

IC 12-15-35.5

Chapter 35.5. Prescription Drugs

IC 12-15-35.5-1

Applicability

Sec. 1. This chapter applies to:

(1) the Medicaid program under this article; and

(2) the children's health insurance program under IC 12-17.6.

As added by P.L.6-2002, SEC.4. Amended by P.L.101-2005, SEC.5.

IC 12-15-35.5-2

"Cross-indicated drug" defined

Sec. 2. As used in this chapter, "cross-indicated drug" means a drug that is used for a purpose generally held to be reasonable, appropriate, and within the community standards of practice even though the use is not included in the federal Food and Drug Administration's approved labeled indications for the drug.

As added by P.L.6-2002, SEC.4.

IC 12-15-35.5-2.5

"Unrestricted access" defined

Sec. 2.5. As used in this chapter, "unrestricted access" means the ability of a recipient to obtain a prescribed drug without being subject to limits or preferences imposed by the office or the board for the purpose of cost savings except as provided under section 7 of this chapter.

As added by P.L.107-2002, SEC.23. Amended by P.L.184-2003, SEC.10.

IC 12-15-35.5-2.6

"Waste"

Sec. 2.6. As used in this chapter, "waste" means inappropriate:

(1) overprescribing;

(2) underprescribing;

(3) overutilization;

(4) underutilization;

(5) recipient noncompliance with the prescribed regimen; or

(6) clinically unjustified utilization;

of a prescription drug.

As added by P.L.11-2010, SEC.2.

IC 12-15-35.5-3

Prohibition on prior authorization of mental health drugs; exception

Sec. 3. (a) Except as provided in subsection (b), the office may establish prior authorization requirements for drugs covered under a program described in section 1 of this chapter.

(b) With the exception of prior authorization for "brand medically necessary" of a brand name drug with a generic equivalent in accordance with IC 16-42-22-10, 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 Psychopharmacology;

(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 March 12, 2002; 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) Except as provided under section 7 of this chapter, a recipient enrolled in a program described in section 1 of this chapter shall have unrestricted access to a drug described in subsection (b).

As added by P.L.6-2002, SEC.4. Amended by P.L.101-2005, SEC.6; P.L.1-2009, SEC.104; P.L.229-2011, SEC.143.

IC 12-15-35.5-4

Prior authorization requirement parameters

Sec. 4. Prior authorization requirements developed under this chapter must:

(1) comply with all applicable state and federal laws, including the provisions of 405 IAC 5-3 and 42 U.S.C. 1396r-8(d)(5); and

(2) provide that the prior authorization number assigned to an approved request be included on the prescription or drug order:

(A) issued by the prescribing practitioner; or

(B) if the prescription is transmitted orally, relayed to the dispensing pharmacist by the prescribing practitioner.

As added by P.L.6-2002, SEC.4. Amended by P.L.107-2002, SEC.24.

IC 12-15-35.5-5

Prior authorization procedures

Sec. 5. Before requiring prior authorization for a single source drug, the office shall seek the advice of the drug utilization review board, established by IC 12-15-35-19, at a public meeting of the board.

As added by P.L.6-2002, SEC.4.

IC 12-15-35.5-6

Publication of prior authorization decision

Sec. 6. (a) The office shall publish the decision to require prior authorization for a single source drug in a provider bulletin.

(b) IC 12-15-13-6 applies to a provider bulletin described in subsection (a).

As added by P.L.6-2002, SEC.4.

IC 12-15-35.5-7

Limitations on drug refills; limitations on restrictions on certain mental health drugs

Sec. 7. (a) Subject to subsections (b) and (c), the office may place limits on quantities dispensed or the frequency of refills for any covered drug as required by law or for the purpose of:

- (1) preventing fraud, abuse, or waste;
- (2) preventing overutilization, inappropriate utilization, or inappropriate prescription practices that are contrary to:
 - (A) clinical quality and patient safety; and
 - (B) accepted clinical practice for the diagnosis and treatment of mental illness and the considerations specified in subsection (h); or
- (3) implementing a disease management program.

(b) Before implementing a limit described in subsection (a), the office shall:

- (1) consider quality of care and the best interests of Medicaid recipients;
- (2) seek the advice of the drug utilization review board, established by IC 12-15-35-19, at a public meeting of the board; and
- (3) publish a provider bulletin that complies with the requirements of IC 12-15-13-6.

(c) Subject to subsection (d), the board may establish and the office may implement a restriction on a drug described in section 3(b) of this chapter if:

- (1) the board determines that data provided by the office indicates that a situation described in IC 12-15-35-28(a)(8)(A) through IC 12-15-35-28(a)(8)(K) requires an intervention to:
 - (A) prevent fraud, abuse, or waste;
 - (B) prevent overutilization, inappropriate utilization, or inappropriate prescription practices that are contrary to:
 - (i) clinical quality and patient safety; and
 - (ii) accepted clinical practice for the diagnosis and treatment of mental illness; or
 - (C) implement a disease management program; and
- (2) the board approves and the office implements an educational intervention program for providers to address the situation.

(d) A restriction established under subsection (c) for any drug described in section 3(b) of this chapter:

- (1) must comply with the procedures described in IC 12-15-35-35;

- (2) may include requiring a recipient to be assigned to one (1) practitioner and one (1) pharmacy provider for purposes of receiving mental health medications;
- (3) may not lessen the quality of care; and
- (4) must be in the best interest of Medicaid recipients.

(e) Implementation of a restriction established under subsection (c) must provide for the dispensing of a temporary supply of the drug for a prescription not to exceed seven (7) business days, if additional time is required to review the request for override of the restriction. This subsection does not apply if the federal Food and Drug Administration has issued a boxed warning under 21 CFR 201.57(e) that applies to the drug and is applicable to the patient.

(f) Before implementing a restriction established under subsection (c), the office shall:

- (1) seek the advice of the mental health Medicaid quality advisory committee established by IC 12-15-35-51; and
- (2) publish a provider bulletin that complies with the requirements of IC 12-15-13-6.

(g) Subsections (c) through (f):

- (1) apply only to drugs described in section 3(b) of this chapter; and
- (2) do not apply to a restriction on a drug described in section 3(b) of this chapter that was approved by the board and implemented by the office before April 1, 2003.

(h) Restrictions referred to in subsection (c) to prevent overutilization, inappropriate utilization, or inappropriate prescription practices that are contrary to accepted clinical practices may include the implementation of the following:

- (1) Encouraging dosages that enhance recipient adherence to a drug regimen.
- (2) Encouraging monotherapy with limitations on the number of drugs from a specific drug class that a recipient may be taking at any one (1) time when there is no documentation of the severity and intensity of the target symptoms.
- (3) Limiting the total number of scheduled psychiatric medications that a recipient may be taking at any one (1) time, when such limit is based on:
 - (A) established best practices; or
 - (B) guidelines implemented by the division of mental health and addiction for mental health state operated facilities.
- (4) Encouraging, in accordance with IC 16-42-22-10, generic substitution when such a substitution would result in a net cost savings to the Medicaid program.

(i) Restrictions under subsection (h) may be overridden through the prior authorization review process in cases in which the prescriber demonstrates medical necessity for the prescribed medication.

As added by P.L.6-2002, SEC.4. Amended by P.L.184-2003, SEC.11; P.L.101-2005, SEC.7; P.L.8-2007, SEC.1; P.L.36-2009, SEC.3; P.L.229-2011, SEC.145.

IC 12-15-35.5-8

Restriction of mental health drugs for individuals less than 18 years of age

Sec. 8. In addition to the limits described in section 7 of this chapter, the office may restrict a mental health drug described in section 3 of this chapter that is prescribed for an individual who is less than eighteen (18) years of age if federal financial participation is not available for reimbursement for the prescription under IC 12-15-5-2.

As added by P.L.11-2010, SEC.3.