A bill to be entitled

An act relating to Medicaid Pharmaceutical and Therapeutics Committees; amending s. 409.91195, F.S.; renaming the Medicaid Pharmaceutical and Therapeutics Committee as the Adult Medicaid Pharmaceutical and Therapeutics Committee; revising the term and membership requirements of the committee; creating the Pediatric Medicaid Pharmaceutical and Therapeutics Committee within the Agency for Health Care Administration; providing for membership and terms; providing for duties and requirements of the committee; amending ss. 409.91196 and 409.912, F.S.; conforming references; providing an effective date.

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

Section 1. Section 409.91195, Florida Statutes, is amended to read:

409.91195 Medicaid Pharmaceutical and Therapeutics Committees ~~Committee~~.--There is created an Adult ~~a~~ Medicaid Pharmaceutical and Therapeutics Committee and a Pediatric Medicaid Pharmaceutical and Therapeutics Committee within the agency for the purpose of developing a Medicaid preferred drug list.

(1)(a) The Adult Medicaid Pharmaceutical and Therapeutics Committee shall be composed of 11 members appointed by the Governor. Four members shall be physicians, licensed under chapter 458; one member licensed under chapter 459; five members

shall be pharmacists licensed under chapter 465; and one member shall be a consumer representative. The members shall be appointed to serve for terms of 2 years staggered from the date of their appointment. Members may be appointed to more than one term. The agency shall serve as staff for the committee and assist them with all ministerial duties. The Governor shall ensure that all ~~at least some~~ of the members of the committee, except for the consumer representative member, represent Medicaid participating physicians and pharmacies serving all segments and diversity of the adult Medicaid population~~,~~ and have experience in either developing or practicing under a preferred drug list. ~~At least~~ One of the members shall represent the interests of pharmaceutical manufacturers.

(b) The Pediatric Medicaid Pharmaceutical and Therapeutics Committee shall be composed of 11 members appointed by the Governor. Four members shall be actively practicing board certified pediatricians licensed under chapter 458; one member shall be a physician licensed under chapter 459 actively practicing pediatrics; five members shall be pharmacists licensed under chapter 465, three of whom shall actively practice in children's hospitals and related institutions; and one member shall be a consumer representative. The physician members shall include two general pediatric practitioners, a pediatric subspecialist and a child psychiatrist, all of whom shall maintain appropriate board certification. Three of the physician members shall also have at least a 25-percent or greater representation of Medicaid patients within their practice. The members shall be appointed to serve terms of 2

years staggered from the date of their appointment. Members may be appointed to more than one term. The agency shall serve as staff for the committee and assist them with all ministerial duties. The Governor shall ensure that all of the members of the committee, except for the consumer representative member, represent Medicaid participating physicians and pharmacies serving all segments and diversity of the child Medicaid population and shall have experience in either developing or practicing under a preferred drug list. One of the pharmacy members shall represent the interests of pharmaceutical manufacturers.

(2) Committee members shall select a chairperson and a vice chairperson each year from the committee membership.

(3) Each ~~The~~ committee shall meet at least quarterly and may meet at other times at the discretion of the chairperson and members. The committees ~~committee~~ shall comply with rules adopted by the agency, including notice of any meeting of the committees ~~committee~~ pursuant to the requirements of the Administrative Procedure Act.

(4) Upon recommendation of the committees ~~committee~~, the agency shall adopt a preferred drug list as described in s. 409.912(39). To the extent feasible, the committees ~~committee~~ shall review all drug classes included on the preferred drug list every 12 months, and may recommend additions to and deletions from the preferred drug list, such that the preferred drug list provides for medically appropriate drug therapies for Medicaid patients which achieve cost savings contained in the General Appropriations Act.

(5) Except for antiretroviral drugs and drugs specifically recommended by the committees to be exempt from prior authorization, reimbursement of drugs not included on the preferred drug list is subject to prior authorization.

(6) The agency shall publish and disseminate the preferred drug list to all Medicaid providers in the state by Internet posting on the agency's website or in other media.

(7) The committees ~~committee~~ shall ensure that interested parties, including pharmaceutical manufacturers agreeing to provide a supplemental rebate as outlined in this chapter, have an opportunity to present public testimony to the committees ~~committee~~ with information or evidence supporting inclusion of a product on the preferred drug list. Such public testimony shall occur prior to any recommendations made by the committees ~~committee~~ for inclusion or exclusion from the preferred drug list. Upon timely notice, the agency shall ensure that any drug that has been approved or had any of its particular uses approved by the United States Food and Drug Administration under a priority review classification will be reviewed by the committees ~~committee~~ at the next regularly scheduled meeting following 3 months of distribution of the drug to the general public.

(8) Each ~~The~~ committee shall develop its preferred drug list recommendations by considering the clinical efficacy, safety, and cost-effectiveness of a product.

(9) Upon timely notice, the agency shall ensure that any therapeutic class of drugs which includes a drug that has been removed from distribution to the public by its manufacturer or

the United States Food and Drug Administration or has been required to carry a black box warning label by the United States Food and Drug Administration because of safety concerns is reviewed by each ~~the~~ committee at the next regularly scheduled meeting. After such review, each ~~the~~ committee must recommend whether to retain the therapeutic class of drugs or subcategories of drugs within a therapeutic class on the preferred drug list and whether to institute prior authorization requirements necessary to ensure patient safety.

(10) Each ~~The Medicaid Pharmaceutical and Therapeutics~~ committee may also make recommendations to the agency regarding the prior authorization of any prescribed drug covered by Medicaid.

(11) Medicaid recipients may appeal agency preferred drug formulary decisions using the Medicaid fair hearing process administered by the Department of Children and Family Services.

Section 2. Subsection (2) of section 409.91196, Florida Statutes, is amended to read:

409.91196 Supplemental rebate agreements; public records and public meetings exemption.--

(2) That portion of a meeting of the Adult Medicaid Pharmaceutical and Therapeutics Committee or the Pediatric Medicaid Pharmaceutical and Therapeutics Committee at which the rebate amount, percent of rebate, manufacturer's pricing, or supplemental rebate, or other trade secrets as defined in s. 688.002 that the agency has identified for use in negotiations, are discussed is exempt from s. 286.011 and s. 24(b), Art. I of the State Constitution. A record shall be made of each exempt

portion of a meeting. Such record must include the times of commencement and termination, all discussions and proceedings, the names of all persons present at any time, and the names of all persons speaking. No exempt portion of a meeting may be held off the record.

Section 3. Section 409.912, Florida Statutes, is amended to read:

409.912 Cost-effective purchasing of health care.--The agency shall purchase goods and services for Medicaid recipients in the most cost-effective manner consistent with the delivery of quality medical care. To ensure that medical services are effectively utilized, the agency may, in any case, require a confirmation or second physician's opinion of the correct diagnosis for purposes of authorizing future services under the Medicaid program. This section does not restrict access to emergency services or poststabilization care services as defined in 42 C.F.R. part 438.114. Such confirmation or second opinion shall be rendered in a manner approved by the agency. The agency shall maximize the use of prepaid per capita and prepaid aggregate fixed-sum basis services when appropriate and other alternative service delivery and reimbursement methodologies, including competitive bidding pursuant to s. 287.057, designed to facilitate the cost-effective purchase of a case-managed continuum of care. The agency shall also require providers to minimize the exposure of recipients to the need for acute inpatient, custodial, and other institutional care and the inappropriate or unnecessary use of high-cost services. The agency shall contract with a vendor to monitor and evaluate the

clinical practice patterns of providers in order to identify trends that are outside the normal practice patterns of a provider's professional peers or the national guidelines of a provider's professional association. The vendor must be able to provide information and counseling to a provider whose practice patterns are outside the norms, in consultation with the agency, to improve patient care and reduce inappropriate utilization. The agency may mandate prior authorization, drug therapy management, or disease management participation for certain populations of Medicaid beneficiaries, certain drug classes, or particular drugs to prevent fraud, abuse, overuse, and possible dangerous drug interactions. The Adult Medicaid Pharmaceutical and Therapeutics Committee and the Pediatric Medicaid Pharmaceutical and Therapeutics Committee shall make recommendations to the agency on drugs for which prior authorization is required. The agency shall inform the committees ~~Pharmaceutical and Therapeutics Committee~~ of its decisions regarding drugs subject to prior authorization. The agency is authorized to limit the entities it contracts with or enrolls as Medicaid providers by developing a provider network through provider credentialing. The agency may competitively bid single-source-provider contracts if procurement of goods or services results in demonstrated cost savings to the state without limiting access to care. The agency may limit its network based on the assessment of beneficiary access to care, provider availability, provider quality standards, time and distance standards for access to care, the cultural competence of the provider network, demographic characteristics of Medicaid

beneficiaries, practice and provider-to-beneficiary standards, appointment wait times, beneficiary use of services, provider turnover, provider profiling, provider licensure history, previous program integrity investigations and findings, peer review, provider Medicaid policy and billing compliance records, clinical and medical record audits, and other factors. Providers shall not be entitled to enrollment in the Medicaid provider network. The agency shall determine instances in which allowing Medicaid beneficiaries to purchase durable medical equipment and other goods is less expensive to the Medicaid program than long-term rental of the equipment or goods. The agency may establish rules to facilitate purchases in lieu of long-term rentals in order to protect against fraud and abuse in the Medicaid program as defined in s. 409.913. The agency may seek federal waivers necessary to administer these policies.

(1) The agency shall work with the Department of Children and Family Services to ensure access of children and families in the child protection system to needed and appropriate mental health and substance abuse services.

(2) The agency may enter into agreements with appropriate agents of other state agencies or of any agency of the Federal Government and accept such duties in respect to social welfare or public aid as may be necessary to implement the provisions of Title XIX of the Social Security Act and ss. 409.901-409.920.

(3) The agency may contract with health maintenance organizations certified pursuant to part I of chapter 641 for the provision of services to recipients.

(4) The agency may contract with:

(a) An entity that provides no prepaid health care services other than Medicaid services under contract with the agency and which is owned and operated by a county, county health department, or county-owned and operated hospital to provide health care services on a prepaid or fixed-sum basis to recipients, which entity may provide such prepaid services either directly or through arrangements with other providers. Such prepaid health care services entities must be licensed under parts I and III of chapter 641. An entity recognized under this paragraph which demonstrates to the satisfaction of the Office of Insurance Regulation of the Financial Services Commission that it is backed by the full faith and credit of the county in which it is located may be exempted from s. 641.225.

(b) An entity that is providing comprehensive behavioral health care services to certain Medicaid recipients through a capitated, prepaid arrangement pursuant to the federal waiver provided for by s. 409.905(5). Such an entity must be licensed under chapter 624, chapter 636, or chapter 641 and must possess the clinical systems and operational competence to manage risk and provide comprehensive behavioral health care to Medicaid recipients. As used in this paragraph, the term "comprehensive behavioral health care services" means covered mental health and substance abuse treatment services that are available to Medicaid recipients. The secretary of the Department of Children and Family Services shall approve provisions of procurements related to children in the department's care or custody prior to enrolling such children in a prepaid behavioral health plan. Any contract awarded under this paragraph must be competitively

procured. In developing the behavioral health care prepaid plan procurement document, the agency shall ensure that the procurement document requires the contractor to develop and implement a plan to ensure compliance with s. 394.4574 related to services provided to residents of licensed assisted living facilities that hold a limited mental health license. Except as provided in subparagraph 8., and except in counties where the Medicaid managed care pilot program is authorized pursuant to s. 409.91211, the agency shall seek federal approval to contract with a single entity meeting these requirements to provide comprehensive behavioral health care services to all Medicaid recipients not enrolled in a Medicaid managed care plan authorized under s. 409.91211 or a Medicaid health maintenance organization in an AHCA area. In an AHCA area where the Medicaid managed care pilot program is authorized pursuant to s. 409.91211 in one or more counties, the agency may procure a contract with a single entity to serve the remaining counties as an AHCA area or the remaining counties may be included with an adjacent AHCA area and shall be subject to this paragraph. Each entity must offer sufficient choice of providers in its network to ensure recipient access to care and the opportunity to select a provider with whom they are satisfied. The network shall include all public mental health hospitals. To ensure unimpaired access to behavioral health care services by Medicaid recipients, all contracts issued pursuant to this paragraph shall require 80 percent of the capitation paid to the managed care plan, including health maintenance organizations, to be expended for the provision of behavioral health care services.

In the event the managed care plan expends less than 80 percent of the capitation paid pursuant to this paragraph for the provision of behavioral health care services, the difference shall be returned to the agency. The agency shall provide the managed care plan with a certification letter indicating the amount of capitation paid during each calendar year for the provision of behavioral health care services pursuant to this section. The agency may reimburse for substance abuse treatment services on a fee-for-service basis until the agency finds that adequate funds are available for capitated, prepaid arrangements.

1. By January 1, 2001, the agency shall modify the contracts with the entities providing comprehensive inpatient and outpatient mental health care services to Medicaid recipients in Hillsborough, Highlands, Hardee, Manatee, and Polk Counties, to include substance abuse treatment services.

2. By July 1, 2003, the agency and the Department of Children and Family Services shall execute a written agreement that requires collaboration and joint development of all policy, budgets, procurement documents, contracts, and monitoring plans that have an impact on the state and Medicaid community mental health and targeted case management programs.

3. Except as provided in subparagraph 8., by July 1, 2006, the agency and the Department of Children and Family Services shall contract with managed care entities in each AHCA area except area 6 or arrange to provide comprehensive inpatient and outpatient mental health and substance abuse services through capitated prepaid arrangements to all Medicaid recipients who

are eligible to participate in such plans under federal law and regulation. In AHCA areas where eligible individuals number less than 150,000, the agency shall contract with a single managed care plan to provide comprehensive behavioral health services to all recipients who are not enrolled in a Medicaid health maintenance organization or a Medicaid capitated managed care plan authorized under s. 409.91211. The agency may contract with more than one comprehensive behavioral health provider to provide care to recipients who are not enrolled in a Medicaid capitated managed care plan authorized under s. 409.91211 or a Medicaid health maintenance organization in AHCA areas where the eligible population exceeds 150,000. In an AHCA area where the Medicaid managed care pilot program is authorized pursuant to s. 409.91211 in one or more counties, the agency may procure a contract with a single entity to serve the remaining counties as an AHCA area or the remaining counties may be included with an adjacent AHCA area and shall be subject to this paragraph. Contracts for comprehensive behavioral health providers awarded pursuant to this section shall be competitively procured. Both for-profit and not-for-profit corporations shall be eligible to compete. Managed care plans contracting with the agency under subsection (3) shall provide and receive payment for the same comprehensive behavioral health benefits as provided in AHCA rules, including handbooks incorporated by reference. In AHCA area 11, the agency shall contract with at least two comprehensive behavioral health care providers to provide behavioral health care to recipients in that area who are enrolled in, or assigned to, the MediPass program. One of the

behavioral health care contracts shall be with the existing provider service network pilot project, as described in paragraph (d), for the purpose of demonstrating the cost-effectiveness of the provision of quality mental health services through a public hospital-operated managed care model. Payment shall be at an agreed-upon capitated rate to ensure cost savings. Of the recipients in area 11 who are assigned to MediPass under the provisions of s. 409.9122(2)(k), a minimum of 50,000 of those MediPass-enrolled recipients shall be assigned to the existing provider service network in area 11 for their behavioral care.

4. By October 1, 2003, the agency and the department shall submit a plan to the Governor, the President of the Senate, and the Speaker of the House of Representatives which provides for the full implementation of capitated prepaid behavioral health care in all areas of the state.

a. Implementation shall begin in 2003 in those AHCA areas of the state where the agency is able to establish sufficient capitation rates.

b. If the agency determines that the proposed capitation rate in any area is insufficient to provide appropriate services, the agency may adjust the capitation rate to ensure that care will be available. The agency and the department may use existing general revenue to address any additional required match but may not over-obligate existing funds on an annualized basis.

c. Subject to any limitations provided for in the General Appropriations Act, the agency, in compliance with appropriate

federal authorization, shall develop policies and procedures that allow for certification of local and state funds.

5. Children residing in a statewide inpatient psychiatric program, or in a Department of Juvenile Justice or a Department of Children and Family Services residential program approved as a Medicaid behavioral health overlay services provider shall not be included in a behavioral health care prepaid health plan or any other Medicaid managed care plan pursuant to this paragraph.

6. In converting to a prepaid system of delivery, the agency shall in its procurement document require an entity providing only comprehensive behavioral health care services to prevent the displacement of indigent care patients by enrollees in the Medicaid prepaid health plan providing behavioral health care services from facilities receiving state funding to provide indigent behavioral health care, to facilities licensed under chapter 395 which do not receive state funding for indigent behavioral health care, or reimburse the unsubsidized facility for the cost of behavioral health care provided to the displaced indigent care patient.

7. Traditional community mental health providers under contract with the Department of Children and Family Services pursuant to part IV of chapter 394, child welfare providers under contract with the Department of Children and Family Services in areas 1 and 6, and inpatient mental health providers licensed pursuant to chapter 395 must be offered an opportunity to accept or decline a contract to participate in any provider network for prepaid behavioral health services.

8. For fiscal year 2004-2005, all Medicaid eligible children, except children in areas 1 and 6, whose cases are open for child welfare services in the HomeSafeNet system, shall be enrolled in MediPass or in Medicaid fee-for-service and all their behavioral health care services including inpatient, outpatient psychiatric, community mental health, and case management shall be reimbursed on a fee-for-service basis. Beginning July 1, 2005, such children, who are open for child welfare services in the HomeSafeNet system, shall receive their behavioral health care services through a specialty prepaid plan operated by community-based lead agencies either through a single agency or formal agreements among several agencies. The specialty prepaid plan must result in savings to the state comparable to savings achieved in other Medicaid managed care and prepaid programs. Such plan must provide mechanisms to maximize state and local revenues. The specialty prepaid plan shall be developed by the agency and the Department of Children and Family Services. The agency is authorized to seek any federal waivers to implement this initiative.

(c) A federally qualified health center or an entity owned by one or more federally qualified health centers or an entity owned by other migrant and community health centers receiving non-Medicaid financial support from the Federal Government to provide health care services on a prepaid or fixed-sum basis to recipients. A federally qualified health center or an entity that is owned by one or more federally qualified health centers and is reimbursed by the agency on a prepaid basis is exempt from parts I and III of chapter 641, but must comply with the

solvency requirements in s. 641.2261(2) and meet the appropriate requirements governing financial reserve, quality assurance, and patients' rights established by the agency.

(d) A provider service network may be reimbursed on a fee-for-service or prepaid basis. A provider service network which is reimbursed by the agency on a prepaid basis shall be exempt from parts I and III of chapter 641, but must comply with the solvency requirements in s. 641.2261(2) and meet appropriate financial reserve, quality assurance, and patient rights requirements as established by the agency. Medicaid recipients assigned to a provider service network shall be chosen equally from those who would otherwise have been assigned to prepaid plans and MediPass. The agency is authorized to seek federal Medicaid waivers as necessary to implement the provisions of this section. Any contract previously awarded to a provider service network operated by a hospital pursuant to this subsection shall remain in effect for a period of 3 years following the current contract expiration date, regardless of any contractual provisions to the contrary. A provider service network is a network established or organized and operated by a health care provider, or group of affiliated health care providers, including minority physician networks and emergency room diversion programs that meet the requirements of s. 409.91211, which provides a substantial proportion of the health care items and services under a contract directly through the provider or affiliated group of providers and may make arrangements with physicians or other health care professionals, health care institutions, or any combination of such individuals

or institutions to assume all or part of the financial risk on a prospective basis for the provision of basic health services by the physicians, by other health professionals, or through the institutions. The health care providers must have a controlling interest in the governing body of the provider service network organization.

(e) An entity that provides only comprehensive behavioral health care services to certain Medicaid recipients through an administrative services organization agreement. Such an entity must possess the clinical systems and operational competence to provide comprehensive health care to Medicaid recipients. As used in this paragraph, the term "comprehensive behavioral health care services" means covered mental health and substance abuse treatment services that are available to Medicaid recipients. Any contract awarded under this paragraph must be competitively procured. The agency must ensure that Medicaid recipients have available the choice of at least two managed care plans for their behavioral health care services.

(f) An entity that provides in-home physician services to test the cost-effectiveness of enhanced home-based medical care to Medicaid recipients with degenerative neurological diseases and other diseases or disabling conditions associated with high costs to Medicaid. The program shall be designed to serve very disabled persons and to reduce Medicaid reimbursed costs for inpatient, outpatient, and emergency department services. The agency shall contract with vendors on a risk-sharing basis.

(g) Children's provider networks that provide care coordination and care management for Medicaid-eligible pediatric

patients, primary care, authorization of specialty care, and other urgent and emergency care through organized providers designed to service Medicaid eligibles under age 18 and pediatric emergency departments' diversion programs. The networks shall provide after-hour operations, including evening and weekend hours, to promote, when appropriate, the use of the children's networks rather than hospital emergency departments.

(h) An entity authorized in s. 430.205 to contract with the agency and the Department of Elderly Affairs to provide health care and social services on a prepaid or fixed-sum basis to elderly recipients. Such prepaid health care services entities are exempt from the provisions of part I of chapter 641 for the first 3 years of operation. An entity recognized under this paragraph that demonstrates to the satisfaction of the Office of Insurance Regulation that it is backed by the full faith and credit of one or more counties in which it operates may be exempted from s. 641.225.

(i) A Children's Medical Services Network, as defined in s. 391.021.

(5) By December 1, 2005, the Agency for Health Care Administration, in partnership with the Department of Elderly Affairs, shall create an integrated, fixed-payment delivery system for Medicaid recipients who are 60 years of age or older. The Agency for Health Care Administration shall implement the integrated system initially on a pilot basis in two areas of the state. In one of the areas enrollment shall be on a voluntary basis. The program must transfer all Medicaid services for eligible elderly individuals who choose to participate into an

integrated-care management model designed to serve Medicaid recipients in the community. The program must combine all funding for Medicaid services provided to individuals 60 years of age or older into the integrated system, including funds for Medicaid home and community-based waiver services; all Medicaid services authorized in ss. 409.905 and 409.906, excluding funds for Medicaid nursing home services unless the agency is able to demonstrate how the integration of the funds will improve coordinated care for these services in a less costly manner; and Medicare coinsurance and deductibles for persons dually eligible for Medicaid and Medicare as prescribed in s. 409.908(13).

(a) Individuals who are 60 years of age or older and enrolled in the developmental disabilities waiver program, the family and supported-living waiver program, the project AIDS care waiver program, the traumatic brain injury and spinal cord injury waiver program, the consumer-directed care waiver program, and the program of all-inclusive care for the elderly program, and residents of institutional care facilities for the developmentally disabled, must be excluded from the integrated system.

(b) The program must use a competitive procurement process to select entities to operate the integrated system. Entities eligible to submit bids include managed care organizations licensed under chapter 641, including entities eligible to participate in the nursing home diversion program, other qualified providers as defined in s. 430.703(7), community care for the elderly lead agencies, and other state-certified community service networks that meet comparable standards as

defined by the agency, in consultation with the Department of Elderly Affairs and the Office of Insurance Regulation, to be financially solvent and able to take on financial risk for managed care. Community service networks that are certified pursuant to the comparable standards defined by the agency are not required to be licensed under chapter 641.

(c) The agency must ensure that the capitation-rate-setting methodology for the integrated system is actuarially sound and reflects the intent to provide quality care in the least restrictive setting. The agency must also require integrated-system providers to develop a credentialing system for service providers and to contract with all Gold Seal nursing homes, where feasible, and exclude, where feasible, chronically poor-performing facilities and providers as defined by the agency. The integrated system must provide that if the recipient resides in a noncontracted residential facility licensed under chapter 400 or chapter 429 at the time the integrated system is initiated, the recipient must be permitted to continue to reside in the noncontracted facility as long as the recipient desires. The integrated system must also provide that, in the absence of a contract between the integrated-system provider and the residential facility licensed under chapter 400 or chapter 429, current Medicaid rates must prevail. The agency and the Department of Elderly Affairs must jointly develop procedures to manage the services provided through the integrated system in order to ensure quality and recipient choice.

(d) Within 24 months after implementation, the Office of Program Policy Analysis and Government Accountability, in

consultation with the Auditor General, shall comprehensively evaluate the pilot project for the integrated, fixed-payment delivery system for Medicaid recipients who are 60 years of age or older. The evaluation must include assessments of cost savings; consumer education, choice, and access to services; coordination of care; and quality of care. The evaluation must describe administrative or legal barriers to the implementation and operation of the pilot program and include recommendations regarding statewide expansion of the pilot program. The office shall submit an evaluation report to the Governor, the President of the Senate, and the Speaker of the House of Representatives no later than June 30, 2008.

(e) The agency may seek federal waivers and adopt rules as necessary to administer the integrated system. The agency must receive specific authorization from the Legislature prior to implementing the waiver for the integrated system.

(6) The agency may contract with any public or private entity otherwise authorized by this section on a prepaid or fixed-sum basis for the provision of health care services to recipients. An entity may provide prepaid services to recipients, either directly or through arrangements with other entities, if each entity involved in providing services:

(a) Is organized primarily for the purpose of providing health care or other services of the type regularly offered to Medicaid recipients;

(b) Ensures that services meet the standards set by the agency for quality, appropriateness, and timeliness;

(c) Makes provisions satisfactory to the agency for insolvency protection and ensures that neither enrolled Medicaid recipients nor the agency will be liable for the debts of the entity;

(d) Submits to the agency, if a private entity, a financial plan that the agency finds to be fiscally sound and that provides for working capital in the form of cash or equivalent liquid assets excluding revenues from Medicaid premium payments equal to at least the first 3 months of operating expenses or $200,000, whichever is greater;

(e) Furnishes evidence satisfactory to the agency of adequate liability insurance coverage or an adequate plan of self-insurance to respond to claims for injuries arising out of the furnishing of health care;

(f) Provides, through contract or otherwise, for periodic review of its medical facilities and services, as required by the agency; and

(g) Provides organizational, operational, financial, and other information required by the agency.

(7) The agency may contract on a prepaid or fixed-sum basis with any health insurer that:

(a) Pays for health care services provided to enrolled Medicaid recipients in exchange for a premium payment paid by the agency;

(b) Assumes the underwriting risk; and

(c) Is organized and licensed under applicable provisions of the Florida Insurance Code and is currently in good standing with the Office of Insurance Regulation.

(8) The agency may contract on a prepaid or fixed-sum basis with an exclusive provider organization to provide health care services to Medicaid recipients provided that the exclusive provider organization meets applicable managed care plan requirements in this section, ss. 409.9122, 409.9123, 409.9128, and 627.6472, and other applicable provisions of law.

(9) The Agency for Health Care Administration may provide cost-effective purchasing of chiropractic services on a fee-for-service basis to Medicaid recipients through arrangements with a statewide chiropractic preferred provider organization incorporated in this state as a not-for-profit corporation. The agency shall ensure that the benefit limits and prior authorization requirements in the current Medicaid program shall apply to the services provided by the chiropractic preferred provider organization.

(10) The agency shall not contract on a prepaid or fixed-sum basis for Medicaid services with an entity which knows or reasonably should know that any officer, director, agent, managing employee, or owner of stock or beneficial interest in excess of 5 percent common or preferred stock, or the entity itself, has been found guilty of, regardless of adjudication, or entered a plea of nolo contendere, or guilty, to:

(a) Fraud;

(b) Violation of federal or state antitrust statutes, including those proscribing price fixing between competitors and the allocation of customers among competitors;

(c) Commission of a felony involving embezzlement, theft, forgery, income tax evasion, bribery, falsification or

destruction of records, making false statements, receiving stolen property, making false claims, or obstruction of justice; or

(d) Any crime in any jurisdiction which directly relates to the provision of health services on a prepaid or fixed-sum basis.

(11) The agency, after notifying the Legislature, may apply for waivers of applicable federal laws and regulations as necessary to implement more appropriate systems of health care for Medicaid recipients and reduce the cost of the Medicaid program to the state and federal governments and shall implement such programs, after legislative approval, within a reasonable period of time after federal approval. These programs must be designed primarily to reduce the need for inpatient care, custodial care and other long-term or institutional care, and other high-cost services. Prior to seeking legislative approval of such a waiver as authorized by this subsection, the agency shall provide notice and an opportunity for public comment. Notice shall be provided to all persons who have made requests of the agency for advance notice and shall be published in the Florida Administrative Weekly not less than 28 days prior to the intended action.

(12) The agency shall establish a postpayment utilization control program designed to identify recipients who may inappropriately overuse or underuse Medicaid services and shall provide methods to correct such misuse.

(13) The agency shall develop and provide coordinated systems of care for Medicaid recipients and may contract with

public or private entities to develop and administer such systems of care among public and private health care providers in a given geographic area.

(14)(a) The agency shall operate or contract for the operation of utilization management and incentive systems designed to encourage cost-effective use services.

(b) The agency shall develop a procedure for determining whether health care providers and service vendors can provide the Medicaid program using a business case that demonstrates whether a particular good or service can offset the cost of providing the good or service in an alternative setting or through other means and therefore should receive a higher reimbursement. The business case must include, but need not be limited to:

1. A detailed description of the good or service to be provided, a description and analysis of the agency's current performance of the service, and a rationale documenting how providing the service in an alternative setting would be in the best interest of the state, the agency, and its clients.

2. A cost-benefit analysis documenting the estimated specific direct and indirect costs, savings, performance improvements, risks, and qualitative and quantitative benefits involved in or resulting from providing the service. The cost-benefit analysis must include a detailed plan and timeline identifying all actions that must be implemented to realize expected benefits. The Secretary of Health Care Administration shall verify that all costs, savings, and benefits are valid and achievable.

(c) If the agency determines that the increased reimbursement is cost-effective, the agency shall recommend a change in the reimbursement schedule for that particular good or service. If, within 12 months after implementing any rate change under this procedure, the agency determines that costs were not offset by the increased reimbursement schedule, the agency may revert to the former reimbursement schedule for the particular good or service.

(15)(a) The agency shall operate the Comprehensive Assessment and Review for Long-Term Care Services (CARES) nursing facility preadmission screening program to ensure that Medicaid payment for nursing facility care is made only for individuals whose conditions require such care and to ensure that long-term care services are provided in the setting most appropriate to the needs of the person and in the most economical manner possible. The CARES program shall also ensure that individuals participating in Medicaid home and community-based waiver programs meet criteria for those programs, consistent with approved federal waivers.

(b) The agency shall operate the CARES program through an interagency agreement with the Department of Elderly Affairs. The agency, in consultation with the Department of Elderly Affairs, may contract for any function or activity of the CARES program, including any function or activity required by 42 C.F.R. part 483.20, relating to preadmission screening and resident review.

(c) Prior to making payment for nursing facility services for a Medicaid recipient, the agency must verify that the

nursing facility preadmission screening program has determined that the individual requires nursing facility care and that the individual cannot be safely served in community-based programs. The nursing facility preadmission screening program shall refer a Medicaid recipient to a community-based program if the individual could be safely served at a lower cost and the recipient chooses to participate in such program. For individuals whose nursing home stay is initially funded by Medicare and Medicare coverage is being terminated for lack of progress towards rehabilitation, CARES staff shall consult with the person making the determination of progress toward rehabilitation to ensure that the recipient is not being inappropriately disqualified from Medicare coverage. If, in their professional judgment, CARES staff believes that a Medicare beneficiary is still making progress toward rehabilitation, they may assist the Medicare beneficiary with an appeal of the disqualification from Medicare coverage. The use of CARES teams to review Medicare denials for coverage under this section is authorized only if it is determined that such reviews qualify for federal matching funds through Medicaid. The agency shall seek or amend federal waivers as necessary to implement this section.

(d) For the purpose of initiating immediate prescreening and diversion assistance for individuals residing in nursing homes and in order to make families aware of alternative long-term care resources so that they may choose a more cost-effective setting for long-term placement, CARES staff shall conduct an assessment and review of a sample of individuals

whose nursing home stay is expected to exceed 20 days, regardless of the initial funding source for the nursing home placement. CARES staff shall provide counseling and referral services to these individuals regarding choosing appropriate long-term care alternatives. This paragraph does not apply to continuing care facilities licensed under chapter 651 or to retirement communities that provide a combination of nursing home, independent living, and other long-term care services.

(e) By January 15 of each year, the agency shall submit a report to the Legislature describing the operations of the CARES program. The report must describe:

1. Rate of diversion to community alternative programs;

2. CARES program staffing needs to achieve additional diversions;

3. Reasons the program is unable to place individuals in less restrictive settings when such individuals desired such services and could have been served in such settings;

4. Barriers to appropriate placement, including barriers due to policies or operations of other agencies or state-funded programs; and

5. Statutory changes necessary to ensure that individuals in need of long-term care services receive care in the least restrictive environment.

(f) The Department of Elderly Affairs shall track individuals over time who are assessed under the CARES program and who are diverted from nursing home placement. By January 15 of each year, the department shall submit to the Legislature a

longitudinal study of the individuals who are diverted from nursing home placement. The study must include:

1. The demographic characteristics of the individuals assessed and diverted from nursing home placement, including, but not limited to, age, race, gender, frailty, caregiver status, living arrangements, and geographic location;

2. A summary of community services provided to individuals for 1 year after assessment and diversion;

3. A summary of inpatient hospital admissions for individuals who have been diverted; and

4. A summary of the length of time between diversion and subsequent entry into a nursing home or death.

(g) By July 1, 2005, the department and the Agency for Health Care Administration shall report to the President of the Senate and the Speaker of the House of Representatives regarding the impact to the state of modifying level-of-care criteria to eliminate the Intermediate II level of care.

(16)(a) The agency shall identify health care utilization and price patterns within the Medicaid program which are not cost-effective or medically appropriate and assess the effectiveness of new or alternate methods of providing and monitoring service, and may implement such methods as it considers appropriate. Such methods may include disease management initiatives, an integrated and systematic approach for managing the health care needs of recipients who are at risk of or diagnosed with a specific disease by using best practices, prevention strategies, clinical-practice improvement, clinical interventions and protocols, outcomes research, information

technology, and other tools and resources to reduce overall costs and improve measurable outcomes.

(b) The responsibility of the agency under this subsection shall include the development of capabilities to identify actual and optimal practice patterns; patient and provider educational initiatives; methods for determining patient compliance with prescribed treatments; fraud, waste, and abuse prevention and detection programs; and beneficiary case management programs.

1. The practice pattern identification program shall evaluate practitioner prescribing patterns based on national and regional practice guidelines, comparing practitioners to their peer groups. The agency and its Drug Utilization Review Board shall consult with the Department of Health and a panel of practicing health care professionals consisting of the following: the Speaker of the House of Representatives and the President of the Senate shall each appoint three physicians licensed under chapter 458 or chapter 459; and the Governor shall appoint two pharmacists licensed under chapter 465 and one dentist licensed under chapter 466 who is an oral surgeon. Terms of the panel members shall expire at the discretion of the appointing official. The advisory panel shall be responsible for evaluating treatment guidelines and recommending ways to incorporate their use in the practice pattern identification program. Practitioners who are prescribing inappropriately or inefficiently, as determined by the agency, may have their prescribing of certain drugs subject to prior authorization or may be terminated from all participation in the Medicaid program.

2. The agency shall also develop educational interventions designed to promote the proper use of medications by providers and beneficiaries.

3. The agency shall implement a pharmacy fraud, waste, and abuse initiative that may include a surety bond or letter of credit requirement for participating pharmacies, enhanced provider auditing practices, the use of additional fraud and abuse software, recipient management programs for beneficiaries inappropriately using their benefits, and other steps that will eliminate provider and recipient fraud, waste, and abuse. The initiative shall address enforcement efforts to reduce the number and use of counterfeit prescriptions.

4. By September 30, 2002, the agency shall contract with an entity in the state to implement a wireless handheld clinical pharmacology drug information database for practitioners. The initiative shall be designed to enhance the agency's efforts to reduce fraud, abuse, and errors in the prescription drug benefit program and to otherwise further the intent of this paragraph.

5. By April 1, 2006, the agency shall contract with an entity to design a database of clinical utilization information or electronic medical records for Medicaid providers. This system must be web-based and allow providers to review on a real-time basis the utilization of Medicaid services, including, but not limited to, physician office visits, inpatient and outpatient hospitalizations, laboratory and pathology services, radiological and other imaging services, dental care, and patterns of dispensing prescription drugs in order to coordinate care and identify potential fraud and abuse.

6. The agency may apply for any federal waivers needed to administer this paragraph.

(17) An entity contracting on a prepaid or fixed-sum basis shall, in addition to meeting any applicable statutory surplus requirements, also maintain at all times in the form of cash, investments that mature in less than 180 days allowable as admitted assets by the Office of Insurance Regulation, and restricted funds or deposits controlled by the agency or the Office of Insurance Regulation, a surplus amount equal to one-and-one-half times the entity's monthly Medicaid prepaid revenues. As used in this subsection, the term "surplus" means the entity's total assets minus total liabilities. If an entity's surplus falls below an amount equal to one-and-one-half times the entity's monthly Medicaid prepaid revenues, the agency shall prohibit the entity from engaging in marketing and preenrollment activities, shall cease to process new enrollments, and shall not renew the entity's contract until the required balance is achieved. The requirements of this subsection do not apply:

(a) Where a public entity agrees to fund any deficit incurred by the contracting entity; or

(b) Where the entity's performance and obligations are guaranteed in writing by a guaranteeing organization which:

1. Has been in operation for at least 5 years and has assets in excess of $50 million; or

2. Submits a written guarantee acceptable to the agency which is irrevocable during the term of the contracting entity's contract with the agency and, upon termination of the contract,

until the agency receives proof of satisfaction of all outstanding obligations incurred under the contract.

(18)(a) The agency may require an entity contracting on a prepaid or fixed-sum basis to establish a restricted insolvency protection account with a federally guaranteed financial institution licensed to do business in this state. The entity shall deposit into that account 5 percent of the capitation payments made by the agency each month until a maximum total of 2 percent of the total current contract amount is reached. The restricted insolvency protection account may be drawn upon with the authorized signatures of two persons designated by the entity and two representatives of the agency. If the agency finds that the entity is insolvent, the agency may draw upon the account solely with the two authorized signatures of representatives of the agency, and the funds may be disbursed to meet financial obligations incurred by the entity under the prepaid contract. If the contract is terminated, expired, or not continued, the account balance must be released by the agency to the entity upon receipt of proof of satisfaction of all outstanding obligations incurred under this contract.

(b) The agency may waive the insolvency protection account requirement in writing when evidence is on file with the agency of adequate insolvency insurance and reinsurance that will protect enrollees if the entity becomes unable to meet its obligations.

(19) An entity that contracts with the agency on a prepaid or fixed-sum basis for the provision of Medicaid services shall reimburse any hospital or physician that is outside the entity's

authorized geographic service area as specified in its contract with the agency, and that provides services authorized by the entity to its members, at a rate negotiated with the hospital or physician for the provision of services or according to the lesser of the following:

(a) The usual and customary charges made to the general public by the hospital or physician; or

(b) The Florida Medicaid reimbursement rate established for the hospital or physician.

(20) When a merger or acquisition of a Medicaid prepaid contractor has been approved by the Office of Insurance Regulation pursuant to s. 628.4615, the agency shall approve the assignment or transfer of the appropriate Medicaid prepaid contract upon request of the surviving entity of the merger or acquisition if the contractor and the other entity have been in good standing with the agency for the most recent 12-month period, unless the agency determines that the assignment or transfer would be detrimental to the Medicaid recipients or the Medicaid program. To be in good standing, an entity must not have failed accreditation or committed any material violation of the requirements of s. 641.52 and must meet the Medicaid contract requirements. For purposes of this section, a merger or acquisition means a change in controlling interest of an entity, including an asset or stock purchase.

(21) Any entity contracting with the agency pursuant to this section to provide health care services to Medicaid recipients is prohibited from engaging in any of the following practices or activities:

(a) Practices that are discriminatory, including, but not limited to, attempts to discourage participation on the basis of actual or perceived health status.

(b) Activities that could mislead or confuse recipients, or misrepresent the organization, its marketing representatives, or the agency. Violations of this paragraph include, but are not limited to:

1. False or misleading claims that marketing representatives are employees or representatives of the state or county, or of anyone other than the entity or the organization by whom they are reimbursed.

2. False or misleading claims that the entity is recommended or endorsed by any state or county agency, or by any other organization which has not certified its endorsement in writing to the entity.

3. False or misleading claims that the state or county recommends that a Medicaid recipient enroll with an entity.

4. Claims that a Medicaid recipient will lose benefits under the Medicaid program, or any other health or welfare benefits to which the recipient is legally entitled, if the recipient does not enroll with the entity.

(c) Granting or offering of any monetary or other valuable consideration for enrollment, except as authorized by subsection (24).

(d) Door-to-door solicitation of recipients who have not contacted the entity or who have not invited the entity to make a presentation.

(e) Solicitation of Medicaid recipients by marketing representatives stationed in state offices unless approved and supervised by the agency or its agent and approved by the affected state agency when solicitation occurs in an office of the state agency. The agency shall ensure that marketing representatives stationed in state offices shall market their managed care plans to Medicaid recipients only in designated areas and in such a way as to not interfere with the recipients' activities in the state office.

(f) Enrollment of Medicaid recipients.

(22) The agency may impose a fine for a violation of this section or the contract with the agency by a person or entity that is under contract with the agency. With respect to any nonwillful violation, such fine shall not exceed $2,500 per violation. In no event shall such fine exceed an aggregate amount of $10,000 for all nonwillful violations arising out of the same action. With respect to any knowing and willful violation of this section or the contract with the agency, the agency may impose a fine upon the entity in an amount not to exceed $20,000 for each such violation. In no event shall such fine exceed an aggregate amount of $100,000 for all knowing and willful violations arising out of the same action.

(23) A health maintenance organization or a person or entity exempt from chapter 641 that is under contract with the agency for the provision of health care services to Medicaid recipients may not use or distribute marketing materials used to solicit Medicaid recipients, unless such materials have been approved by the agency. The provisions of this subsection do not

apply to general advertising and marketing materials used by a health maintenance organization to solicit both non-Medicaid subscribers and Medicaid recipients.

(24) Upon approval by the agency, health maintenance organizations and persons or entities exempt from chapter 641 that are under contract with the agency for the provision of health care services to Medicaid recipients may be permitted within the capitation rate to provide additional health benefits that the agency has found are of high quality, are practicably available, provide reasonable value to the recipient, and are provided at no additional cost to the state.

(25) The agency shall utilize the statewide health maintenance organization complaint hotline for the purpose of investigating and resolving Medicaid and prepaid health plan complaints, maintaining a record of complaints and confirmed problems, and receiving disenrollment requests made by recipients.

(26) The agency shall require the publication of the health maintenance organization's and the prepaid health plan's consumer services telephone numbers and the "800" telephone number of the statewide health maintenance organization complaint hotline on each Medicaid identification card issued by a health maintenance organization or prepaid health plan contracting with the agency to serve Medicaid recipients and on each subscriber handbook issued to a Medicaid recipient.

(27) The agency shall establish a health care quality improvement system for those entities contracting with the agency pursuant to this section, incorporating all the standards

and guidelines developed by the Medicaid Bureau of the Health Care Financing Administration as a part of the quality assurance reform initiative. The system shall include, but need not be limited to, the following:

(a) Guidelines for internal quality assurance programs, including standards for:

1. Written quality assurance program descriptions.

2. Responsibilities of the governing body for monitoring, evaluating, and making improvements to care.

3. An active quality assurance committee.

4. Quality assurance program supervision.

5. Requiring the program to have adequate resources to effectively carry out its specified activities.

6. Provider participation in the quality assurance program.

7. Delegation of quality assurance program activities.

8. Credentialing and recredentialing.

9. Enrollee rights and responsibilities.

10. Availability and accessibility to services and care.

11. Ambulatory care facilities.

12. Accessibility and availability of medical records, as well as proper recordkeeping and process for record review.

13. Utilization review.

14. A continuity of care system.

15. Quality assurance program documentation.

16. Coordination of quality assurance activity with other management activity.

17. Delivering care to pregnant women and infants; to elderly and disabled recipients, especially those who are at risk of institutional placement; to persons with developmental disabilities; and to adults who have chronic, high-cost medical conditions.

(b) Guidelines which require the entities to conduct quality-of-care studies which:

1. Target specific conditions and specific health service delivery issues for focused monitoring and evaluation.

2. Use clinical care standards or practice guidelines to objectively evaluate the care the entity delivers or fails to deliver for the targeted clinical conditions and health services delivery issues.

3. Use quality indicators derived from the clinical care standards or practice guidelines to screen and monitor care and services delivered.

(c) Guidelines for external quality review of each contractor which require: focused studies of patterns of care; individual care review in specific situations; and followup activities on previous pattern-of-care study findings and individual-care-review findings. In designing the external quality review function and determining how it is to operate as part of the state's overall quality improvement system, the agency shall construct its external quality review organization and entity contracts to address each of the following:

1. Delineating the role of the external quality review organization.

2. Length of the external quality review organization contract with the state.

3. Participation of the contracting entities in designing external quality review organization review activities.

4. Potential variation in the type of clinical conditions and health services delivery issues to be studied at each plan.

5. Determining the number of focused pattern-of-care studies to be conducted for each plan.

6. Methods for implementing focused studies.

7. Individual care review.

8. Followup activities.

(28) In order to ensure that children receive health care services for which an entity has already been compensated, an entity contracting with the agency pursuant to this section shall achieve an annual Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) Service screening rate of at least 60 percent for those recipients continuously enrolled for at least 8 months. The agency shall develop a method by which the EPSDT screening rate shall be calculated. For any entity which does not achieve the annual 60 percent rate, the entity must submit a corrective action plan for the agency's approval. If the entity does not meet the standard established in the corrective action plan during the specified timeframe, the agency is authorized to impose appropriate contract sanctions. At least annually, the agency shall publicly release the EPSDT Services screening rates of each entity it has contracted with on a prepaid basis to serve Medicaid recipients.

(29) The agency shall perform enrollments and disenrollments for Medicaid recipients who are eligible for MediPass or managed care plans. Notwithstanding the prohibition contained in paragraph (21)(f), managed care plans may perform preenrollments of Medicaid recipients under the supervision of the agency or its agents. For the purposes of this section, "preenrollment" means the provision of marketing and educational materials to a Medicaid recipient and assistance in completing the application forms, but shall not include actual enrollment into a managed care plan. An application for enrollment shall not be deemed complete until the agency or its agent verifies that the recipient made an informed, voluntary choice. The agency, in cooperation with the Department of Children and Family Services, may test new marketing initiatives to inform Medicaid recipients about their managed care options at selected sites. The agency shall report to the Legislature on the effectiveness of such initiatives. The agency may contract with a third party to perform managed care plan and MediPass enrollment and disenrollment services for Medicaid recipients and is authorized to adopt rules to implement such services. The agency may adjust the capitation rate only to cover the costs of a third-party enrollment and disenrollment contract, and for agency supervision and management of the managed care plan enrollment and disenrollment contract.

(30) Any lists of providers made available to Medicaid recipients, MediPass enrollees, or managed care plan enrollees shall be arranged alphabetically showing the provider's name and specialty and, separately, by specialty in alphabetical order.

(31) The agency shall establish an enhanced managed care quality assurance oversight function, to include at least the following components:

(a) At least quarterly analysis and followup, including sanctions as appropriate, of managed care participant utilization of services.

(b) At least quarterly analysis and followup, including sanctions as appropriate, of quality findings of the Medicaid peer review organization and other external quality assurance programs.

(c) At least quarterly analysis and followup, including sanctions as appropriate, of the fiscal viability of managed care plans.

(d) At least quarterly analysis and followup, including sanctions as appropriate, of managed care participant satisfaction and disenrollment surveys.

(e) The agency shall conduct regular and ongoing Medicaid recipient satisfaction surveys.

The analyses and followup activities conducted by the agency under its enhanced managed care quality assurance oversight function shall not duplicate the activities of accreditation reviewers for entities regulated under part III of chapter 641, but may include a review of the finding of such reviewers.

(32) Each managed care plan that is under contract with the agency to provide health care services to Medicaid recipients shall annually conduct a background check with the Florida Department of Law Enforcement of all persons with

ownership interest of 5 percent or more or executive management responsibility for the managed care plan and shall submit to the agency information concerning any such person who has been found guilty of, regardless of adjudication, or has entered a plea of nolo contendere or guilty to, any of the offenses listed in s. 435.03.

(33) The agency shall, by rule, develop a process whereby a Medicaid managed care plan enrollee who wishes to enter hospice care may be disenrolled from the managed care plan within 24 hours after contacting the agency regarding such request. The agency rule shall include a methodology for the agency to recoup managed care plan payments on a pro rata basis if payment has been made for the enrollment month when disenrollment occurs.

(34) The agency and entities that contract with the agency to provide health care services to Medicaid recipients under this section or ss. 409.91211 and 409.9122 must comply with the provisions of s. 641.513 in providing emergency services and care to Medicaid recipients and MediPass recipients. Where feasible, safe, and cost-effective, the agency shall encourage hospitals, emergency medical services providers, and other public and private health care providers to work together in their local communities to enter into agreements or arrangements to ensure access to alternatives to emergency services and care for those Medicaid recipients who need nonemergent care. The agency shall coordinate with hospitals, emergency medical services providers, private health plans, capitated managed care networks as established in s. 409.91211, and other public and

private health care providers to implement the provisions of ss. 395.1041(7), 409.91255(3)(g), 627.6405, and 641.31097 to develop and implement emergency department diversion programs for Medicaid recipients.

(35) All entities providing health care services to Medicaid recipients shall make available, and encourage all pregnant women and mothers with infants to receive, and provide documentation in the medical records to reflect, the following:

(a) Healthy Start prenatal or infant screening.

(b) Healthy Start care coordination, when screening or other factors indicate need.

(c) Healthy Start enhanced services in accordance with the prenatal or infant screening results.

(d) Immunizations in accordance with recommendations of the Advisory Committee on Immunization Practices of the United States Public Health Service and the American Academy of Pediatrics, as appropriate.

(e) Counseling and services for family planning to all women and their partners.

(f) A scheduled postpartum visit for the purpose of voluntary family planning, to include discussion of all methods of contraception, as appropriate.

(g) Referral to the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC).

(36) Any entity that provides Medicaid prepaid health plan services shall ensure the appropriate coordination of health care services with an assisted living facility in cases where a Medicaid recipient is both a member of the entity's prepaid

health plan and a resident of the assisted living facility. If the entity is at risk for Medicaid targeted case management and behavioral health services, the entity shall inform the assisted living facility of the procedures to follow should an emergent condition arise.

(37) The agency may seek and implement federal waivers necessary to provide for cost-effective purchasing of home health services, private duty nursing services, transportation, independent laboratory services, and durable medical equipment and supplies through competitive bidding pursuant to s. 287.057. The agency may request appropriate waivers from the federal Health Care Financing Administration in order to competitively bid such services. The agency may exclude providers not selected through the bidding process from the Medicaid provider network.

(38) The agency shall enter into agreements with not-for-profit organizations based in this state for the purpose of providing vision screening.

(39)(a) The agency shall implement a Medicaid prescribed-drug spending-control program that includes the following components:

1. A Medicaid preferred drug list, which shall be a listing of cost-effective therapeutic options recommended by the Adult Medicaid Pharmaceutical ~~Pharmacy~~ and Therapeutics Committee and the Pediatric Medicaid Pharmaceutical and Therapeutics Committee established pursuant to s. 409.91195 and adopted by the agency for each therapeutic class on the preferred drug list. At the discretion of the committees ~~committee~~, and when feasible, the preferred drug list should

include at least two products in a therapeutic class. The agency may post the preferred drug list and updates to the preferred drug list on an Internet website without following the rulemaking procedures of chapter 120. Antiretroviral agents are excluded from the preferred drug list. The agency shall also limit the amount of a prescribed drug dispensed to no more than a 34-day supply unless the drug products' smallest marketed package is greater than a 34-day supply, or the drug is determined by the agency to be a maintenance drug in which case a 100-day maximum supply may be authorized. The agency is authorized to seek any federal waivers necessary to implement these cost-control programs and to continue participation in the federal Medicaid rebate program, or alternatively to negotiate state-only manufacturer rebates. The agency may adopt rules to implement this subparagraph. The agency shall continue to provide unlimited contraceptive drugs and items. The agency must establish procedures to ensure that:

a. There will be a response to a request for prior consultation by telephone or other telecommunication device within 24 hours after receipt of a request for prior consultation; and

b. A 72-hour supply of the drug prescribed will be provided in an emergency or when the agency does not provide a response within 24 hours as required by sub-subparagraph a.

2. Reimbursement to pharmacies for Medicaid prescribed drugs shall be set at the lesser of: the average wholesale price (AWP) minus 15.4 percent, the wholesaler acquisition cost (WAC) plus 5.75 percent, the federal upper limit (FUL), the state

maximum allowable cost (SMAC), or the usual and customary (UAC) charge billed by the provider.

3. The agency shall develop and implement a process for managing the drug therapies of Medicaid recipients who are using significant numbers of prescribed drugs each month. The management process may include, but is not limited to, comprehensive, physician-directed medical-record reviews, claims analyses, and case evaluations to determine the medical necessity and appropriateness of a patient's treatment plan and drug therapies. The agency may contract with a private organization to provide drug-program-management services. The Medicaid drug benefit management program shall include initiatives to manage drug therapies for HIV/AIDS patients, patients using 20 or more unique prescriptions in a 180-day period, and the top 1,000 patients in annual spending. The agency shall enroll any Medicaid recipient in the drug benefit management program if he or she meets the specifications of this provision and is not enrolled in a Medicaid health maintenance organization.

4. The agency may limit the size of its pharmacy network based on need, competitive bidding, price negotiations, credentialing, or similar criteria. The agency shall give special consideration to rural areas in determining the size and location of pharmacies included in the Medicaid pharmacy network. A pharmacy credentialing process may include criteria such as a pharmacy's full-service status, location, size, patient educational programs, patient consultation, disease management services, and other characteristics. The agency may

impose a moratorium on Medicaid pharmacy enrollment when it is determined that it has a sufficient number of Medicaid-participating providers. The agency must allow dispensing practitioners to participate as a part of the Medicaid pharmacy network regardless of the practitioner's proximity to any other entity that is dispensing prescription drugs under the Medicaid program. A dispensing practitioner must meet all credentialing requirements applicable to his or her practice, as determined by the agency.

5. The agency shall develop and implement a program that requires Medicaid practitioners who prescribe drugs to use a counterfeit-proof prescription pad for Medicaid prescriptions. The agency shall require the use of standardized counterfeit-proof prescription pads by Medicaid-participating prescribers or prescribers who write prescriptions for Medicaid recipients. The agency may implement the program in targeted geographic areas or statewide.

6. The agency may enter into arrangements that require manufacturers of generic drugs prescribed to Medicaid recipients to provide rebates of at least 15.1 percent of the average manufacturer price for the manufacturer's generic products. These arrangements shall require that if a generic-drug manufacturer pays federal rebates for Medicaid-reimbursed drugs at a level below 15.1 percent, the manufacturer must provide a supplemental rebate to the state in an amount necessary to achieve a 15.1-percent rebate level.

7. The agency may establish a preferred drug list as described in this subsection, and, pursuant to the establishment

of such preferred drug list, it is authorized to negotiate supplemental rebates from manufacturers that are in addition to those required by Title XIX of the Social Security Act and at no less than 14 percent of the average manufacturer price as defined in 42 U.S.C. s. 1936 on the last day of a quarter unless the federal or supplemental rebate, or both, equals or exceeds 29 percent. There is no upper limit on the supplemental rebates the agency may negotiate. The agency may determine that specific products, brand-name or generic, are competitive at lower rebate percentages. Agreement to pay the minimum supplemental rebate percentage will guarantee a manufacturer that the Adult Medicaid Pharmaceutical and Therapeutics Committee or the Pediatric Medicaid Pharmaceutical and Therapeutics Committee will consider a product for inclusion on the preferred drug list. However, a pharmaceutical manufacturer is not guaranteed placement on the preferred drug list by simply paying the minimum supplemental rebate. Agency decisions will be made on the clinical efficacy of a drug and recommendations of the Adult Medicaid Pharmaceutical and Therapeutics Committee and the Pediatric Medicaid Pharmaceutical and Therapeutics Committee, as well as the price of competing products minus federal and state rebates. The agency is authorized to contract with an outside agency or contractor to conduct negotiations for supplemental rebates. For the purposes of this section, the term "supplemental rebates" means cash rebates. Effective July 1, 2004, value-added programs as a substitution for supplemental rebates are prohibited. The agency is authorized to seek any federal waivers to implement this initiative.

8. The Agency for Health Care Administration shall expand home delivery of pharmacy products. To assist Medicaid patients in securing their prescriptions and reduce program costs, the agency shall expand its current mail-order-pharmacy diabetes-supply program to include all generic and brand-name drugs used by Medicaid patients with diabetes. Medicaid recipients in the current program may obtain nondiabetes drugs on a voluntary basis. This initiative is limited to the geographic area covered by the current contract. The agency may seek and implement any federal waivers necessary to implement this subparagraph.

9. The agency shall limit to one dose per month any drug prescribed to treat erectile dysfunction.

10.a. The agency may implement a Medicaid behavioral drug management system. The agency may contract with a vendor that has experience in operating behavioral drug management systems to implement this program. The agency is authorized to seek federal waivers to implement this program.

b. The agency, in conjunction with the Department of Children and Family Services, may implement the Medicaid behavioral drug management system that is designed to improve the quality of care and behavioral health prescribing practices based on best practice guidelines, improve patient adherence to medication plans, reduce clinical risk, and lower prescribed drug costs and the rate of inappropriate spending on Medicaid behavioral drugs. The program may include the following elements:

(I) Provide for the development and adoption of best practice guidelines for behavioral health-related drugs such as

antipsychotics, antidepressants, and medications for treating bipolar disorders and other behavioral conditions; translate them into practice; review behavioral health prescribers and compare their prescribing patterns to a number of indicators that are based on national standards; and determine deviations from best practice guidelines.

(II) Implement processes for providing feedback to and educating prescribers using best practice educational materials and peer-to-peer consultation.

(III) Assess Medicaid beneficiaries who are outliers in their use of behavioral health drugs with regard to the numbers and types of drugs taken, drug dosages, combination drug therapies, and other indicators of improper use of behavioral health drugs.

(IV) Alert prescribers to patients who fail to refill prescriptions in a timely fashion, are prescribed multiple same-class behavioral health drugs, and may have other potential medication problems.

(V) Track spending trends for behavioral health drugs and deviation from best practice guidelines.

(VI) Use educational and technological approaches to promote best practices, educate consumers, and train prescribers in the use of practice guidelines.

(VII) Disseminate electronic and published materials.

(VIII) Hold statewide and regional conferences.

(IX) Implement a disease management program with a model quality-based medication component for severely mentally ill

individuals and emotionally disturbed children who are high users of care.

11.a. The agency shall implement a Medicaid prescription drug management system. The agency may contract with a vendor that has experience in operating prescription drug management systems in order to implement this system. Any management system that is implemented in accordance with this subparagraph must rely on cooperation between physicians and pharmacists to determine appropriate practice patterns and clinical guidelines to improve the prescribing, dispensing, and use of drugs in the Medicaid program. The agency may seek federal waivers to implement this program.

b. The drug management system must be designed to improve the quality of care and prescribing practices based on best practice guidelines, improve patient adherence to medication plans, reduce clinical risk, and lower prescribed drug costs and the rate of inappropriate spending on Medicaid prescription drugs. The program must:

(I) Provide for the development and adoption of best practice guidelines for the prescribing and use of drugs in the Medicaid program, including translating best practice guidelines into practice; reviewing prescriber patterns and comparing them to indicators that are based on national standards and practice patterns of clinical peers in their community, statewide, and nationally; and determine deviations from best practice guidelines.

(II) Implement processes for providing feedback to and educating prescribers using best practice educational materials and peer-to-peer consultation.

(III) Assess Medicaid recipients who are outliers in their use of a single or multiple prescription drugs with regard to the numbers and types of drugs taken, drug dosages, combination drug therapies, and other indicators of improper use of prescription drugs.

(IV) Alert prescribers to patients who fail to refill prescriptions in a timely fashion, are prescribed multiple drugs that may be redundant or contraindicated, or may have other potential medication problems.

(V) Track spending trends for prescription drugs and deviation from best practice guidelines.

(VI) Use educational and technological approaches to promote best practices, educate consumers, and train prescribers in the use of practice guidelines.

(VII) Disseminate electronic and published materials.

(VIII) Hold statewide and regional conferences.

(IX) Implement disease management programs in cooperation with physicians and pharmacists, along with a model quality-based medication component for individuals having chronic medical conditions.

12. The agency is authorized to contract for drug rebate administration, including, but not limited to, calculating rebate amounts, invoicing manufacturers, negotiating disputes with manufacturers, and maintaining a database of rebate collections.

13. The agency may specify the preferred daily dosing form or strength for the purpose of promoting best practices with regard to the prescribing of certain drugs as specified in the General Appropriations Act and ensuring cost-effective prescribing practices.

14. The agency may require prior authorization for Medicaid-covered prescribed drugs. The agency may, but is not required to, prior-authorize the use of a product:

a. For an indication not approved in labeling;

b. To comply with certain clinical guidelines; or

c. If the product has the potential for overuse, misuse, or abuse.

The agency may require the prescribing professional to provide information about the rationale and supporting medical evidence for the use of a drug. The agency may post prior authorization criteria and protocol and updates to the list of drugs that are subject to prior authorization on an Internet website without amending its rule or engaging in additional rulemaking.

15. The agency, in conjunction with the committees ~~Pharmaceutical and Therapeutics Committee~~, may require age-related prior authorizations for certain prescribed drugs. The agency may preauthorize the use of a drug for a recipient who may not meet the age requirement or may exceed the length of therapy for use of this product as recommended by the manufacturer and approved by the Food and Drug Administration. Prior authorization may require the prescribing professional to

provide information about the rationale and supporting medical evidence for the use of a drug.

16. The agency shall implement a step-therapy prior authorization approval process for medications excluded from the preferred drug list. Medications listed on the preferred drug list must be used within the previous 12 months prior to the alternative medications that are not listed. The step-therapy prior authorization may require the prescriber to use the medications of a similar drug class or for a similar medical indication unless contraindicated in the Food and Drug Administration labeling. The trial period between the specified steps may vary according to the medical indication. The step-therapy approval process shall be developed in accordance with the committees ~~committee~~ as stated in s. 409.91195(7) and (8). A drug product may be approved without meeting the step-therapy prior authorization criteria if the prescribing physician provides the agency with additional written medical or clinical documentation that the product is medically necessary because:

a. There is not a drug on the preferred drug list to treat the disease or medical condition which is an acceptable clinical alternative;

b. The alternatives have been ineffective in the treatment of the beneficiary's disease; or

c. Based on historic evidence and known characteristics of the patient and the drug, the drug is likely to be ineffective, or the number of doses have been ineffective.

The agency shall work with the physician to determine the best alternative for the patient. The agency may adopt rules waiving the requirements for written clinical documentation for specific drugs in limited clinical situations.

17. The agency shall implement a return and reuse program for drugs dispensed by pharmacies to institutional recipients, which includes payment of a $5 restocking fee for the implementation and operation of the program. The return and reuse program shall be implemented electronically and in a manner that promotes efficiency. The program must permit a pharmacy to exclude drugs from the program if it is not practical or cost-effective for the drug to be included and must provide for the return to inventory of drugs that cannot be credited or returned in a cost-effective manner. The agency shall determine if the program has reduced the amount of Medicaid prescription drugs which are destroyed on an annual basis and if there are additional ways to ensure more prescription drugs are not destroyed which could safely be reused. The agency's conclusion and recommendations shall be reported to the Legislature by December 1, 2005.

(40) Notwithstanding the provisions of chapter 287, the agency may, at its discretion, renew a contract or contracts for fiscal intermediary services one or more times for such periods as the agency may decide; however, all such renewals may not combine to exceed a total period longer than the term of the original contract.

(41) The agency shall provide for the development of a demonstration project by establishment in Miami-Dade County of a

long-term-care facility licensed pursuant to chapter 395 to improve access to health care for a predominantly minority, medically underserved, and medically complex population and to evaluate alternatives to nursing home care and general acute care for such population. Such project is to be located in a health care condominium and colocated with licensed facilities providing a continuum of care. The establishment of this project is not subject to the provisions of s. 408.036 or s. 408.039.

(42) The agency shall develop and implement a utilization management program for Medicaid-eligible recipients for the management of occupational, physical, respiratory, and speech therapies. The agency shall establish a utilization program that may require prior authorization in order to ensure medically necessary and cost-effective treatments. The program shall be operated in accordance with a federally approved waiver program or state plan amendment. The agency may seek a federal waiver or state plan amendment to implement this program. The agency may also competitively procure these services from an outside vendor on a regional or statewide basis.

(43) The agency may contract on a prepaid or fixed-sum basis with appropriately licensed prepaid dental health plans to provide dental services.

(44) The Agency for Health Care Administration shall ensure that any Medicaid managed care plan as defined in s. 409.9122(2)(f), whether paid on a capitated basis or a shared savings basis, is cost-effective. For purposes of this subsection, the term "cost-effective" means that a network's per-member, per-month costs to the state, including, but not

limited to, fee-for-service costs, administrative costs, and case-management fees, if any, must be no greater than the state's costs associated with contracts for Medicaid services established under subsection (3), which may be adjusted for health status. The agency shall conduct actuarially sound adjustments for health status in order to ensure such cost-effectiveness and shall publish the results on its Internet website and submit the results annually to the Governor, the President of the Senate, and the Speaker of the House of Representatives no later than December 31 of each year. Contracts established pursuant to this subsection which are not cost-effective may not be renewed.

(45) Subject to the availability of funds, the agency shall mandate a recipient's participation in a provider lock-in program, when appropriate, if a recipient is found by the agency to have used Medicaid goods or services at a frequency or amount not medically necessary, limiting the receipt of goods or services to medically necessary providers after the 21-day appeal process has ended, for a period of not less than 1 year. The lock-in programs shall include, but are not limited to, pharmacies, medical doctors, and infusion clinics. The limitation does not apply to emergency services and care provided to the recipient in a hospital emergency department. The agency shall seek any federal waivers necessary to implement this subsection. The agency shall adopt any rules necessary to comply with or administer this subsection.

(46) The agency shall seek a federal waiver for permission to terminate the eligibility of a Medicaid recipient who has

been found to have committed fraud, through judicial or administrative determination, two times in a period of 5 years.

(47) The agency shall conduct a study of available electronic systems for the purpose of verifying the identity and eligibility of a Medicaid recipient. The agency shall recommend to the Legislature a plan to implement an electronic verification system for Medicaid recipients by January 31, 2005.

(48) A provider is not entitled to enrollment in the Medicaid provider network. The agency may implement a Medicaid fee-for-service provider network controls, including, but not limited to, competitive procurement and provider credentialing. If a credentialing process is used, the agency may limit its provider network based upon the following considerations: beneficiary access to care, provider availability, provider quality standards and quality assurance processes, cultural competency, demographic characteristics of beneficiaries, practice standards, service wait times, provider turnover, provider licensure and accreditation history, program integrity history, peer review, Medicaid policy and billing compliance records, clinical and medical record audit findings, and such other areas that are considered necessary by the agency to ensure the integrity of the program.

(49) The agency shall contract with established minority physician networks that provide services to historically underserved minority patients. The networks must provide cost-effective Medicaid services, comply with the requirements to be a MediPass provider, and provide their primary care physicians with access to data and other management tools necessary to

assist them in ensuring the appropriate use of services, including inpatient hospital services and pharmaceuticals.

(a) The agency shall provide for the development and expansion of minority physician networks in each service area to provide services to Medicaid recipients who are eligible to participate under federal law and rules.

(b) The agency shall reimburse each minority physician network as a fee-for-service provider, including the case management fee for primary care, if any, or as a capitated rate provider for Medicaid services. Any savings shall be shared with the minority physician networks pursuant to the contract.

(c) For purposes of this subsection, the term "cost-effective" means that a network's per-member, per-month costs to the state, including, but not limited to, fee-for-service costs, administrative costs, and case-management fees, if any, must be no greater than the state's costs associated with contracts for Medicaid services established under subsection (3), which shall be actuarially adjusted for case mix, model, and service area. The agency shall conduct actuarially sound audits adjusted for case mix and model in order to ensure such cost-effectiveness and shall publish the audit results on its Internet website and submit the audit results annually to the Governor, the President of the Senate, and the Speaker of the House of Representatives no later than December 31. Contracts established pursuant to this subsection which are not cost-effective may not be renewed.

(d) The agency may apply for any federal waivers needed to implement this subsection.

(50) To the extent permitted by federal law and as allowed under s. 409.906, the agency shall provide reimbursement for emergency mental health care services for Medicaid recipients in crisis stabilization facilities licensed under s. 394.875 as long as those services are less expensive than the same services provided in a hospital setting.

(51) The agency shall work with the Agency for Persons with Disabilities to develop a home and community-based waiver to serve children and adults who are diagnosed with familial dysautonomia or Riley-Day syndrome caused by a mutation of the IKBKAP gene on chromosome 9. The agency shall seek federal waiver approval and implement the approved waiver subject to the availability of funds and any limitations provided in the General Appropriations Act. The agency may adopt rules to implement this waiver program.

(52) The agency shall implement a program of all-inclusive care for children. The program of all-inclusive care for children shall be established to provide in-home hospice-like support services to children diagnosed with a life-threatening illness and enrolled in the Children's Medical Services network to reduce hospitalizations as appropriate. The agency, in consultation with the Department of Health, may implement the program of all-inclusive care for children after obtaining approval from the Centers for Medicare and Medicaid Services.

Section 4. This act shall take effect July 1, 2007.