

AMENDED IN ASSEMBLY APRIL 26, 2016

AMENDED IN ASSEMBLY APRIL 7, 2016

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL

No. 2209

Introduced by Assembly Member Bonilla

February 18, 2016

An act to add Section 1372.5 ~~of~~ *to* the Health and Safety Code, and to add Section 10123.25 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 2209, as amended, Bonilla. Health care coverage: clinical pathways.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care. A willful violation of the act is a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance. Existing law requires health care service plan contracts and health insurance policies to provide coverage for specified benefits.

~~The~~

This bill would require a health care service plan or health insurer that ~~adopts the use of~~ *develops and implements* a clinical pathway, as defined, to comply with certain requirements, including that the plan or health insurer ensures that each clinical pathway is developed in accordance with specified procedures. The bill would prohibit a plan or health insurer from, among other things, ~~adopting~~ *developing and implementing* a clinical pathway that ~~hinders education, research, patient~~

~~screening, or discourages~~ patient access to clinical trials. The bill would require a plan or health insurer that ~~adopts the use of~~ *develops and implements* a clinical pathway to make publicly available specified information for each clinical pathway ~~adopted: developed and implemented~~. Because a willful violation of the act by a health care service plan would be a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 1372.5 is added to the Health and Safety
2 Code, to read:
3 1372.5. (a) This section shall be known and may be cited as
4 ~~the Patient-Centered Clinical Pathway Act of 2016.~~
5 (b) For purposes of this section, the following definitions shall
6 apply:
7 (1) “Clinical pathway” means a ~~multidisciplinary management~~
8 ~~tool treatment plan~~ based on evidence-based practices used by
9 providers ~~involved in~~ *to direct* patient care, for a defined *patient*
10 *or patient group with a particular specific* disease or condition, or
11 undergoing a ~~particular specific~~ procedure, that is used by the
12 provider ~~as a tool~~ to make medical treatment decisions ~~to manage~~
13 ~~the~~ *for an enrollee’s or subscriber’s* care, in which the different
14 tasks, interventions, or treatment regimens used by the provider
15 involved in the enrollee’s *or subscriber’s* care are ~~defined;~~
16 ~~optimized,~~ *strictly defined* and sequenced. The use of a clinical
17 pathway by a provider relates to the practice of medicine and is
18 not a coverage decision.
19 (2) “Coverage decision” shall have the same meaning as set
20 forth in subdivision (c) of Section 1374.30.
21 (3) *Care provided as a result of a clinical pathway is subject*
22 *to this chapter, including the provisions regarding grievances,*
23 *appeals, or independent medical review (Article 5.55 (commencing*

1 *with Section 1374.30)), and the external medical review process*
2 *to examine coverage decisions regarding experimental or*
3 *investigational therapies pursuant to Section 1370.4.*

4 (c) (1) A health care service plan that ~~adopts the use of~~ *develops*
5 *and implements* a clinical pathway shall do all of the following:

6 (A) Ensure that each clinical pathway is developed in accordance
7 with the following procedures:

8 (i) The clinical pathway is developed by a multidisciplinary
9 group of actively practicing physicians with clinical expertise in
10 the therapeutic area or an organization generally recognized within
11 the relevant medical community as a body with clinical expertise
12 in the therapeutic area. A health care service plan may collaborate
13 with prescribing practitioners to include clinical pathways that are
14 already established or integrated into the prescribing practitioners'
15 treatment patterns, provided the clinical pathway is in compliance
16 with the requirements of this subparagraph.

17 (ii) Prior to finalization, the clinical pathway is reviewed and
18 endorsed by a formal, identified review panel of which all panel
19 members are actively practicing physicians within their respective
20 medical specialties, and a majority of panel members are
21 board-certified physicians in the relevant medical specialty.

22 ~~(iii) Prior to finalization, the clinical pathway is subject to an~~
23 ~~opportunity for review by stakeholders, including, but not limited~~
24 ~~to, prescribing practitioners and their professional societies,~~
25 ~~medical institutions or organizations, patients, patient advocacy~~
26 ~~groups, pharmaceutical and medical device manufacturers, and~~
27 ~~public input that is to be considered in finalizing the clinical~~
28 ~~pathway.~~

29 (B) Ensure that each clinical pathway specifies that a prescribing
30 practitioner participating in a clinical pathway should make
31 recommendations concerning the treatment, management, or
32 prevention of the relevant disease or condition for a specific patient
33 in accordance with the prescribing practitioner's clinical judgment
34 and the individual patient's needs and medical circumstances.

35 (C) ~~(i) Review and update, as appropriate, but not less than~~
36 ~~annually, each clinical pathway. However, if a clinical pathway's~~
37 ~~therapeutic area is subject to rapid changes or a major development~~
38 ~~occurs in that therapeutic area, the health care service plan shall~~
39 ~~review and update that clinical pathway on a more frequent or~~

1 ~~regular basis.~~ *Health care service providers shall consider requests*
2 *from network physicians on initiating a review of clinical pathways.*

3 ~~(ii) Establish and maintain a procedure by which prescribing~~
4 ~~practitioners may seek a review or an update of a clinical pathway~~
5 ~~when a new treatment option becomes available and disclose those~~
6 ~~procedures to prescribing practitioners.~~

7 (D) Provide prescribing practitioners, enrollees or subscribers,
8 and the public with readily available access to all of the following:

9 (i) Each clinical pathway.

10 (ii) All scientific data and evidence summaries evaluated in the
11 development of the pathway.

12 (iii) The names of the physicians and other members who
13 conducted the research, developed the analysis, and assessed the
14 clinical pathway.

15 (2) A health care service plan shall not do either of the
16 following:

17 (A) ~~Adopt~~ *Develop and implement* a clinical pathway that
18 ~~hinders education, research, patient screening, or discourages~~
19 ~~patient access to clinical trials.~~

20 (B) Require any practitioner participation in a pathway protocol
21 or adherence to specific treatments within the clinical pathway.

22 (d) A health care service plan that ~~adopts the use of~~ *develops*
23 *and implements* a clinical pathway shall make publicly available
24 for each clinical pathway all of the following information:

25 (1) The scope of the clinical pathway, including the therapeutic
26 area covered by the clinical pathway and any limitations on the
27 patient population or treatment setting for which the clinical
28 pathway was designed, or other limitations on the scope of the
29 clinical pathway.

30 (2) The key clinical features of the clinical pathway, including
31 the decisionmaking steps and key treatment recommendations to
32 be made at each step.

33 (3) The names, qualifications, and any conflicts of interest of
34 the physicians or organization that developed the clinical pathway.

35 (4) A listing of all panel members who participated in the review
36 of the clinical pathway. The listing shall include the institutional
37 affiliations, medical specialties, and any conflicts of interest of the
38 panel members.

39 (5) The sources of evidence on which the clinical pathway is
40 based. ~~If the clinical pathway is based in part on a clinical practice~~

~~guideline or similar document with recommendations on treatment, management, or prevention of a particular disease or condition, but the clinical pathway uses a more narrow set of items or services than the underlying clinical practice guideline or similar document, the individuals or organization that developed the clinical pathway shall identify the differences between the clinical pathway and the underlying clinical practice guideline or similar document, and explain why the clinical pathway excludes particular items or services.~~

~~(6) A narrative providing a comprehensive summary of the evidence on which the clinical pathway is based, including important issues the physicians or organization considered in interpreting the evidence and developing the clinical pathway. based.~~

~~(7) Information on the process for, and timing of, the health care service plan's review and update of clinical pathways, as required under subparagraph (C) of paragraph (1) of subdivision (c).~~

~~(e) Nothing in this section shall be construed to require a health care service plan contract to cover a benefit not otherwise required by law or not otherwise covered under the plan contract.~~

SEC. 2. Section 10123.25 is added to the Insurance Code, to read:

10123.25. (a) This section shall be known and may be cited as the ~~Patient-Centered Clinical Pathway Act of 2016.~~

(b) For purposes of this section, the following definitions shall apply:

(1) "Clinical pathway" means a ~~multidisciplinary management tool~~ *treatment plan* based on evidence-based practices used by providers ~~involved in~~ *to direct* patient care, for a defined *patient or* patient group with a ~~particular specific~~ disease or condition, or undergoing a ~~particular specific~~ procedure, that is used by the provider ~~as a tool~~ to make medical treatment decisions ~~to manage the for an insured's or policyholder's~~ care, in which the different tasks, interventions, or treatment regimens used by the provider involved in the insured's *or policyholder's* care are ~~defined, optimized,~~ *strictly defined* and sequenced. The use of a clinical pathway by a provider relates to the practice of medicine and is not a coverage decision.

(2) “Coverage decision” shall have the same meaning as set forth in subdivision (c) of Section 10169.

(3) *Care provided as a result of a clinical pathway is subject to this chapter, including filing a complaint or appeal and independent medical review (Article 3.5 (commencing with Section 10169)).*

(c) (1) A health insurer that ~~adopts the use of~~ *develops and implements* a clinical pathway shall do all of the following:

(A) Ensure that each clinical pathway is developed in accordance with the following procedures:

(i) The clinical pathway is developed by a multidisciplinary group of actively practicing physicians with clinical expertise in the therapeutic area or an organization generally recognized within the relevant medical community as a body with clinical expertise in the therapeutic area. A health insurer may collaborate with prescribing practitioners to include clinical pathways that are already established or integrated into the prescribing practitioners’ treatment patterns, provided the clinical pathway is in compliance with the requirements of this subparagraph.

(ii) Prior to finalization, the clinical pathway is reviewed and endorsed by a formal, identified review panel of which all panel members are actively practicing physicians within their respective medical specialties, and a majority of panel members are board-certified physicians in the relevant medical specialty.

~~(iii) Prior to finalization, the clinical pathway is subject to an opportunity for review by stakeholders, including, but not limited to, prescribing practitioners and their professional societies, medical institutions or organizations, patients, patient advocacy groups, pharmaceutical and medical device manufacturers, and public input that is to be considered in finalizing the clinical pathway.~~

(B) Ensure that each clinical pathway specifies that a prescribing practitioner participating in a clinical pathway should make recommendations concerning the treatment, management, or prevention of the relevant disease or condition for a specific patient in accordance with the prescribing practitioner’s clinical judgment and the individual patient’s needs and medical circumstances.

(C) ~~(i) Review and update, as appropriate, but not less than annually, each clinical pathway. However, if a clinical pathway’s therapeutic area is subject to rapid changes or a major development~~

1 occurs in that therapeutic area, the health insurer shall review and
2 update that clinical pathway on a more frequent or regular basis.
3 *Health care service providers shall consider requests from network*
4 *physicians on initiating a review of clinical pathways.*

5 ~~(ii) Establish and maintain a procedure by which prescribing~~
6 ~~practitioners may seek a review or an update of a clinical pathway~~
7 ~~when a new treatment option becomes available and disclose those~~
8 ~~procedures to prescribing practitioners.~~

9 (D) Provide prescribing practitioners, ~~insureds~~, *insureds or*
10 *policyholders*, and the public with readily available access to all
11 of the following:

12 (i) Each clinical pathway.

13 (ii) All scientific data and evidence summaries evaluated in the
14 development of the pathway.

15 (iii) The names of the physicians and other members who
16 conducted the research, developed the analysis, and assessed the
17 clinical pathway.

18 (2) A health insurer shall not do either of the following:

19 (A) ~~Adopt~~ *Develop and implement* a clinical pathway that
20 ~~hinders education, research, patient screening, or discourages~~
21 ~~patient access to clinical trials.~~

22 (B) Require any practitioner participation in a pathway protocol
23 or adherence to specific treatments within the clinical pathway.

24 (d) A health insurer that ~~adopts the use of~~ *develops and*
25 *implements* a clinical pathway shall make publicly available for
26 each clinical pathway all of the following information:

27 (1) The scope of the clinical pathway, including the therapeutic
28 area covered by the clinical pathway and any limitations on the
29 patient population or treatment setting for which the clinical
30 pathway was designed, or other limitations on the scope of the
31 clinical pathway.

32 (2) The key clinical features of the clinical pathway, including
33 the decisionmaking steps and key treatment recommendations to
34 be made at each step.

35 (3) The names, qualifications, and any conflicts of interest of
36 the physicians or organization that developed the clinical pathway.

37 (4) A listing of all panel members who participated in the review
38 of the clinical pathway. The listing shall include the institutional
39 affiliations, medical specialties, and any conflicts of interest of the
40 panel members.

(5) The sources of evidence on which the clinical pathway is based. ~~If the clinical pathway is based in part on a clinical practice guideline or similar document with recommendations on treatment, management, or prevention of a particular disease or condition, but the clinical pathway uses a more narrow set of items or services than the underlying clinical practice guideline or similar document, the individuals or organization that developed the clinical pathway shall identify the differences between the clinical pathway and the underlying clinical practice guideline or similar document, and explain why the clinical pathway excludes particular items or services.~~

(6) A narrative providing a ~~comprehensive~~ summary of the evidence on which the clinical pathway is ~~based, including important issues the physicians or organization considered in interpreting the evidence and developing the clinical pathway.~~ based.

(7) Information on the process for, and timing of, the health insurer's review and update of clinical pathways, as required under subparagraph (C) of paragraph (1) of subdivision (c).

(e) Nothing in this section shall be construed to require a health insurance policy to cover a benefit not otherwise required by law or not otherwise covered under the health insurance policy.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.