensure action but considered the facility's compliance history and those enforcement actions taken in making the determination of facilities to be involved in this Medicaid purchasing decision. The Agency believes that we have demonstrated a clear

pattern of thought and consideration in all actions, including this purchasing decision. Operators of all facilities are aware, and will be reminded as needed, that initial, less serious enforcement actions will be followed by more severe enforcement actions as APPROPRIATE according to applicable guidelines.

Contrary to the criticism by OPPAGA, the Medicaid Quality Purchasing Initiative did in fact effect positive change. The standards for the delivery of care in nursing homes were elevated. Four of the involved facilities were members of multi-state chains. In response to this initiative they developed quality assurance programs to measure and ensure quality for the residents. These programs serve as a prototype for positive change nationwide.

Also regarding the comments on page 14 of this report, the Agency does not agree that the purpose of the performance based budgeting standards is to increase enforcement actions. The Agency will only take enforcement actions as appropriate and will not set quotas based on standards included in performance based budgeting. Recent improvements in survey and enforcement processes have been designed to identify and encourage sustained compliance in licensed and certified health care facilities.

Recommendation:

AHCA should improve its system for informing consumers about the quality of care provided in nursing homes by incorporating quantitative data as well as more detail into their reports on the records of nursing facilities.

Agency Response:

OPPAGA argues that the current Watch List is too limited and does not provide information on the frequency and seriousness of deficiencies, and the date the deficiencies were cited. OPPAGA ignores the details of the web version of the Nursing Home Guide that is under development and apparently does not understand that this version will provide the details that OPPAGA is in fact recommending. The web version already under development to enhance consumer's access to information authorized under Chapter 400.191, FS will provide a list of all the deficiencies, the severity and scope (i.e. seriousness) of the deficiencies, and the date of each survey on which the deficiency was cited. These voluminous details must be on the web, as including them in the printed guide would render the printed version too cumbersome to be effective to consumers. (Note that although OPPAGA suggests that the Agency report the percentage of residents who were affected by noted deficiencies, this is not feasible since our survey teams do not literally assess every resident. Surveys are based on a sampling methodology whereby the general scope of deficiencies are determined as outlined above.)

Although the Agency does not currently list the deficiencies and severity and scope on its web site, we do provide a link from the Watch List web site to HCFA's Nursing Home Compare web site, which does provide these details. The survey reports are public information, and the Agency routinely provides these details to individuals upon request. Although this data is currently readily available, the Agency has clearly informed

OPPAGA of the details that are underway to further enhance accessibility of this information to the public.

Recommendation:

We recommend that the agency report within six months to the Legislature the status of its progress in carrying out these recommendations.

Agency Response:

The Agency will report within six month to the Legislature the status of its progress in carrying out these recommendations.

Appendix A -- Statutory Requirements for Program Evaluation and Justification Review / Table A-1 -- Summary of the Program Evaluation and Justification Review of the Health Care Regulation Program

Agency Response to OPPAGA Conclusions on Pages 38 through 41

Issue:

Progress towards achieving the outputs and outcomes associated with the program

OPPAGA Conclusion:

In addition, the program is not meeting performance standards for taking emergency actions against practitioners in the length of time required to take emergency actions against practitioners has worsened.

Agency Response:

Although the days to take emergency action increased, the Agency considers the emergency action program a success. As noted, the number of emergency actions has increased. For example, in fiscal year 1999/2000, there were 102 emergency actions. In the 9 months of this fiscal year, the Agency has already issued 127 emergency actions. Additionally, the success of the program is evidenced by the Agency prevailing when, and if the emergency action is challenged in the District Court of Appeals and the fact that the outcome of the disciplinary actions on these emergency order cases usually result in revocation, suspension, restrictions or other significant limitations on practice. Therefore, this statement is not completely accurate because the inability to meet the legislative standards is controlled by the gravity of the course of action recommended by the Agency versus the balance of due process rights of the individual practitioner. This is the most serious and immediate type of action the Agency (on behalf of the Department of Health) can recommend in that the licensee's ability to practice his/her profession is summarily suspended or restricted. The Agency responds to complaints where possible emergency action is warranted. The follow-up response includes, but is not limited to, the interviewing of critical witnesses, the collection of evidence that is supported with indicia of authenticity and the ability to have a successful outcome as a result of thorough preparedness for an expedited hearing (which can be as soon as 72 hours from issuance of the emergency order). As such, a non-quantifiable amount of time, legal and investigative energy is required to gather the necessary evidence to support this serious

action. No real-time measure can be mandated in the collection of the necessary evidence to sustain this course of action. Therefore, the measure imposed on the Agency to accomplish this performance measure is a guide at best. In recognition of this performance measure, the Agency has affirmatively developed specific criteria in identifying complaints that pose an immediate threat to the health, safety and welfare of the citizens and visitors of Florida. These complaints are placed on a priority fast track and best efforts are made to accomplish the emergency action, or downgrade the complaint to a lesser priority if the immediate threat is not substantiated.

Issue:

The consequences of discontinuing the program

OPPAGA Conclusion:

Florida's program to regulate health care practitioners and to license and regulate health care facilities and services is vital to ensure that Floridians have access to quality health care. The program is needed to provide adequate safeguards against practitioners who might practice while impaired and health care facilities and providers that might endanger the public.

Agency Response:

Florida ranks third in the nation in the number of physicians disciplined and third among large states in the percentage of licensed physicians disciplined, according to the 2000 Annual Disciplinary Report of the Federation of State Medical Board of the United States (FSMB). According to statistics released by the FSMB, Florida took disciplinary action against 258 doctors in 2000, compared with 218 in 1999. This 18% increase was substantially above the national increase in physician discipline of 3%. The Agency agrees that this program is vital to ensure the quality, accessibility and affordability of health care services to citizens and visitors of Florida. Moreover, the continuity and continued improvement of the program demands the retention of the program in the existing agency. Previous transfers of the program to various agencies have historically shown to be disruptive, costly, and ineffective.

Issue:

Whether the state agency management has established control systems sufficient to ensure that performance data are maintained and supported by state agency records and accurately presented in state agency performance reports.

Appendix B -- Program Performance in Meeting Performance for Fiscal Year 1999-2000

Agency Comments Regarding Performance Standards Not Met for Fiscal Year 1999-2000 -- Pages 42 through 44:

Percent of Priority I practitioner Investigations resulting in Emergency Action

The inability to meet the legislative standards is driven by the gravity of the action versus the balance of due process rights of the individual practitioner. This is the most serious type of action the Agency (on behalf of the Department of Health) can recommend in that the licensee's ability to practice his/her profession is summarily suspended or restricted without the opportunity for a due process proceeding. As such, time is required to gather the necessary evidence to support this serious action. No real-time measure can be mandated in the collection of the necessary evidence to sustain this course of action. Therefore, the measure imposed on the Agency to accomplish this performance measure is a guide at best. Although the number of days to take emergency action increased, the number of emergency actions also increased. For example, in fiscal year 1999/2000, there were 102 emergency actions. In the 9 months of this fiscal year, the Agency has already issued 127 emergency actions. It should be noted that the Agency requested and obtained approval by the Governor's office to change the requested standard for this measure to 16%. The Agency's performance was 13%.

Average length of time (in days) to take emergency action in Priority I practitioner investigations

No real-time measure can be mandated in the collection of the necessary evidence to sustain this course of action. Therefore, the measure imposed on the Agency to accomplish this performance measure is a guide at best. In recognition of this performance measure, the Agency has affirmatively developed specific criteria in identifying complaints that pose an immediate threat to the health, safety and welfare of the citizens and visitors of Florida. These complaints are placed on a priority fast track and best efforts are made to accomplish the emergency and immediate action or downgrade the complaint to a lesser priority if the immediate threat is not substantiated.

Number of legally sufficient practitioner complaints resolved by findings of no probable cause (notice of non-compliance)

The number of complaints identified as Notice of Non-compliance is the same or similar to the violations identified for citations. As a result, the Boards have generally instructed the Agency to issue citations. As a result, the Agency has suggested the repeal of the Notice of Non-compliance statutory section.

Number of legally sufficient practitioner complaints resolved by findings of formal hearings

The number of hearings is driven by factors beyond the control of the Agency staff. For example, due process entitles a licensee to engage in full discovery and defense preparation. As a result, hearings may be advanced to accommodate that due process requirement beyond a year's period. Moreover, the Division of Administrative Hearings may determine the number of trials by the dates of availability. Therefore, these two factors alone can impact the Agency's ability to meet the performance standard.

Percent of investigations completed within the timeframe:

Priority I (45 days)

Priority II (180 days)

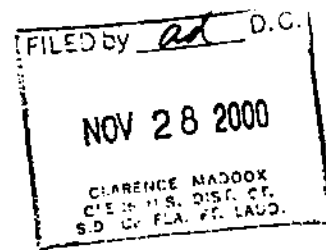
Other (180 days)

Florida has one, if not the highest standards and shortest schedules in the country to complete investigations to a recommendation of probable cause. The overall compliance rate for meeting the 180-day mandate for fiscal year 1999-2000 from receipt of a complaint to a recommendation of probable cause (including citations and administrative closures) was 83%. When the 180-day mandate was directed by the legislature, the average number of days to complete an investigation to recommendation of probable cause was 512 days. Currently, the average number of days is 74 days, including administrative closures. The average number of days for legally sufficient complaints to a recommendation of probable cause is 202 days. Although the Agency may not be meeting the 180-day requirement 100% of the time, in 3 ½ years, the Agency has dramatically reduced the time to probable cause to approximately half the amount of time. This is significant because the caseload continued to increase and the additional staff to accomplish this mandate was not provided until July 1999.

Number of inquiries to call center regarding practitioner licensure and disciplinary information

The Call Center was privatized in July 2000 to more effectively serve the consumers of Florida. Baseline standards for the Call Center were set based on the Call Center providing licensure and disciplinary information. Through agreement with the Department of Health, the Agency's Call Center now provides only disciplinary information. The Department of Health provides the licensure information through its own call center.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA



STERLING PHARMACY CORP.,
A Florida corporation,

Case No. 00-7637-CIV-FERGUSON

Plaintiff,

v.

RUBEN J. KING-SHAW, as
Secretary of the FLORIDA AGENCY
FOR HEALTH CARE
ADMINISTRATION,

Defendant.

ORDER DENYING TEMPORARY RESTRAINING ORDER

Plaintiff, Sterling Pharmacy Corporation ("Sterling"), requests that the Court grant it injunctive relief preventing Defendant Ruben J. King-Shaw ("King-Shaw") from terminating Sterling's Medicaid Provider Agreement. This cause came before the Court on Plaintiff's Motion for Preliminary Injunction [D.E. 2].

FACTUAL BACKGROUND

Sterling is a healthcare provider which has complied with all the requirements for participation in the Florida Medicaid program through its certification process. On or about May 12, 2000, King-Shaw, by and through his agents at the Florida Agency for Health Care Administration ("AHCA"), sent Sterling a letter terminating without cause the Medicaid Provider

Agreement between the parties, effective thirty days from the date of the letter.¹ No reason was given.

Specifically as to its termination, Sterling argues that AHCA violated the Federal Medicaid Act because it did not obtain approval from the federal government for the baseless termination. Sterling also alleges that AHCA cannot show that its without cause termination was made in good faith. Shortly after receiving the May 12th termination letter Sterling was placed on pre-payment review which means it must provide supporting documentation (e.g., prescription and proof of delivery) for pending Medicaid claims. After review of the documentation AHCA either pays the claims, requests additional information or denies the claims. During this review process the Medicaid provider is ineligible for additional Medicaid payments for new claims. Sterling complains that King-Shaw has continued it on pre-payment review status even though it provided all the information requested by AHCA months ago.

In response to Sterling's petition for a formal administrative hearing AHCA filed a motion to dismiss claiming that the relationship between Sterling and AHCA is merely contractual and thus could be terminated at anytime without cause. In reply, Sterling argues that the Medicaid Provider Enrollment Guide ("Guide"), published by the AHCA, states that "[i]f the provider is subject to appeal rights and files an appeal within the allowable 30-day notification period, termination will not occur until appeal rights are exhausted." Sterling argues that because an administrative appeal

¹ The May 12, 2000, letter states "[p]lease be advised that the Agency has elected to exercise its termination rights under Section 7 of the provider agreement." Section 7 of the agreement states in full "(7) Termination and Equitable Relief. This agreement may be terminated, with or without cause, upon thirty (30) days written notice by either party. The Agency may terminate this agreement for cause and may apply for injunctive or other relief in the Circuit Court of Leon County, Florida to enforce this provision or any other provisions of this agreement."

of AHCA's decision to terminate the parties' agreement is still pending it has a right to continued participation in the Medicaid Program.

As to the irreparable harm Sterling alleges that AHCA's actions have caused its business to suffer over the last several months and has interrupted its ability to provide medication to bedridden HIV and AIDS patients who are covered by Medicaid. So as to prevent business ruination Sterling requests the following injunctive relief:

(1) An Order enjoining King-Shaw from taking any further action to terminate Sterling's Medicaid Provider Agreement;

(2) An Order directing King-Shaw to recognize Sterling as a Medicaid provider within the State of Florida;

(3) An Order directing King-Shaw to either immediately reject or accept Sterling's claims for payment presently under pre-payment review; and

(4) An Order awarding Sterling any and all reasonable attorneys' fees and costs.

QUESTION PRESENTED

The threshold question presented is whether the state is authorized to terminate a health care provider from participation in a Medicaid program without cause absent federal approval.

DISCUSSION

Statutory Law Regarding the Termination of Medicaid Providers

Title 42 U.S.C.A. § 1395j establishes a voluntary insurance program, Medicare, to provide medical insurance benefits for aged and disabled individuals. The program is financed by the enrollees' premium payments and funds appropriated by the Federal Government. Section 1395cc(b) of the same statute sets forth the standards for "[t]ermination or nonrenewal of

agreements" for providers of service. Specifically it states:

(2) The Secretary may refuse to enter into an agreement under this section or, upon such reasonable notice to the provider and the public as may be specified in regulations, may refuse to renew or may terminate such an agreement after the Secretary -

(A) has determined that the provider fails to comply substantially with the provisions of the agreement, with the provisions of this subchapter and regulations thereunder, or with a corrective action required under section 1395ww(f)(2)(B)² of this title,

(B) has determined that the provider fails substantially to meet the applicable provisions of section 1395x³ of this title, or

(C) has excluded the provider from participation in a program under this subchapter pursuant to section 1320a-7⁴ or section 1320a-7a of this title.

*none from
w/o
cause*

No provisions in the Federal Medicaid Act address the termination of Medicaid providers

without cause. Florida statutory law is also silent on this issue. This Court has found no legal authority for the proposition that a state must obtain federal approval prior to terminating Medicaid providers without cause.

Florida Statute §409.913 sets forth the rules regulating "[o]versight of the integrity of the Medicaid program." Section 409.913(12) states the agency "may terminate participation of a Medicaid provider in the Medicaid program and may seek civil remedies or impose other administrative sanctions against a Medicaid provider" for a number of specific reasons.⁵

² § 1395ww(f)(B) requires that if the Secretary determines that a hospital, in order to circumvent the established payment method, has taken an action that results in the admission of otherwise ineligible individuals, the Secretary may require the hospital to take other corrective action necessary to prevent or correct the inappropriate practice.

³ § 1395x sets forth the definitions of terms used in this chapter.

⁴ § 1320a-7 sets forth the regulations for exclusion of certain individuals and entities from participation in Medicare and State health care programs.

⁵ Fla. Stat. §409.913 sets forth standards of for cause terminations.

While both Florida and Federal statutory law are silent on a state's right to terminate a Medicaid provider without cause, Page 1-5 of the Guide, issued by AHCA, states "[a] provider agreement can be terminated for any reason, at any time, by the provider or the state with 30 days written notice. All the conditions of the agreement remain in effect during the 30-day notice period and until termination is completed" (emphasis added). Specifically, the Guide states at page 3-6 "the provider or the State can terminate the provider number with or without cause at any time" (emphasis added).

Case Law Regarding Without Cause Terminations of Medicaid Providers

Sterling cites Vencor Nursing Ctr. East, LLC v. Ruben King-Shaw, Case No. 8:00-CV-2051-T-27B where the United States District Court for the Middle District of Florida entered a temporary restraining order against King-Shaw enjoining him from "taking any further action, without cause, to terminate the Medicaid Provider Agreements between the State of Florida and [three nursing home facilities] . . . including any action to terminate, without cause, the Plaintiff's participation in the Medicaid Program . . ." Sterling argues that in Vencor the court found that constitutional (i.e. due process) violations could exist if AHCA failed to adhere to the termination guidelines set forth in the Federal Medicaid Act.⁶ Lastly, Sterling contends that neither the Medicaid Provider Agreement nor the Guide referring to AHCA's without cause termination policy are valid or

⁶ Sterling cannot rely on Vencor, where a temporary restraining order was granted without discussion of the merits of the case. It is well established that findings of fact made during injunctive relief hearings have no preclusive effect in later proceedings. See Univ. of Texas v. Camenisch, 101 S. Ct. 1830, 1834 (1981) ("the findings of fact and conclusions of law made by a court granting a preliminary injunction are not binding at trial on the merits"); McArthur et al v. Firestone, Sec. of State, et al., 817 F.2d 1548, 1552 (11th Cir. 1987) ("a decision concerning a preliminary injunction is not tantamount to a decision on the underlying merits of the case. . . [t]hus the district court's denial of the plaintiffs' motion for a temporary restraining order cannot be viewed as a ruling on the merits of the plaintiff's claim"). Conclusions reached for the purpose of a temporary restraining order carry even less weight than those reached after a hearing on a motion for preliminary injunction.

*Vencor
cannot be
used.*

dispositive because they are contrary to federal laws and regulations permitting Florida's participation in the Medicaid Program.

Sterling's argument that the AHCA's without cause termination policy violates the Federal Medicaid Act is not persuasive. It has not directed the Court to any law which requires states to obtain federal approval for terminating a provider without cause. For the purpose of enjoining state action there must be a stronger showing of unlawfulness. In a similar case the United States Supreme Court held that injunctive relief should be denied for persons claiming that a state statute conflicts with federal law where the Federal Medicaid Act is "silent" on the particular issue. See Atkins, Comm'r. Mass. Dep't. of Pub. Welfare v. Rivera et al, 106 S. Ct. 2456 (1986).

In Atkins, the respondents requested injunctive relief against the state department after a determination that they were ineligible for Medicaid benefits based on their incomes. 106 S. Ct. at 2459. Specifically, the respondents claimed that the state's methodology for determining eligibility, using a six-month spenddown period, was "manifestly contrary to the statute". Atkins, 106 S. Ct. at 2461. The United States Supreme Court held that "[t]he Medicaid Act itself is silent as to how many months' excess income the State may require an individual or family to contribute to medical expenses before Medicaid coverage of further medical expenses begins". Atkins, 109 S. Ct. at 2463. The Court concluded that the state's choice of six months for a spenddown period did not violate federal Medicaid laws where the applicable statutes were silent as to how many months' excess income a state may require. Atkins, 109 S. Ct. at 2463.

Application of the reasoning of the United States Supreme Court in Atkins to this case requires the finding that AHCA's without cause termination of Sterling, absent federal approval,

does not conflict with or violate federal Medicaid laws.⁷ This Court finds that Sterling has made no showing that AHCA's without cause termination of the provider agreement violates federal procedural or substantive law.

Preliminary Injunctive Relief

A district court may grant preliminary injunctive relief if the movant establishes:

- (1) substantial likelihood of success on the merits;
- (2) substantial threat of irreparable injury will be suffered unless the requested injunctive relief issues;
- (3) the threatened injury to the movant outweighs whatever damage the proposed injunction may cause the opposing party; and
- (4) if issued, the injunction would not be adverse to the public interest.

Because Sterling has not proved that AHCA's without cause termination policy conflicts with federal or state law it does not satisfy the first prerequisite for granting injunctive relief--likelihood of success on the merits. It is not necessary to consider the other factors.

Having considered the motion, responsive pleadings and oral arguments, it is hereby

ORDERED AND ADJUDGED that Plaintiff's Motion for Preliminary Injunction⁸ [D.E.

⁷ AHCA cites three Second Circuit Court of Appeals cases in support of its position that states may terminate healthcare providers' participation in the federal Medicaid program both without cause and without federal approval. See Senape v. Constantino, 936 F.2d 687 (2d Cir. 1991); 701 Pharmacy Corp. v. Perales, 930 F.2d 163 (2d Cir. 1991); Kelly Kare, Ltd. v. O'Rourke, 930 F.2d 170 (2nd Cir. 1991). Unlike Florida, the state of New York clearly had statutory without cause termination provisions which were reviewed by district and appellate courts without comment as to a real or potential conflict with the Federal Medicaid Act.

In sum, the three Second Circuit Court of Appeals cases proffered by AHCA all upheld the underlying without cause terminations of Medicaid providers. None of those cases held that states had to obtain approval from the federal government prior to terminating Medicaid providers without cause.

⁸ Plaintiff's Motion for Preliminary Injunction [D.E. 2] is treated as a motion for a temporary restraining order due to the inadequacy of notice to the Defendant. See Siegel, et al v. Lepore, et al, 2000 U.S. Dist. LEXIS

2], treated as a Motion for Temporary Restraining Order, is **DENIED**. This denial is without prejudice to exhaust administrative remedies. A timetable setting discovery deadlines shall be entered by separate order.

DONE AND ORDERED in Chambers at Ft. Lauderdale, Florida, this 28TH day of November, 2000.



WILKIE D. FERGUSON, JR.
UNITED STATES DISTRICT JUDGE

copies provided:
Omar Arcia, Esq.
William Porter, Esq.

16333, *9 (November 13, 2000)(stating that "Federal Rule of Civil Procedure 65(a) permits federal district courts to issue a preliminary injunction only after proper notice has been given to the adverse party. . . Federal Rule of Civil Procedure 65(b), however, permits federal district courts to issue a temporary restraining order without written or oral notice to the adverse party. . ." under specific circumstances). In this case, the Court granted the Plaintiff's motion for a hearing on the motion for preliminary injunction on November 7, 2000. The Defendant was notified of the hearing on the afternoon of November 8, 2000. The hearing was held on the morning of November 9, 2000 before the Defendant could file a written response.

STATE OF FLORIDA
AHCA
AGENCY FOR HEALTH CARE ADMINISTRATION

JEB BUSH, GOVERNOR

RUBEN J. KING-SHAW, JR., SECRETARY

October 19, 2000

Mr. Timothy M. Westmoreland, Director
Center for Medicaid and State Operations
Department of Health and Human Services
Health Care Financing Administration
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Mr. Westmoreland:

I am writing in response to your letter of October 17, 2000 regarding the State of Florida's recent cancellation of six Medicaid contracts with nursing homes. Your letter describing HCFA's position is both puzzling and disappointing.

After years of concern and frustration over inadequate performance, we notified six homes of our intent to end our business relationship. This action is expressly permitted by the language of our Medicaid contract with these providers. Also, while you speak of your pledge to the quality of care in nursing homes, your actions do not reflect this promise. The State took bold and strong action to demonstrate Florida's commitment to nursing home residents.

The "termination without cause" provision of the Florida Medicaid contract has been in place for three years with HCFA's knowledge and approval. You must recall that for the last three years this clause has been a part of the Florida Medicaid Provider Handbook and other documents that have been submitted to you and your staff regularly. During that period, our staffs have had numerous interactions over the content of the handbooks and other related documents that provide the framework of the Florida Medicaid Program. While our Agency staff has worked on several issues raised by HCFA the "termination without cause" language was never identified as a problem. In the absence of any communication to the contrary, and in accordance with HCFA's standard operating procedures all provisions contained in Medicaid documents are deemed approved.

Moreover, the "termination without cause" provision has been recognized recently by the General Accounting Office as a best practice that ensures provider integrity by giving states more flexibility to terminate contracts without delay. Concurrence has been acknowledged by HCFA staff, representatives of the Federal Bureau of Investigations, and the House Commerce Subcommittee on Oversight and Investigations.



Of further note, when Deputy Secretary Pete Buigas and I met with Rose Crum-Johnson, Gene Grasser and Rick James of the HCFA Regional Office in Atlanta on October 5th, we discussed the provisions of our contract as a basis of our action. Ms. Crum-Johnson expressed that HCFA should have been consulted earlier in our process, that HCFA could not have stopped us, and that HCFA wanted to be a participant to answer any questions. She acknowledged the contracts were Florida's contracts, and she did not suggest they were contrary to federal law. Finally, other states, such as Connecticut, Georgia, and Texas, include similar clauses as part of their Medicaid provider agreements. We are aware of no communication of HCFA's disapproval or concern over this termination language. HCFA's apparent reversal of its established position of approval raises grave concern over the credibility of your current stance.

In your correspondence, you state that the "...procedure you [Florida] used to cancel nursing home provider agreements is not consistent with Federal law." Yet your letter identifies no basis in law for this new position. My legal staff has researched relevant Federal statutes and finds no prohibition on our action or the contract language that enabled it. I formally request that you identify the basis of your legal conclusion in the absence of any identifiable Federal law that addresses the issue.

As to your concerns about the "impact of your [Florida's] decision on the Medicaid residents being transferred and on the Medicare and private pay residents in these homes," we have addressed this issue with you on several previous phone conferences. Our relocation plan maximizes individual and family choice, which is a core value of the Medicaid program. State of Florida staff from several state agencies—including the Departments of Children and Families, Elder Affairs and Veterans Affairs,—joined AHCA to work cooperatively to develop the information package presented to each resident and family. Spanish translators were available in each facility. Additionally, staff consulted with residents, patients and families on the various options available, in order to manage a smooth transition.

Our Agency transition staff included nurses, quality monitors, health quality surveyors and social workers. Over 200 individuals have been successfully transferred to date. We have assisted Medicare beneficiaries, private pay residents, and veterans — a population you omitted in your letter—to find improved care. Some have successfully returned home or to home-and-community-based care programs. No patient or resident was left unassisted in any of the six homes that received notice.

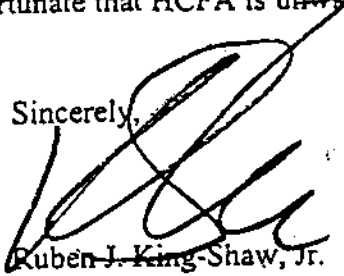
You refer to the visits the Regional Office made to the six homes. I am surprised by and disappointed with the incomplete and shallow assessment conducted by your staff. Visits were limited essentially to discussions with employees of the six homes and residents and families who had yet to make selections of alternative locations. Without having received any credible feedback from HCFA survey staff, it is unclear that these teams made sufficient contact with appropriate agencies that have had the responsibility of coordinating the daily transition activities. Several important actions that would have given you an accurate assessment of our performance and therefore a credible analysis were not included. A thorough assessment should have included:

- Conversations with patients, residents and their families who had completed a transfer to another facility with the assistance of State personnel;
- Conversations with staff at the receiving facilities to assess the facilities' willingness and level of cooperation with the State initiative;
- Conversations with local long-term care providers who make up the area long-term care delivery system to assess their ability and commitment to accommodate the needs of the affected individuals and families;
- Recognition that nursing home staff would not share positive thoughts of the State, its staff, the process and the information provided when the State had terminated its provider agreement only days prior to your visit;
- Recognition that patients, residents and families were vulnerable to "disinformation" efforts on the part of nursing home management; and
- Conversations with community-based organizations, consumer advocacy groups and industry and professional associations that have first-hand knowledge of the State's initiative and performance.

The failure to include these items in your assessment reflects poorly on the survey teams' capabilities and calls into question your commitment to quality care for Florida's elder and frail residents in nursing homes. Furthermore, this incomplete assessment casts doubt on your assertion that HCFA has taken steps to fulfill its responsibilities to the state, the homes and the beneficiaries.

Florida has taken bold, strong action to improve the quality of long-term care services rendered through the Medicaid program. It is unfortunate that HCFA is unwilling to support our mission.

Sincerely,



Ruben J. King-Shaw, Jr.
Secretary

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

VENCOR NURSING CENTERS EAST,
LLC d/b/a COLONIAL OAKS
REHABILITATION CENTER and d/b/a
REHABILITATION AND HEALTHCARE
CENTER OF TAMPA; and PERSONACARE
ST. PETERSBURG, INC, d/b/a THE
ABBEY REHABILITATION CENTER,

Plaintiffs,

vs.

Case No. 8:00-CV-2051-T-27B

RUBEN J. KING-SHAW, Jr.,
as Secretary of the FLORIDA
AGENCY FOR HEALTH
CARE ADMINISTRATION,

Defendant.

DEFENDANT RUBEN KING-SHAW'S NOTICE OF ADDITIONAL LEGAL AUTHORITIES

Pursuant to the Court's instructions at the hearing on Plaintiffs' Motion for a Temporary Restraining Order, the Agency for Health Care Administration (AHCA) hereby provides supplemental authority clarifying its legal authority for taking the termination action at issue, reconciling AHCA's action with federal provisions, and asserting AHCA's authority to act in the absence of proscriptive federal law. AHCA respectfully urges the Court to reconsider its position regarding the applicability of the federal provisions relied on by Plaintiffs and offers the following argument in support of its position.

At the hearing on Plaintiffs' Motion for a Temporary Restraining Order, the Court recommended several issues for AHCA's consideration. See, Transcript of Proceedings at 84-5. Specifically, the Court asked AHCA to consider (1) whether there is any authority that derives

from any statute or regulation promulgated under the Medicaid Act that supports AHCA's action; (2) whether section 409.907(2), Florida Statutes, supports AHCA's action, and whether the action can be reconciled with the Medicaid Act and its regulatory scheme; and (3) whether the federal regulatory scheme that requires AHCA to submit a state plan limits AHCA's ability to terminate a contract without cause. Id.

1. Authority under the Medicaid Act

The Medicaid Act requires states to submit a state plan to the federal Health Care Financing Administration (HCFA) for approval before federal funding will be provided. The Florida Medicaid program submitted a plan in accordance with this requirement. The handbook referring to the provider agreement and asserting a chain of state authority for that provider agreement was submitted with the state plan. HCFA approved the state plan. Due to the cooperative nature of the Medicaid program, however, AHCA suggests that the Court should more appropriately consider whether any express language in the Medicaid Act prohibits AHCA's action. AHCA submits that no specific authority is required under the Act. A careful review of federal law reveals that no code provision or regulation forbids AHCA from terminating the contract of a compliant provider. There is no code provision or regulation that limits AHCA's power to terminate provider contracts to instances where a finding of non-compliance has been made.

Plaintiffs cite 42 U.S.C. 1396r(h) and 42 C.F.R. Sections 431.151 and 431.153, as evidence of a federal regulatory scheme that prohibits AHCA's actions. These federal provisions, however, do not apply to this termination action. 42 U.S.C. 1396r(h) sets out a federal enforcement process. The instant action is not an enforcement action. Enforcement actions are intended to deter noncompliance. See 42 U.S.C. 1396r(h)(2)(B)(ii). AHCA has taken

enforcement actions as a result of noncompliance findings in the past. However, the facilities have shown themselves to be undeterred and incapable of significant improvement. Rather than an enforcement action, this is a contract action -- a budgetary choice to invest the taxpayer's money in facilities with better outcomes.

AHCA stresses that 42 U.S.C. 1396r(h) contemplates termination based on a finding of noncompliance or de-certification. This is borne out by the case law on 1396r(h). All cases citing this section relate to terminations based on de-certification or findings of noncompliance. No such finding was made in this action. 42 U.S.C. 1396r(h) provides an enforcement process and specific (but not exclusive) remedies for the State to use against nursing facilities when the State makes a finding "that a nursing facility no longer meets a requirement of subsection (b), (c) or (d) of this section . . ." 42 U.S.C. 1396r(b) relates to service provision, including quality of care; 1396r(c) relates to residents' rights; 1396r(d) relates to administration. At issue here is 1396r(b). That finding must be made as the result of a standard, extended, or partial extended survey, as defined in 1396r(g)(2).

Although the code does not expressly indicate whether a finding "that a nursing facility no longer meets the requirements of subsection (b), (c), or (d) of this section . . ." is equivalent to a finding of noncompliance under 42 C.F.R. 431.151, a logical interpretation leads to this conclusion. This conclusion is bolstered by consideration of 42 U.S.C. 1396r(g)(1)(A), which requires that each State certify the compliance of nursing facilities with the requirements of 1396r(b), using the surveys outlined in 1396r(g)(2). The standards outlined in (b) and the survey methods outlined in (g) exist for the purpose of certifying (and de-certifying) nursing home compliance. 42 U.S.C. 1396r(h) refers to the outcomes of that process by delineating its

enforcement options without actually using the same language, ie., 'compliance' and 'certification'.

Therefore, because 42 U.S.C. 1396r(h) enforcement methods are reliant on 1396(g) survey methods, which are used for certification of compliance, the enforcement methods must contemplate use only where a nursing facility is de-certified or determined non-compliant. Unless AHCA's action can be construed as a 1396r(h) 'finding of non-compliance', or de-certification, the 1396r(h) enforcement provisions do not apply. As a consequence, the code provisions relating to hearing rights, which implement 1396r(h), also do not apply.

Even assuming, *arguendo*, that the quality basis for the termination decision may be termed a "finding of noncompliance," or some lesser finding under 42 U.S.C. 1396r(h), that 'finding' was not made "on the basis of a standard, extended, or partial extended survey under subsection (g)(2) . . ." 42 U.S.C. 1396r(h). Clearly, the decision was not based on one of the three types of surveys. Rather, it was based on a different type of survey, consisting of a review of many factors, including geography, demographics, cultural factors, the needs of the network, bed availability, and the facilities two-year history.

In addition, 42 U.S.C. 1396r(h) refers to a finding made "on the basis of a . . . survey under subsection (g)(2)." (emphasis added). By its plain language, the code provisions contemplate a situation where a single survey is conducted, a finding of noncompliance issues, and enforcement occurs. In this action, AHCA reviewed many past surveys, rather than just one, and made a decision based on the cumulative compliance history of the facilities, a recurring cycle of marked by survey, finding of non-compliance, sanction, and subsequent compliance.

Based on the foregoing, the Court should conclude that federal law is silent as to this action and that the enforcement provisions discussed, *supra*, cannot preempt unrelated state law.

Federal law is silent on the issue of whether a state can engage in a broad review of a provider's history, including surveys and previous findings, and make contract decisions based on that review. Clearly, 42 U.S.C. 1396r does not indicate that the only way to terminate a provider is by a finding of noncompliance based on a single survey, rather, it merely provides that where a finding of non-compliance is based on a single survey, termination is an enforcement option, and that termination must be conducted according to the law. 42 U.S.C. 1396r(h)(1) makes clear that other enforcement remedies not set out therein are not restricted: "[n]othing in this paragraph shall be construed as restricting the remedies available to a State to remedy a nursing facility's deficiencies." While it provides a civil money penalty to remedy historic non-compliance, it is an option that AHCA may exercise but not one it must exercise, and not one that excludes all other remedies.

Even if federal law spoke to the issue of without cause contract terminations, the doctrine of federal preemption is particularly weak in the area of assistance programs. See, State of Washington, Department of Social and Health Services v. Bowen, 815 F.2d 549, 553, 554, 557 (9th Cir. 1987). This court set aside a decision by DHHS vetoing a state plan amendment. The court accorded the state deference in its interpretation of a Medicaid regulation, finding that the federal and state governments share the responsibility for ensuring that Medicaid provides adequate and efficient nursing home care. *Id.* at 554.

The Bowen Court cites Harris v. McRae, 448 U.S. 297, 308, 100 S.Ct. 2671, 2683, 65 L.Ed.2d 784 (1980): "The Medicaid program created by Title XIX is a cooperative endeavor in which the Federal Government provides financial assistance to participating States to aid them in furnishing Health care to needy persons. Under this system of 'cooperative federalism,' . . . if a State agrees to establish a Medicaid plan that satisfies the requirements of Title XIX, which

include several mandatory categories of health services, the Federal Government agrees to pay a specified percentage of 'the total amount expended.'" Harris at 308; Bowen at 557.

The Bowen Court also cites New York Department of Social Services v. Dublino, 413 U.S. 405, 93 S.Ct. 2507, 37 L.Ed.2d 688 (1973): "Where coordinate state and federal efforts exist within a complementary administrative framework, and in the pursuit of common purposes, the case for federal pre-emption becomes a less persuasive one." Dublino at 421; Bowen at 557. See also, Keith v. Rizzuto, 212 F.3d 1190 (9th Cir. 2000). The court cites Southwestern Bell Wireless Inc. v. Johnson County Board of County Commissioners, 199 F.3d 1185, 1189-90 (10th Cir. 1999) for the finding that "[c]onflict preemption 'occurs either when compliance with both the federal and state laws is a physical impossibility, or when the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress'." Keith at 1193.

Two cases dealing with termination for noncompliance refer to Congress' objectives regarding termination of Medicaid/Medicare contracts. The issue in these cases was whether DHHS termination for noncompliance without a finding of immediate jeopardy was permitted by the Medicaid Act. The courts referred to Congressional intent in allowing such a termination: "Congress, in enacting the 1987 amendments, was concerned about a 'yo-yo' or 'roller coaster' phenomenon among nursing facilities, such that facilities which were chronically out of compliance when surveyed temporarily corrected the deficiencies found in the surveys and then relapsed into non-compliance until the next survey. H.R. Rep. 100-391(I), at 474 reprinted in 1987 U.S.C.C.A.N. 2313-1, 2313-291. . . . The Secretary's termination of Randolph Crossings could send a signal that consistent substandard service will result in serious action even if there is not an immediate threat of harm" Mediplex of Massachusetts, Inc., v. Shalala, 39

F.Supp.2d 88 at 100-101. See also, Vencor Nursing Centers, L.P. v. Shalala, 63 F.Supp.2d 1 at 9. This clear expression of intent supports AHCA's action in the instant case. Although they go a step beyond the actions contemplated in federal law and in the above cases, terminations without cause clearly go to the accomplishment and execution of the full purposes and objectives of Congress.

The federal government's silence affords the states' latitude in shaping their Medicaid programs. The Florida Medicaid program is a program of cooperative federalism in which a framework is set out in federal law. AHCA has the right and responsibility to augment this framework with practical and specific provisions. Purchasing, enrollment, and contract decisions are areas left to the states. Federal law does not speak to whether and how a state may terminate a compliant provider without cause in a contract action. Federal code provisions and regulations only speak to whether and how a state may terminate a non-compliant provider in an enforcement action. It is a basic principle of Constitutional law that where the federal government has declined to legislate, the state may do so. Florida has exercised its state right to make a decision in an area where the federal government has not. See, the U.S. Constitution, Amendment 10: "[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the states, are reserved to the states respectively, or to the people;" see also U.S. Constitution, Article VI: "this Constitution, and the laws of the United States which shall be made in pursuance thereof; . . . shall be the supreme law of the land"

The federal government knows how to limit the reasons for termination of a provider contract. It has chosen to do so for the Department of Health and Human Services (DHHS). 42 U.S.C. 1395cc(b)(2) limits the reasons for which the Secretary of DHHS can terminate a contract

between the Secretary and the provider. There is no similar provision limiting the states. The federal government has clearly chosen not to so limit the states.

2. Section 409.907(2), Florida Statutes, and the Medicaid Act

Section 409.907(2), Florida Statutes, supports AHCA's action. It provides that the provider agreement is a voluntary contract, terminable by either party after reasonable notice. Section 409.919, Florida Statutes, grants AHCA rulemaking authority to implement Chapter 409, Florida Statutes, including section 409.907. Florida Administrative Code 59G-4.200, promulgated under the authority of section 409.919, Florida Statutes, requires nursing facilities enrolled in the Medicaid program and bearing a provider agreement to comply with the Florida Medicaid Provider Reimbursement Handbook. The Handbook is incorporated into the rule. The Handbook defines "reasonable notice" by providing for the termination of provider agreements on thirty days notice. The provider agreements at issue were drafted in accordance with the Handbook, with the rule, and the relevant statutory provisions. Section 409.907, Florida Statutes, does not need to be reconciled with the Medicaid Act and its regulatory scheme. There is no conflict between the statute and federal law.

3. Florida's state plan

At the hearing on Plaintiffs' Motion for a Temporary Restraining Order, the Court asked for guidance regarding the contents and effect of Florida's state plan. Specifically, the Court asked for a discussion of the federal regulatory scheme that requires Florida to submit a state plan and whether the "termination without cause" provision is included in the state plan and subject to approval and review by the Health Care Financing Administration (HCFA). See Transcript of Proceedings at 84-5.

An understanding of the state plan and its role in Florida's administration of the Medicaid program is essential to a fair resolution of this matter. Plaintiffs would have the Court believe that the state plan is the sole document that contemplates each and every aspect of the administration of an 8 billion-dollar federal-state insurance program. Of course, the state plan is not such a document but rather it is an agreement by the states to administer their Medicaid programs in accordance with applicable federal law. As such, although the plan does contain Florida's promise to abide by federal enforcement policies and procedures, it does not contain any reference to Florida's independent right to sever a business relationship without cause.

The federal code provisions regarding the state plan requirements are instructive. 42 C.F.R. Section 430.0 sets out the general provisions regarding the Medicaid program. It provides that "[w]ithin *broad Federal rules*, each State decides eligible groups, types and range of services, *and administrative and operating procedures*." (emphasis supplied). Clearly, states are permitted to supplement the federal rules with provisions that are necessary to the fair and efficient operation of the program. 42 CFR Section 430.10 further illustrates this point. It specifically addresses state plans and provides that a state plan is simply a

comprehensive written statement submitted by the agency describing the *nature and scope* of its Medicaid program and giving assurance that it will be administered in conformity with the specific requirements of title XIX, the regulations in this Chapter IV, and other applicable issuances of the Department. The State plan contains all information *necessary for HCFA to determine whether the plan can be approved* to serve as a basis for Federal financial participation (FFP) in the State program.

(emphasis supplied). This code provision cannot be read to limit a state's ability to pass laws and promulgate rules to refine its Medicaid program. Instead, it must be read simply as a requirement to assure HCFA of the state's agreement to abide by all applicable federal requirements.

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

VENCOR NURSING CENTERS EAST,
LLC d/b/a COLONIAL OAKS
REHABILITATION CENTER and d/b/a
REHABILITATION AND HEALTHCARE
CENTER OF TAMPA; and PERSONACARE
ST. PETERSBURG, INC, d/b/a THE
ABBEY REHABILITATION CENTER,

Plaintiffs,

v.

Case No. 8:00-CV-2051-T-27B

RUBEN J. KING-SHAW,
as Secretary of the FLORIDA
AGENCY FOR HEALTH
CARE ADMINISTRATION,

Defendant.

AFFIDAVIT OF GARY L. CRAYTON

STATE OF FLORIDA

ss.

COUNTY OF LEON

GARY L. CRAYTON being first duly sworn on oath, deposes and states that he has personal knowledge of the matters set forth in the Affidavit and if called as a witness would testify as follows:

1. My name is Gary L. Crayton. I live in Tallahassee, Florida. I am over 18 years old, and give this affidavit after having been first duly sworn, under penalty or perjury, and testify here as to events of which I have personal knowledge.

2. I have worked with the Florida Medicaid program since 1984 with the exception of an eighteen-month period between 1997 and 1999. I was the Director of the Florida Medicaid program from 1995 to 1997 and again from 1999 to 2000. Medicaid is a state and federal partnership to provide health care services to the poor, elderly and disabled. Federal statutes and

regulations outline the basic parameters of the Medicaid program. The States are given great latitude and flexibility to design the details of their programs to suit the particular needs of their states. The fact that a particular aspect of a state Medicaid program is not specifically authorized by federal statute or rule does not mean the states are prohibited from having or maintaining that aspect of their program. Rather, the States are free to design and maintain their program as they see fit. Should any aspect of a state's program conflict with, or otherwise be contrary to, federal statute or regulation, the federal Health Care Financing Administration (HCFA) (which conducts federal oversight of the Medicaid program) will advise the states of any concern or objection and recommend necessary changes. Similarly, the States are not required to include every detail of their program in their State Plan. That document, too, is a general document that contains basic information required by HCFA. It is not intended to reflect every detail of the administration of the program.

In keeping with this framework, matters such as provider enrollment or termination of provider contracts -- whether the providers are compliant with regulatory requirements or not compliant -- are left to the State to administer and such matters are not subject to prior approval of HCFA. More specifically, the contents of the Medicaid provider contracts are not required to be included in the State Plan and are not required to be approved by HCFA.

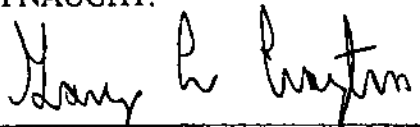
3. I personally administered, participated and helped to implement the provisions of Florida Statute 409.907 which relate to termination of provider agreements upon reasonable notice to the parties. This process began in 1995 and continued into 1996. I worked with my staff, the Director of AHCA, Douglas Cook, and the General Counsel, Jerome Hoffman, in so doing. Our primary objective was to enact legislation to specifically take the issue of provider contract termination out of the realm of enforcement or compliance and render it a contract matter or decision.

4. Each and every step of the process was conducted in accordance with law, both letter and spirit. The HCFA was integrally involved in it. I have personally, on many occasions, interacted with HCFA on the issue of termination as a contract matter, including termination of compliant providers without cause, and the provisions in our Provider agreements that set those conditions forth. At all times, up to and including the various symposiums and conferences with the highest levels of HCFA, including combined meetings of the entire Southeastern and Southwestern consortiums, HCFA was apprised of the mutual no-cause termination provision,

were supportive of it, and offered no criticism or any objection to it. Similarly, HCFA, via their in-house auditor, reviewed the Provider handbooks on an ongoing basis, and offered comments on possible problem areas. At no time did any HCFA official, including their in-house auditor, whose job it is to do so, ever state that the Agency's no-cause termination provision conflicted with any provision of federal statute or regulation.

5. My general counsel at the time, Jerome Hoffman, assisted me with the legal analysis, and worked with HCFA on the enactments. Based on his analysis and my own experience with HCFA, there has been no question at all that this provision -- a mutual no-cause termination provision in the Medicaid provider contracts, which could affect even compliant providers, and was developed pursuant to F.S. 409.907(2), and the Provider handbook (which incorporates the 30 day clause and also is promulgated by Rule in the Florida Administrative Code) -- was consistent with all applicable federal law governing the Medicaid Program, including, but not limited to the Medicaid Act, and 42 U.S.C. 1396(r)(h), and all other enactments under that regulatory framework.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

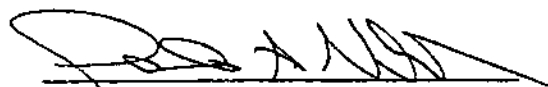

GARY L. CRAYTON

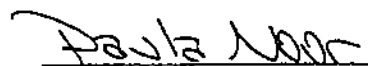
BEFORE ME, the undersigned authority, this day personally appeared GARY L. CRAYTON, who, after being duly cautioned and sworn, deposes and says that he has read the foregoing Affidavit and that the same is true and correct to the best of his knowledge, information and belief.

WITNESS my hand and official seal of office this 13~~th~~ day of October, 2000.



Paula A. Noor
MY COMMISSION # CCB27248 EXPIRES
April 18, 2003
BONDED THRU TROY FAIN INSURANCE, INC.


NOTARY PUBLIC in and for the
State of Florida


PRINTED NAME OF NOTARY PUBLIC

Personally known X

Produced Identification _____

42 CFR Section 430.12 states that "[a] State plan for Medicaid consists of preprinted material that covers the *basic requirements*, and *individualized content* that reflects the characteristics of the particular State's program." (emphasis supplied). This language is important for several reasons. First, it underscores the states' ability to design plans that meet their individualized needs. More importantly, it emphasizes that a state plan is the foundation upon which a state's Medicaid plan must be constructed.

Florida's state plan specifically references required provider agreements in Section 4.13. However, this section simply provides that

[w]ith respect to agreements between the Medicaid agency and each provider furnishing services under the plan: (a) for all providers, the requirements of 42 CFR 431.107 and 42 CFR Part 442, Subparts A and B (if applicable) are met; (b) for providers of NF services, the requirements of 42 CFR 483, Subpart B, and section 1919 of the Act are also met; (c) for providers of ICF/MR services, the requirements of participation in 42 CFR Part 483, Subpart D are also met; and (d) for each provider that is eligible under the plan to furnish ambulatory prenatal care to pregnant women during a presumptive eligibility period, all the requirements of section 1920(b)(2) and (c) are met.

See, Florida's State Plan at 45. Again, the federal government's insistence on state compliance with certain federal provisions is evident. Absent from this list, however, are any requirements or prohibitions regarding supplemental state law. Of course, the Agency does not suggest that Florida may administer its Medicaid program contrary to the specific provisions of Federal law. AHCA respectfully disagrees with the Court's finding that Florida's without cause termination provision is "in contrast to the federal statutory scheme." See, Temporary Restraining Order (TRO) at 3. AHCA submits that the termination clause at issue is not in conflict with the federal regulatory scheme specifically because it is not penal or remedial. The federal regulatory scheme simply does not address terminations that are not penal or remedial. Therefore, the Court must

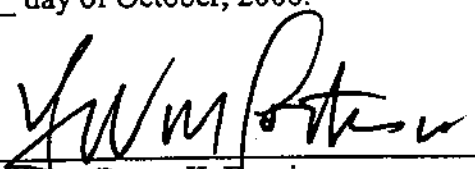
consider whether Florida's "without cause" termination provision is an allowable supplement to the basic administrative framework that the federal government requires.

To be clear, Florida's state plan does assure federal authorities that, regarding disciplinary or compliance matters, Florida will follow the guidelines established in Federal law. However, the Court should not end its analysis there. The Agency's representations before this Court that the termination action in this case is not a compliance action must be carefully considered. Rather than an attempt to circumvent the federal regulations regarding procedures for termination upon a finding of noncompliance, Florida has supplemented federal termination authority with a basic contractual right to terminate a contract without cause. Federal law is silent as to this right and this silence can only be construed as an acknowledgement of states' rights. This is the only interpretation that can follow from recognition of the "cooperative federalism" that is the hallmark of the Medicaid program. AHCA takes issue with Plaintiffs' attempt to portray the exercise of its contractual termination right as a ruse designed to trick Plaintiff out of due process. Plaintiffs' due process is clearly set out in Florida law and the contract provision at issue. Section 409.907(2), Florida Statutes, 1999 provides that "[e]ach provider agreement shall be effective for a stipulated period of time, shall be terminable by either party after reasonable notice, and shall be renewable by mutual agreement." The process flowing from this clear statutory provision is reasonable notice. Plaintiffs have not alleged that it did not receive reasonable notice of AHCA's decision to terminate the contract. Furthermore, the plain language of the contract refined the concept of "reasonable notice" by specifying a 30-day pre-termination requirement. Plaintiffs have received all the process due under the contract, but now seek sanctuary in inapplicable remedial provisions of federal law. Plaintiffs should not be permitted to infuse this simple contract action with a complex litany of noncompliance processes. AHCA

agrees that Plaintiffs are in compliance. However, AHCA has chosen to sever its business relationship with Plaintiffs and should not be further constrained from doing so.

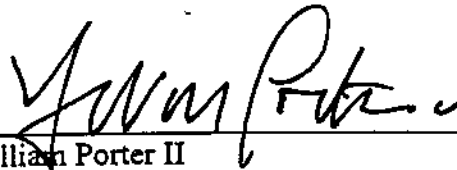
WHEREFORE, AHCA respectfully requests that the Court reconsider its position regarding the applicability of the federal provisions relied on by Plaintiffs and recognize AHCA's right to act pursuant to state and federal law. AHCA's termination of the provider agreements at should not be measured against the inapplicable and cumbersome procedures for sanctioning non-compliant providers under federal law. Despite reference to Plaintiffs' provision of sub-standard care to Florida nursing-home residents, AHCA's ability to exercise its contract rights is not limited by federal law. Plaintiffs received notice of the contract terminations, as required by Florida law, and have, therefore, been afforded due process. *16*

Respectfully submitted this *16* day of October, 2000.


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Texas Bar I.D. No. 00793196
Assistant General Counsel
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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing has been served by U.S. Mail and facsimile on this 16 day of October, 2000 to: Morris Weinberg, Jr., Zuckerman, Spaeder, Taylor & Evans, LLP, 401 East Jackson Street, Suite 2525, Tampa, Florida 33602.

A handwritten signature in black ink, appearing to read "L. William Porter II", written over a horizontal line.

L. William Porter II
Assistant General Counsel, AHCA