Regular Session, 2013

HOUSE BILL NO. 393

BY REPRESENTATIVES ANDERS AND STUART BISHOP

Prefiled pursuant to Article III, Section 2(A)(4)(b)(i) of the Constitution of Louisiana.

MEDICAID: Provides relative to prescription drug benefits of managed care organizations participating in the La. Medicaid coordinated care network program

AN ACT

To enact Part XI of Chapter 3 of Title 46 of the Louisiana Revised Statutes of 1950, to be comprised of R.S. 46:460.31 through 460.34, relative to the medical assistance program; to provide relative to managed care organizations which provide health care services to medical assistance program enrollees; to provide relative to prescription drugs; to create and provide for composition and duties of the Medicaid Managed Care Pharmaceutical and Therapeutics Committee; to provide for a minimum drug formulary; to provide for approval of a drug pharmacopoeia by certain legislative committees; to provide for a standard form for the prior authorization of prescription drugs; to provide for certain procedures relative to step therapy and fail first protocols; to provide for promulgation of rules; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. Part XI of Chapter 3 of Title 46 of the Louisiana Revised Statutes of 1950, comprised of R.S. 46:460.31 through 460.34, is hereby enacted to read as follows:

PART XI. MEDICAID MANAGED CARE PRESCRIPTION DRUG BENEFITS

§460.31. Definitions

As used in this Part, the following terms shall have the meaning ascribed to them in this Section unless the context clearly indicates otherwise:

(1) "Department" means the Department of Health and Hospitals.

(2) "Committee" means the Medicaid Managed Care Pharmaceutical and Therapeutics Committee created by this Part.

(3) "Managed care organization" shall have the same meaning as provided for that term in 42 CFR 438.2 and shall also mean any entity providing primary care case management services to Medicaid recipients pursuant to a contract with the department.

(4) "Medicaid" and "medical assistance program" mean the medical assistance program provided for in Title XIX of the Social Security Act.

(5) "Primary care case management" means a system in which an entity contracts with the state to furnish case management services, which include but are not limited to the location, coordination, and monitoring of primary health care service to Medicaid beneficiaries.

(6) "Secretary" means the secretary of the Department of Health and Hospitals.

§460.32. Formulary; Medicaid Managed Care Pharmaceutical and Therapeutics Committee

A. Beginning January 1, 2014, all managed care organizations shall provide as a pharmacy benefit the minimum drug pharmacopoeia in conjunction with a prior approval process which is developed and maintained by the Medicaid Managed Care Pharmaceutical and Therapeutics Committee pursuant to the provisions of this Section. Nothing in this Part shall prohibit a managed care organization from providing drug benefits which are not listed on the minimum drug pharmacopoeia.

B.(1) The Medicaid Managed Care Pharmaceutical and Therapeutics Committee, hereinafter referred to as the "committee", is hereby created within the Department of Health and Hospitals. The committee shall be composed of members as provided in this Subsection who are appointed by the governor and submitted to the Senate for confirmation. The committee shall be representative of the state's geographic and demographic composition, including women and minorities.

(2) The committee shall be comprised of sixteen members as follows:

(a) Two physicians nominated by each managed care organization with expertise in the area of pharmacology.

(b) One practicing physician who is participating in the Medicaid program as a family practitioner recommended from a list of three names submitted by the Louisiana Academy of Family Physicians.

(c) One practicing physician who is participating in the Medicaid program as an internal medicine specialist recommended from a list of three names submitted by the Louisiana State Medical Society.

(d) One practicing physician who is participating in the Medicaid program as a pediatrician recommended from a list of three names submitted by the Louisiana Chapter of the American Academy of Pediatrics.

(e) One practicing physician who is participating in the Medicaid program as an obstetrician and gynecologist recommended from a list of three names submitted by the Louisiana Chapter of the American College of Obstetricians and Gynecologists.

(f) One practicing physician who is participating in the Medicaid program as a psychiatrist recommended from a list of three names submitted by the Louisiana Psychiatric Medical Association.

(g) Two practicing physicians who are participating in the Medicaid program recommended from a list of six names submitted by the Louisiana Medical Association.

(h) Two practicing pharmacists who are participating in the Medicaid pharmacy program recommended from a list of six names submitted by the Louisiana Pharmacy Association. One pharmacist shall be an independent pharmacist, and one pharmacist shall be a pharmacist representing a chain pharmacy.

(i) The secretary of the Department of Health and Hospitals or his designee.

(j) The director of the Medicaid program in the Department of Health and Hospitals or his designee.

(k) The president of the Senate or his designee.

(l) The speaker of the House of Representatives or his designee.

(m) A Medicaid recipient who is enrolled with a prepaid entity.

(3) Other physicians who participate in the Medicaid program in various subspecialties may act as consultants to the committee as needed.

(4) Members of the committee shall be governed by either the Code of Governmental Ethics, R.S. 42:1101 et seq., or the code of ethics of their respective profession.

(5) The committee shall meet only in public and shall permit public comment prior to voting on any changes in the preferred drug list. Minutes of each meeting shall be made available to the public within five days after the minutes are approved by the committee. All documents that are distributed to the committee and not subject to state or federal confidentiality laws shall be made available to the public within five days after the committee meets.

(6) The pharmacopoeia developed by the committee shall comply with all applicable state and federal laws, rules, and regulations. The committee may recommend additions and deletions to the pharmacopoeia, and the pharmacopoeia may change in accordance with those recommendations. The committee shall also advise the secretary on policy recommendations related to the prudent administration of the Medicaid managed care drug program. The secretary shall ensure that all actions of the committee comply with applicable state and federal laws, rules, and regulations prior to implementation or modification of the pharmacopoeia. The clinical decisions regarding the preferred drug list shall be made transparent through a written report that is publicly available. If a decision of the committee is contrary to clinical evidence found in labeling, drug compendia, or peer reviewed literature, such decisions shall be justified in writing.

(7) The committee may establish a drug list to be utilized by all managed care organizations that utilize a prior approval process or any other process or combination of processes that prove to be cost-effective in the medical assistance

program. At minimum, any prior approval process shall meet all of the following criteria:

(a) Provide for a response by telephone or other form of telecommunication device within a maximum of twenty-four hours of a request for prior authorization.

(b) Provide for the dispensing of a minimum of a seventy-two hour supply of a covered outpatient prescription drug in an emergency situation as provided by federal rule or regulation.

(c) Comply with all applicable federal laws, rules, and regulations.

(d) Involve medical personnel, including but not limited to pharmacists, pharmacy technicians, nurses, and physicians.

(e) Assure that a qualified, licensed physician is available for consultation during the prior approval process.

(8) Any drug approved by the United States Food and Drug Administration shall be added to the formulary as soon as it becomes commercially available. The committee shall conduct an evidence-based analysis of the drug to determine if the drug shall be maintained on the formulary. The analysis shall include but not be limited to the medical evidence of the clinical effectiveness of the drug as well as evidence of the cost-effectiveness of the drug in treating illness and disease. The determination by the committee on any new drug approval by the United States Food and Drug Administration shall be made no later than ninety days after the drug becomes commercially available. Prior to a drug being prior authorized, it must have been reviewed by the committee.

(9) The department shall not implement the pharmacopoeia authorized by this Section until the initial pharmacopoeia is submitted to and approved by the House and Senate committees on health and welfare. The committees may only approve or reject the pharmacopoeia and may not add specific drugs to or delete specific drugs from the pharmacopoeia.

C. The department is hereby authorized to promulgate all such rules and regulations, in accordance with the Administrative Procedure Act, as are necessary to implement the provisions of this Section.

§460.33. Prior authorization form; requirements

A. Beginning January 1, 2014, all managed care organizations shall utilize a single-page prior authorization form duly promulgated by the department in accordance with the Administrative Procedure Act.

B. The department shall promulgate rules and regulations prior to January 1, 2014, that establish the form which shall be utilized by all managed care organizations. The department may consult with the managed care organizations as necessary in development of the prior authorization form.

§460.34. Step therapy; fail first protocols; requirements

A. Each managed care organization which utilizes step therapy or fail first protocols shall comply with the provisions of this Section.

B. When medications for the treatment of any medical condition are restricted for use by a managed care organization by a step therapy or fail first protocol, the prescribing physician shall be provided with and have access to a clear and convenient process to expeditiously request an override of such restriction from the managed care organization. The managed care organization shall expeditiously grant an override of such restriction under any of the following circumstances:

(1) The prescribing physician can demonstrate to the managed care organization, based on sound clinical evidence, that the preferred treatment required under step therapy or fail first protocol has been ineffective in the treatment of the Medicaid enrollee's disease or medical condition.

(2) The prescribing physician can demonstrate to the managed care organization, based on sound clinical evidence, that the preferred treatment required under the step therapy or fail first protocol is reasonably expected to be ineffective based on the known relevant physical or mental characteristics and medical history of the Medicaid enrollee and known characteristics of the drug regimen.

(3) The prescribing physician can demonstrate to the managed care organization, based on sound clinical evidence, that the preferred treatment required under the step therapy or fail first protocol will cause or will likely cause an adverse reaction or other physical harm to the Medicaid enrollee.

C. The duration of any step therapy or fail first protocol shall not be longer in duration than the customary period for the medication when such treatment is demonstrated by the prescribing physician to be clinically ineffective. When the managed care organization can demonstrate, through sound clinical evidence, that the originally prescribed medication is likely to require more than the customary period for such medication to provide any relief or an amelioration to the Medicaid enrollee, the step therapy or fail first protocol may be extended for an additional period of time no longer than the original customary period for the medication.

Section 2. This Act shall become effective upon signature by the governor or, if not signed by the governor, upon expiration of the time for bills to become law without signature by the governor, as provided by Article III, Section 18 of the Constitution of Louisiana. If vetoed by the governor and subsequently approved by the legislature, this Act shall become effective on the day following such approval.

DIGEST

The digest printed below was prepared by House Legislative Services. It constitutes no part of the legislative instrument. The keyword, one-liner, abstract, and digest do not constitute part of the law or proof or indicia of legislative intent. [R.S. 1:13(B) and 24:177(E)]

Anders HB No. 393

Abstract: Provides relative to prescription drug benefits of managed care organizations participating in the La. Medicaid coordinated care network program.

Provisions relative to Medicaid Managed Care Pharmaceutical and Therapeutics Committee and drug formulary:

Proposed law requires, beginning Jan. 1, 2014, that all managed care organizations participating in the La. Medicaid program provide as a pharmacy benefit the minimum drug pharmacopoeia in conjunction with a prior approval process developed by the Medicaid Managed Care Pharmaceutical and Therapeutics Committee established by proposed law. Provides that nothing in proposed law shall prohibit a managed care organization from providing drug benefits which are not listed on the minimum drug pharmacopoeia.

Proposed law creates the Medicaid Managed Care Pharmaceutical and Therapeutics Committee ("committee") within the Department of Health and Hospitals (DHH). Provides

that the committee shall be composed of 16 members appointed by the governor and submitted to the Senate for confirmation. Further provides that the committee shall be representative of the state's geographic and demographic composition, including women and minorities.

Proposed law provides that the committee shall be comprised of the following persons:

(1) Two physicians nominated by each managed care organization with expertise in the area of pharmacology.

(2) One practicing physician who is participating in the Medicaid program as a family practitioner recommended from a list of three names submitted by the Louisiana Academy of Family Physicians.

(3) One practicing physician who is participating in the Medicaid program as an internal medicine specialist recommended from a list of three names submitted by the Louisiana State Medical Society.

(4) One practicing physician who is participating in the Medicaid program as a pediatrician recommended from a list of three names submitted by the Louisiana Chapter of the American Academy of Pediatrics.

(5) One practicing physician who is participating in the Medicaid program as an obstetrician and gynecologist recommended from a list of three names submitted by the Louisiana Chapter of the American College of Obstetricians and Gynecologists.

(6) One practicing physician who is participating in the Medicaid program as a psychiatrist recommended from a list of three names submitted by the Louisiana Psychiatric Medical Association.

(7) Two practicing physicians who are participating in the Medicaid program recommended from a list of six names submitted by the Louisiana Medical Association.

(8) Two practicing pharmacists who are participating in the Medicaid pharmacy program recommended from a list of six names submitted by the Louisiana Pharmacy Association. One pharmacist shall be an independent pharmacist and one pharmacist shall be a pharmacist representing a chain pharmacy.

(9) The secretary of DHH or his designee.

(10) The director of the Medicaid program in DHH or his designee.

(11) The president of the Senate or his designee.

(12) The speaker of the House of Representatives or his designee.

(13) A Medicaid recipient who is enrolled with a prepaid entity.

Proposed law provides that other physicians who participate in the Medicaid program in various subspecialties may act as consultants to the committee as needed.

Proposed law provides that members of the committee shall be governed by either the Code of Governmental Ethics or the code of ethics of their respective profession.

Proposed law requires all of the following of the committee:

(1) That it meet only in public.

(2) That it permit public comment prior to voting on any changes in the preferred drug list.

(3) That it make available minutes of each meeting to the public within five days after approval of the minutes.

(4) That it make available to the public within five days of any committee meeting all documents distributed to it which are not subject to state or federal confidentiality laws shall be made available.

Proposed law stipulates that the pharmacopoeia developed by the committee shall comply with all applicable state and federal laws, rules, and regulations. Provides that the committee may recommend additions and deletions to the pharmacopoeia. Further requires that the committee advise the secretary of DHH on policy recommendations related to the prudent administration of the Medicaid managed care drug program.

Proposed law requires the secretary of DHH to ensure that all actions of the committee comply with applicable state and federal laws, rules, and regulations prior to implementation or modification of the pharmacopoeia. Provides that clinical decisions regarding the preferred drug list shall be made transparent through a written report that is publicly available. Further provides that if a decision of the committee is contrary to clinical evidence found in labeling, drug compendia, or peer reviewed literature, such decisions shall be justified in writing.

Proposed law authorizes the committee to establish a drug list to be utilized by all managed care organizations that utilize a prior approval process or any other process or combination of processes that prove to be cost-effective in the medical assistance program. Requires that any prior approval process shall meet, at minimum, the following criteria:

(1) Provide for a response by telephone or other form of telecommunication device within 24 hours of a request for prior authorization.

(2) Provide for the dispensing of a minimum of a 72-hour supply of a covered outpatient prescription drug in an emergency situation as provided by federal rule or regulation.

(3) Comply with all applicable federal laws, rules, and regulations.

(4) Involve medical personnel, including but not limited to pharmacists, pharmacy technicians, nurses, and physicians.

(5) Assure that a qualified, licensed physician is available for consultation during the prior approval process.

Proposed law provides that any drug approved by the U.S. Food and Drug Administration shall be added to the formulary as soon as it becomes commercially available. Provides procedures by which the committee may determine whether the drug will be maintained on the formulary.

Proposed law prohibits DHH from implementing the pharmacopoeia authorized by proposed law before the initial pharmacopoeia is submitted to and approved by the legislative committees on health and welfare. Provides that the legislative committees may only approve or reject the pharmacopoeia and may not add or delete specific drugs.

Provisions relative to step therapy and fail first protocols:

Proposed law requires, beginning Jan. 1, 2014, that all managed care organizations participating in the La. Medicaid program utilize a single page prior authorization form to be issued by DHH. Requires DHH to promulgate rules and regulations that establish the

form, and authorizes DHH to consult with the managed care organizations as necessary in development of the form.

Proposed law requires that each managed care organization which utilizes step therapy or fail first protocols comply with the provisions of proposed law.

Proposed law provides that when medications are restricted for use by a managed care organization by a step therapy or fail first protocol, the prescribing physician shall be provided with and have access to a clear and convenient process to expeditiously request an override of such restriction from the managed care organization. Requires the managed care organization to expeditiously grant an override of such restriction under any of the following circumstances:

(1) The prescribing physician can demonstrate to the managed care organization, based on sound clinical evidence, that the preferred treatment required under step therapy or fail first protocol has been ineffective in the treatment of the Medicaid enrollee's disease or medical condition.

(2) The prescribing physician can demonstrate to the managed care organization, based on sound clinical evidence, that the preferred treatment required under the step therapy or fail first protocol is reasonably expected to be ineffective based on the known relevant physical or mental characteristics and medical history of the Medicaid enrollee and known characteristics of the drug regimen.

(3) The prescribing physician can demonstrate to the managed care organization, based on sound clinical evidence, that the preferred treatment required under the step therapy or fail first protocol will cause or will likely cause an adverse reaction or other physical harm to the Medicaid enrollee.

Proposed law provides that the duration of any step therapy or fail first protocol shall not be longer in duration than the customary period for the medication when such treatment is demonstrated by the prescribing physician to be clinically ineffective. Provides that when the managed care organization can demonstrate, through sound clinical evidence, that the originally prescribed medication is likely to require more than the customary period for such medication to provide any relief or an amelioration to the Medicaid enrollee, the step therapy or fail first protocol may be extended for an additional period of time no longer than the original customary period for the medication.

Effective date:

Effective upon signature of governor or lapse of time for gubernatorial action.

(Adds R.S. 46:460.31-460.34)