SLS 13RS-487 **ORIGINAL**

Regular Session, 2013

SENATE BILL NO. 185

BY SENATOR MURRAY

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

HEALTH CARE. Provides relative to Medicaid and certain managed health care organizations providing health care services to Medicaid beneficiaries. (gov sig)

AN ACT

To enact R.S. 36:259(D)(10) and 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 460.53, relative to Medicaid; to create within the Department of Health and Hospitals the Medicaid Managed Care Pharmaceutical and Therapeutics Committee; to provide for managed care organizations providing health care services to Medicaid beneficiaries; to provide for the standardized credentialing of providers; to provide for prescription drugs; to provide for the Medicaid Managed Care Pharmaceutical and Therapeutics Committee; to provide for committee membership, powers, and meetings; to provide for a minimum drug formulary; to provide for a standard form for the prior authorization of prescription drugs; to provide for procedures for utilizing step therapy and fail first protocols; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 36:259(D)(10) is hereby enacted to read as follows:

§259. Transfer of agencies and functions to Department of Health and Hospitals

* * *

D. The following agencies, as defined in R.S. 36:3, are placed within the

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Department of Health and Hospitals and shall perform and exercise their powers, duties, functions, and responsibilities as otherwise provided by law:

* * *

(10) Medicaid Managed Care Pharmaceutical and Therapeutics Committee (R.S. 46:460.51 et seq.)

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Section 2. Part XI of Chapter 3 of Title 46 of the Louisiana Revised Statutes of 1950, comprised of R.S. 46:460.31 through 460.53, is hereby enacted to read as follows:

PART XI. MEDICAID MANAGED CARE

§460.31 Definitions

The following terms shall have the following meanings unless the context clearly indicates otherwise:

(1) "Applicant" means a health care provider seeking to be approved or credentialed by a managed care organization to provide health care services to Medicaid enrollees.

(2) "Credentialing" or "recredentialing" means the process of assessing and validating the qualifications of health care providers applying to be approved by a managed care organization to provide health care services to Medicaid enrollees.

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

(4) "Enrollee" means an individual who is enrolled in the Medicaid program.

(5) "Health care provider" or "provider" means a physician licensed to practice medicine by the Louisiana State Board of Medical Examiners or other individual health care practitioner licensed, certified, or registered to perform specified health care services consistent with state law.

(6) "Health care services" or "services" means the services, items, supplies, or drugs for the diagnosis, prevention, treatment, cure, or relief of a health condition, illness, injury, or disease.

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(7) "Managed care organization" shall have the same definition as the term is defined by 42 C.F.R. 438.2 and shall include any entity providing primary care case management services to Medicaid recipients pursuant to a contract with the department.

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

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

(10) "Standardized information" means the customary universal data concerning an applicant's identity, education, and professional experience relative to a managed care organization's credentialing process, including but not limited to name, address, telephone number, date of birth, social security number, educational background, state licensing board number, residency program, internship, specialty, subspecialty, fellowship, or certification by a regional or national health care or medical specialty college, association or society, prior and current place of employment, an adverse medical review panel opinion, a pending professional liability lawsuit, final disposition of a professional liability settlement or judgment, and information mandated by health insurance issuer accrediting organizations.

(11) "Verification" or "verification supporting statement" means the documentation confirming the information submitted by an applicant for a credentialing application from a specifically named entity or a regional, national, or general data depository providing primary source verification, including but not limited to a college, university, medical school, teaching hospital, health care facility or institution, state licensing board, federal agency or department, professional liability insurer, or the National Practitioner Data Bank.

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SUBPART A. PROVIDER CREDENTIALING

§460.41. Provider credentialing

A. (1) Any managed care organization that requires a health care provider to be credentialed, recredentialed, or approved prior to rendering health care services to a Medicaid recipient shall complete a credentialing process within ninety days from the date on which the managed care organization has received all the information needed for credentialing, including the health care provider's correctly completed application and attestations and all verifications or verification supporting statements required by the managed care organization to comply with accreditation requirements and generally accepted industry practices and provisions to obtain reasonable applicant-specific information relative to the particular or precise services proposed to be rendered by the applicant.

(2)(a) Within thirty days of the date of receipt of an application, a managed care organization shall inform the applicant of all defects and reasons known at the time by the managed care organization in the event a submitted application is deemed to be not correctly completed.

(b) A managed care organization shall inform the applicant in the event that any needed verification or a verification supporting statement has not been received within sixty days of the date of the managed care organization's request.

(3) In order to establish uniformity in the submission of an applicant's standardized information to each managed care organization for which he may seek to provide health care services, until submission of an applicant's standardized information in a hard-copy, paper format shall be superseded by a provider's required submission and a managed care organization's required acceptance by electronic submission, an applicant shall utilize and a managed care organization shall accept either of the following at the sole discretion of the managed care organization:

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(a) The current version of the Louisiana Standardized Credentialing Application Form, or its successor, as promulgated by the Department of Insurance; or

(b) The current format used by the Council for Affordable Quality Healthcare (CAQH), or its successor.

B. Nothing in this Section shall be construed to require a managed care organization credentialing or approval in determining inclusion or participation in the managed care organization's contracted network.

§460.42. Interim credentialing requirements

A. Under certain circumstances and when the provisions of R.S. 46:460.41 are met, a managed care organization contracting with a group of physicians that bills a managed care organization utilizing a group identification number, such as the group federal tax identification number or the group National Provider Identifier as set forth in 45 CFR 162.402 et seq., shall pay the contracted reimbursement rate of the physician group for covered health care services rendered by a new physician to the group, without health care provider credentialing as described in this Subpart. This provision shall apply in either of the following circumstances:

(1) When the new physician has already been credentialed by the managed care organization and the physician's credentialing is still active with the managed care organization.

(2) When the managed care organization has received the required credentialing application and information, including proof of active hospital privileges, from the new physician and the managed care organization has not notified the physician group that credentialing of the new physician has been denied.

B. A managed care organization shall comply with the provisions of R.S. 46:460.41 no later than thirty days after receipt of a written request from the physician group.

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C. Compliance by a managed care organization with the provisions of R.S. 46:460.41 shall not be construed to mean that a physician has been credentialed by the managed care organization, or the managed care organization shall be required to list the physician in a directory of contracted physicians.

D. If, upon compliance with R.S. 46:460.41, a managed care organization completes the credentialing process on the new physician and determines the physician does not meet the managed care organization's credentialing requirements, the managed care organization may recover from the physician or the physician group an amount equal to the difference between appropriate payments for in-network benefits and out-of-network benefits provided the managed care organization has notified the applicant physician of the adverse determination and provided that the prepaid entity has initiated action regarding such recovery within thirty days of the adverse determination.

SUBPART B. PRESCRIPTION DRUG FORMULARY

§460.51. 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 that is developed and maintained by the Medicaid Managed Care Pharmaceutical and Therapeutics Committee pursuant to this Part. Nothing in this Part shall prohibit a managed care organization from providing drug benefits that are not listed on the minimum drug pharmacopoeia.

B.(1) The Medicaid Managed Care Pharmaceutical and Therapeutics Committee, hereinafter referred to as "the committee", shall be created within the Department of Health and Hospitals. The committee shall be composed of the following members appointed by the governor and confirmed by the Senate. The committee shall be representative of the state's geographic and

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demographic composition, including women and minorities.

(2) The committee shall be comprised of the following persons:

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

(b) One practicing physician who is participating in the Title XIX of the Social Security Act 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 Title XIX of the Social Security Act 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 Title XIX of the Social Security Act 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 Title XIX of the Social Security Act program as an obstetrics 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 Title XIX of the Social Security Act 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 Title XIX of the Social Security Act program recommended from a list of six names submitted by the Louisiana Medical Association.

(h) Two practicing pharmacists who are participating in the Title XIX of the Social Security Act drug 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

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representing a chain pharmacy.

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

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

(k) The president of the Senate, or the president's designee.

(l) The speaker of the House of Representatives, or the speaker's designee.

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

(3) Other physicians who participate 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 governing their respective profession.

(5) The committee shall meet in public and shall permit public comments prior to voting on any changes in the preferred drug list. Minutes of the meeting shall be made available to the public within five days after the minutes are approved. All documents 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 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 advise the secretary on policy recommendations related to the prudent administration of the Medicaid managed care drug program. The secretary shall assure 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

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transparent through a written report that is publicly available. If the decision of the Medicaid Managed Care Pharmaceutical and Therapeutics Committee is contrary to the clinical evidence found in labeling, drug compendia, or peer review literature, such decisions shall be justified in writing.

(7) The Medicaid Managed Care Pharmaceutical and Therapeutics 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 a 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 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 Medicaid Managed Care Pharmaceutical and Therapeutics 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 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

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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 shall be reviewed by the Medicaid Managed Care Pharmaceutical and Therapeutics Committee.

(9) The department shall not implement the pharmacopoeia authorized by this Subsection until the initial pharmacopoeia shall be submitted to and approved by the Senate and House 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.

(10) The department shall be authorized to promulgate rules and regulations in accordance with the Administrative Procedure Act to implement the provisions of this Section.

§460.52. Prescription drug prior authorization

A. Beginning January 1, 2014, managed care organizations shall utilize a single page prior authorization form promulgated, pursuant to the Administrative Procedure Act, by the department.

B. The department shall promulgate rules and regulations prior to January 1, 2014, which provides for the form which must 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.

§460.53. Step therapy

A. Managed care organizations that utilize step therapy or fail first protocols shall comply with the provisions of this Section.

B. When medications for the treatment of any medical condition shall be 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 request an override of such restriction from the managed care organization. An override of such restriction shall be granted by the managed care organization under any of the following circumstances:

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(1) The prescribing physician demonstrates to the managed care organization, based on sound clinical evidence, 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 demonstrates to the managed care organization, based on sound clinical evidence, 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 demonstrates to the managed care organization, based on sound clinical evidence, the preferred treatment required under the step therapy or fail first protocol causes or likely causes 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 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 demonstrates, through sound clinical evidence, 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 3. 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.

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The original instrument and the following digest, which constitutes no part of the legislative instrument, were prepared by Christopher D. Adams.

DIGEST

Proposed law creates within the Department of Health and Hospitals the Medicaid Managed Care Pharmaceutical and Therapeutics Committee.

Proposed law provides for provider credentialing. Proposed law requires managed care organizations requiring a health care provider to be credentialed, recredentialed, or approved prior to rendering health care services to a Medicaid recipient within 90 days from the date receiving the information needed for credentialing.

Proposed law provides for a managed care organization informing a applicant within 30 days of the date of the receipt of the application of all defects and reasons known for the application being deemed incorrectly completed.

Proposed law provides for a managed care organization informing an applicant in the event verification or a verification supporting statement not received within 60 days of the date of the managed care organization's request.

Proposed law provides for interim credentialing requirements.

Proposed law provides for prescription drug formularies by managed care organizations. Proposed law provides beginning January 1, 2014, all managed care organizations will provide as a pharmacy benefit the minimum drug pharmacopoeia in conjunction with a prior approval process developed and maintained by the Medicaid Managed Care Pharmaceutical and Therapeutics Committee pursuant to proposed law.

Proposed law creates within DHH the Medicaid Managed Care Pharmaceutical and Therapeutics Committee (committee). The committee shall be composed of:

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

(2) One practicing physician who is participating in the Title XIX 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 Title XIX 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 Title XIX 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 Title XIX program as an obstetrics 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 Title XIX 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 Title XIX program recommended from a list of six names submitted by the Louisiana Medical

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Association.

(8) Two practicing pharmacists who are participating in the Title XIX drug 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 the Department of Health and Hospitals, or his designee.

(10) The director of the Medicaid program within the Department of Health and Hospitals, or his designee.

(11) The president of the Senate, or the president's designee.

(12) The speaker of the House of Representatives, or the speaker's designee.

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

Proposed law provides other physicians who participate in various subspecialties may act as consultants to the committee as needed. Proposed law provides the committee members will be appointed by the governor, confirmed by the Senate, and be representative of the state's geographic and demographic composition, including women and minorities.

Proposed law provides the committee's meeting will be open to the public and will have public comments. Proposed law provides the deadlines for the committee to make available meeting minutes and documents distributed to the committee during meetings.

Proposed law provides the committee may recommend additions and deletions to the pharmacopoeia.

Proposed law provides 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 a minimum any prior approval process will meet all of the following criteria:

(1) Provide for a response by telephone or other form of telecommunication device within a maximum of 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 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 any drug approved by the United States Food and Drug Administration will be added to the formulary as soon as it becomes commercially available. Proposed law provides the committee will conduct an evidence-based analysis of the drug to determine if the drug will be maintained on the formulary. Proposed law provides prior to a drug being prior authorized, the committee will review.

Proposed law provides DHH will not implement the pharmacopoeia authorized by the proposed law until the initial pharmacopoeia is submitted to and approved by the Senate and House committees on health and welfare. Proposed law provides the Senate and House

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committees on health and welfare may only approve or reject the pharmacopoeia and may not add specific drugs to or delete specific drugs from the pharmacopoeia.

Proposed law provides DHH will be authorized to promulgate rules and regulations in accordance with the Administrative Procedure Act to implement the proposed law.

Proposed law provides beginning January 1, 2014, managed care organizations shall utilize a single page prior authorization form promulgated, pursuant to the Administrative Procedure Act, by DHH.

Proposed law provides managed care organizations utilizing step therapy or fail first protocols will comply with the proposed law. Proposed law provides when medications for the treatment of any medical condition will be restricted for use by a managed care organization by a step therapy or fail first protocol, the prescribing physician will be provided with and have access to a clear and convenient process to request an override. Proposed law provides an override will be granted under the following circumstances:

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

Proposed law provides the duration of any step therapy or fail first protocol will not be longer than the customary period for the medication when such treatment is demonstrated by the prescribing physician to be clinically ineffective.

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

(Adds R.S. 36:259(D)(10) and R.S. 46:460.31-460.53)

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