HOUSE BILL No. 1437

DIGEST OF INTRODUCED BILL

Citations Affected: IC 12-15.

Synopsis: Prior authorization of bronchial drugs. Prohibits a managed care organization or the office of Medicaid policy and planning from requiring prior authorization for a prescription drug that is: (1) used in an outpatient setting; and (2) used to treat a life threatening acute bronchial spasm condition.

Effective: July 1, 2005.

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January 18, 2005, read first time and referred to Committee on Public Health.

Introduced

First Regular Session 114th General Assembly (2005)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2004 Regular Session of the General Assembly.

HOUSE BILL No. 1437

A BILL FOR AN ACT to amend the Indiana Code concerning Medicaid.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 12-15-35-28, AS AMENDED BY P.L.28-2004, SECTION 104, AND AS AMENDED BY P.L.97-2004, SECTION 51, IS CORRECTED AND AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 28. (a) The board has the following duties:

(1) The adoption of rules to carry out this chapter, in accordance with the provisions of IC 4-22-2 and subject to any office approval that is required by the federal Omnibus Budget Reconciliation Act of 1990 under Public Law 101-508 and its implementing regulations.

(2) The implementation of a Medicaid retrospective and prospective DUR program as outlined in this chapter, including the approval of software programs to be used by the pharmacist for prospective DUR and recommendations concerning the provisions of the contractual agreement between the state and any other entity that will be processing and reviewing Medicaid drug claims and profiles for the DUR program under this chapter.

(3) The development and application of the predetermined criteria and standards for appropriate prescribing to be used in retrospective and prospective DUR to ensure that such criteria and standards for appropriate prescribing are based on the compendia and developed with professional input with provisions for timely revisions and assessments as necessary.

(4) The development, selection, application, and assessment of interventions for physicians, pharmacists, and patients that are educational and not punitive in nature.

(5) The publication of an annual report that must be subject to public comment before issuance to the federal Department of Health and Human Services and to the Indiana legislative council by December 1 of each year. The report *issued* to the legislative council must be in an electronic format under IC 5-14-6.

(6) The development of a working agreement for the board to clarify the areas of responsibility with related boards or agencies, including the following:

(A) The Indiana board of pharmacy.

(B) The medical licensing board of Indiana.

(C) The SURS staff.

(7) The establishment of a grievance and appeals process for physicians or pharmacists under this chapter.

(8) The publication and dissemination of educational information to physicians and pharmacists regarding the board and the DUR program, including information on the following:

(A) Identifying and reducing the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and recipients.

(B) Potential or actual severe or adverse reactions to drugs.

(C) Therapeutic appropriateness.

(D) Overutilization or underutilization.

(E) Appropriate use of generic drugs.

(F) Therapeutic duplication.

(G) Drug-disease contraindications.

(H) Drug-drug interactions.

(I) Incorrect drug dosage and duration of drug treatment.

(J) Drug allergy interactions.

(K) Clinical abuse and misuse.

(9) The adoption and implementation of procedures designed to ensure the confidentiality of any information collected, stored, retrieved, assessed, or analyzed by the board, staff to the board, or

contractors to the DUR program that identifies individual physicians, pharmacists, or recipients.

(10) The implementation of additional drug utilization review with respect to drugs dispensed to residents of nursing facilities shall not be required if the nursing facility is in compliance with the drug regimen procedures under 410 IAC 16.2-3-8 and 42 CFR 483.60.

(11) The research, development, and approval of a preferred drug list for:

(A) Medicaid's fee for service program;

(B) Medicaid's primary care case management program; and

(C) the primary care case management component of the children's health insurance program under IC 12-17.6;

in consultation with the therapeutics committee.

(12) The approval of the review and maintenance of the preferred drug list at least two (2) times per year.

(13) The preparation and submission of a report concerning the preferred drug list at least two (2) times per year to the select joint commission on Medicaid oversight established by IC 2-5-26-3.

(14) The collection of data reflecting prescribing patterns related to treatment of children diagnosed with attention deficit disorder or attention deficit hyperactivity disorder.

(15) Advising the Indiana comprehensive health insurance association established by IC 27-8-10-2.1 concerning implementation of chronic disease management and pharmaceutical management programs under IC 27-8-10-3.5.

(b) The board shall use the clinical expertise of the therapeutics committee in developing a preferred drug list. The board shall also consider expert testimony in the development of a preferred drug list.

(c) In researching and developing a preferred drug list under subsection (a)(11), the board shall do the following:

(1) Use literature abstracting technology.

(2) Use commonly accepted guidance principles of disease management.

(3) Develop therapeutic classifications for the preferred drug list.

(4) Give primary consideration to the clinical efficacy or appropriateness of a particular drug in treating a specific medical condition.

(5) Include in any cost effectiveness considerations the cost implications of other components of the state's Medicaid program and other state funded programs.

(d) Prior authorization is required for coverage under a program

described in subsection (a)(11) of a drug that is not included on the preferred drug list.

(e) The board shall determine whether to include a single source covered outpatient drug that is newly approved by the federal Food and Drug Administration on the preferred drug list not later than sixty (60) days after the date on which the manufacturer notifies the board in writing of the drug's approval. However, if the board determines that there is inadequate information about the drug available to the board to make a determination, the board may have an additional sixty (60) days to make a determination from the date that the board receives adequate information to perform the board's review. Prior authorization may not be automatically required for a single source drug that is newly approved by the federal Food and Drug Administration, and that is:

(1) in a therapeutic classification:

(A) that has not been reviewed by the board; and

(B) for which prior authorization is not required; or

(2) the sole drug in a new therapeutic classification that has not been reviewed by the board.

(f) The board may not exclude a drug from the preferred drug list based solely on price.

(g) The following requirements apply to a preferred drug list developed under subsection (a)(11):

(1) Except as provided by IC 12-15-35.5-3(b) ~~and IC 12-15-35.5-3(c),~~ **through IC 12-15-35.5-3(d),** the office or the board may require prior authorization for a drug that is included on the preferred drug list under the following circumstances:

(A) To override a prospective drug utilization review alert.

(B) To permit reimbursement for a medically necessary brand name drug that is subject to generic substitution under IC 16-42-22-10.

(C) To prevent fraud, abuse, waste, overutilization, or inappropriate utilization.

(D) To permit implementation of a disease management program.

(E) To implement other initiatives permitted by state or federal law.

(2) All drugs described in IC 12-15-35.5-3(b) **and IC 12-15-35.5-3(c)** must be included on the preferred drug list.

(3) The office may add a drug that has been approved by the federal Food and Drug Administration to the preferred drug list without prior approval from the board.

(4) The board may add a drug that has been approved by the

federal Food and Drug Administration to the preferred drug list.

(h) At least two (2) times each year, the board shall provide a report to the select joint commission on Medicaid oversight established by IC 2-5-26-3. The report must contain the following information:

(1) The cost of administering the preferred drug list.

(2) Any increase in Medicaid physician, laboratory, or hospital costs or in other state funded programs as a result of the preferred drug list.

(3) The impact of the preferred drug list on the ability of a Medicaid recipient to obtain prescription drugs.

(4) The number of times prior authorization was requested, and the number of times prior authorization was:

(A) approved; and

(B) disapproved.

(i) The board shall provide the first report required under subsection (h) not later than six (6) months after the board submits an initial preferred drug list to the office.

SECTION 2. IC 12-15-35-46 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 46. (a) This section applies to a managed care organization that enters into an initial contract with the office to be a Medicaid managed care organization after May 13, 1999.

(b) Before a Medicaid managed care organization described in subsection (a) implements a formulary, the managed care organization shall submit the formulary to the office at least thirty-five (35) days before the date that the managed care organization implements the formulary for Medicaid recipients.

(c) The office shall forward the formulary to the board for the board's review and recommendation.

(d) The office shall provide at least thirty (30) days notification to the public that the board will review a Medicaid managed care organization's proposed formulary at a particular board meeting. The notification shall contain the following information:

(1) A statement of the date, time, and place at which the board meeting will be convened.

(2) A general description of the subject matter of the board meeting.

(3) An explanation of how a copy of the formulary to be discussed may be obtained.

The board shall meet to review the formulary at least thirty (30) days but not more than sixty (60) days after the notification.

(e) In reviewing the formulary, the board shall do the following:

(1) Make a determination, after considering evidence and credible information provided to the board by the office and the public, that the use of the formulary will not:

(A) impede the quality of patient care in the Medicaid program; or

(B) increase costs in other parts of the Medicaid program, including hospital costs and physician costs.

(2) Make a determination that:

(A) there is access to at least two (2) alternative drugs within each therapeutic classification, if available, on the formulary;

(B) a process is in place through which a Medicaid member has access to medically necessary drugs; and

(C) the managed care organization otherwise meets the requirements of IC 27-13-38.

(f) The board shall consider:

(1) health economic data;

(2) cost data; and

(3) the use of formularies in the non-Medicaid markets;

in developing its recommendation to the office.

(g) Within thirty (30) days after the board meeting, the board shall make a recommendation to the office regarding whether the proposed formulary should be approved, disapproved, or modified.

(h) The office shall rely significantly on the clinical expertise of the board. If the office does not agree with the recommendations of the board, the office shall, at a public meeting, discuss the disagreement with the board and present any additional information to the board for the board's consideration. The board's consideration of additional information must be conducted at a public meeting.

(i) Based on the final recommendations of the board, the office shall approve, disapprove, or require modifications to the Medicaid managed care organization's proposed formulary. The office shall notify the managed care organization of the office's decision within fifteen (15) days of receiving the board's final recommendation.

(j) The managed care organization must comply with the office's decision within sixty (60) days after receiving notice of the office's decision.

(k) Notwithstanding the other provisions of this section, the office may temporarily approve a Medicaid managed care organization's proposed formulary pending a final recommendation from the board.

(l) A Medicaid managed care organization may not require prior authorization for a prescription drug that is used:

(1) in an outpatient setting; and

(2) for the treatment of a life threatening acute bronchial spasm condition.

SECTION 3. IC 12-15-35.5-3 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 3. (a) Except as provided in subsection (b) **or (c),** the office may establish prior authorization requirements for drugs covered under a program described in section 1(a) of this chapter.

(b) The office may not require prior authorization for the following single source or brand name multisource drugs:

(1) A drug that is classified as an antianxiety, antidepressant, or antipsychotic central nervous system drug in the most recent publication of Drug Facts and Comparisons (published by the Facts and Comparisons Division of J.B. Lippincott Company).

(2) A drug that, according to:

(A) the American Psychiatric Press Textbook of Psychopharmacy;

(B) Current Clinical Strategies for Psychiatry;

(C) Drug Facts and Comparisons; or

(D) a publication with a focus and content similar to the publications described in clauses (A) through (C);

is a cross-indicated drug for a central nervous system drug classification described in subdivision (1).

(3) A drug that is:

(A) classified in a central nervous system drug category or classification (according to Drug Facts and Comparisons) that is created after the effective date of this chapter; and

(B) prescribed for the treatment of a mental illness (as defined in the most recent publication of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders).

(c) The office may not require prior authorization for a prescription drug that is used by a Medicaid recipient:

(1) in an outpatient setting; and

(2) for the treatment of a life threatening acute bronchial spasm condition.

~~(c)~~ **(d)** Except as provided under section 7 of this chapter, a recipient enrolled in a program described in section 1(a) of this chapter shall have unrestricted access to a drug described in subsection (b).