

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 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-care 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.

~~This bill would prohibit, on and after January 1, 2017, a health care service plan or health insurer that provides hospital, medical, or surgical expenses from implementing clinical care pathways, as defined, for use by providers in order to manage an enrollee’s or insured’s care. Because a willful violation of this prohibition by a health care service plan would be a crime, this bill would impose a state-mandated local program.~~

The bill would require a health care service plan or health insurer that adopts the use of 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 a clinical pathway that hinders education, research, patient screening, or patient access to clinical trials. The bill would require a plan or health insurer that adopts the use of a clinical pathway to make publicly available specified information for each clinical pathway adopted. 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 based on evidence-based practices used by providers involved*
- 9 *in patient care, for a defined patient group with a particular*
- 10 *disease or condition, or undergoing a particular procedure, that*
- 11 *is used by the provider as a tool to make medical treatment*
- 12 *decisions to manage the enrollee's care, in which the different*
- 13 *tasks, interventions, or treatment regimens used by the provider*
- 14 *involved in the enrollee's care are defined, optimized, and*
- 15 *sequenced. The use of a clinical pathway by a provider relates to*
- 16 *the practice of medicine and is not a coverage decision.*
- 17 *(2) "Coverage decision" shall have the same meaning as set*
- 18 *forth in subdivision (c) of Section 1374.30.*
- 19 *(c) (1) A health care service plan that adopts the use of a*
- 20 *clinical pathway shall do all of the following:*
- 21 *(A) Ensure that each clinical pathway is developed in*
- 22 *accordance with the following procedures:*

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

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

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

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

30 (C) (i) *Review and update, as appropriate, but not less than*
31 *annually, each clinical pathway. However, if a clinical pathway's*
32 *therapeutic area is subject to rapid changes or a major*
33 *development occurs in that therapeutic area, the health care service*
34 *plan shall review and update that clinical pathway on a more*
35 *frequent or regular basis.*

36 (ii) *Establish and maintain a procedure by which prescribing*
37 *practitioners may seek a review or an update of a clinical pathway*
38 *when a new treatment option becomes available and disclose those*
39 *procedures to prescribing practitioners.*

1 (D) Provide prescribing practitioners, enrollees or subscribers,
2 and the public with readily available access to all of the following:
3 (i) Each clinical pathway.
4 (ii) All scientific data and evidence summaries evaluated in the
5 development of the pathway.
6 (iii) The names of the physicians and other members who
7 conducted the research, developed the analysis, and assessed the
8 clinical pathway.
9 (2) A health care service plan shall not do either of the
10 following:
11 (A) Adopt a clinical pathway that hinders education, research,
12 patient screening, or patient access to clinical trials.
13 (B) Require any practitioner participation in a pathway protocol
14 or adherence to specific treatments within the clinical pathway.
15 (d) A health care service plan that adopts the use of a clinical
16 pathway shall make publicly available for each clinical pathway
17 all of the following information:
18 (1) The scope of the clinical pathway, including the therapeutic
19 area covered by the clinical pathway and any limitations on the
20 patient population or treatment setting for which the clinical
21 pathway was designed, or other limitations on the scope of the
22 clinical pathway.
23 (2) The key clinical features of the clinical pathway, including
24 the decisionmaking steps and key treatment recommendations to
25 be made at each step.
26 (3) The names, qualifications, and any conflicts of interest of
27 the physicians or organization that developed the clinical pathway.
28 (4) A listing of all panel members who participated in the review
29 of the clinical pathway. The listing shall include the institutional
30 affiliations, medical specialties, and any conflicts of interest of the
31 panel members.
32 (5) The sources of evidence on which the clinical pathway is
33 based. If the clinical pathway is based in part on a clinical practice
34 guideline or similar document with recommendations on treatment,
35 management, or prevention of a particular disease or condition,
36 but the clinical pathway uses a more narrow set of items or services
37 than the underlying clinical practice guideline or similar document,
38 the individuals or organization that developed the clinical pathway
39 shall identify the differences between the clinical pathway and the
40 underlying clinical practice guideline or similar document, and

1 *explain why the clinical pathway excludes particular items or*
2 *services.*

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

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

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

13 *10123.25. (a) This section shall be known and may be cited*
14 *as the Patient-Centered Clinical Pathway Act of 2016.*

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

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

27 *(2) "Coverage decision" shall have the same meaning as set*
28 *forth in subdivision (c) of Section 10169.*

29 *(c) (1) A health insurer that adopts the use of a clinical pathway*
30 *shall do all of the following:*

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

33 *(i) The clinical pathway is developed by a multidisciplinary*
34 *group of actively practicing physicians with clinical expertise in*
35 *the therapeutic area or an organization generally recognized*
36 *within the relevant medical community as a body with clinical*
37 *expertise in the therapeutic area. A health insurer may collaborate*
38 *with prescribing practitioners to include clinical pathways that*
39 *are already established or integrated into the prescribing*

1 *practitioners' treatment patterns, provided the clinical pathway*
2 *is in compliance with the requirements of this subparagraph.*

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

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

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

22 *(C) (i) Review and update, as appropriate, but not less than*
23 *annually, each clinical pathway. However, if a clinical pathway's*
24 *therapeutic area is subject to rapid changes or a major*
25 *development occurs in that therapeutic area, the health insurer*
26 *shall review and update that clinical pathway on a more frequent*
27 *or regular basis.*

28 *(ii) Establish and maintain a procedure by which prescribing*
29 *practitioners may seek a review or an update of a clinical pathway*
30 *when a new treatment option becomes available and disclose those*
31 *procedures to prescribing practitioners.*

32 *(D) Provide prescribing practitioners, insureds, and the public*
33 *with readily available access to all of the following:*

34 *(i) Each clinical pathway.*

35 *(ii) All scientific data and evidence summaries evaluated in the*
36 *development of the pathway.*

37 *(iii) The names of the physicians and other members who*
38 *conducted the research, developed the analysis, and assessed the*
39 *clinical pathway.*

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

1 (A) Adopt a clinical pathway that hinders education, research,
2 patient screening, or patient access to clinical trials.

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

5 (d) A health insurer that adopts the use of a clinical pathway
6 shall make publicly available for each clinical pathway all of the
7 following information:

8 (1) The scope of the clinical pathway, including the therapeutic
9 area covered by the clinical pathway and any limitations on the
10 patient population or treatment setting for which the clinical
11 pathway was designed, or other limitations on the scope of the
12 clinical pathway.

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

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

18 (4) A listing of all panel members who participated in the review
19 of the clinical pathway. The listing shall include the institutional
20 affiliations, medical specialties, and any conflicts of interest of the
21 panel members.

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

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

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

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

10 ~~SECTION 1. Section 1372.5 is added to the Health and Safety~~
11 ~~Code, to read:~~

12 ~~1372.5. (a) On and after January 1, 2017, a health care service~~
13 ~~plan that provides coverage for hospital, medical, or surgical~~
14 ~~expenses shall not implement clinical care pathways for use by~~
15 ~~providers in order to manage an enrollee's care.~~

16 ~~(b) For purposes of this section, "clinical care pathways" means~~
17 ~~a multidisciplinary management tool based on evidence-based~~
18 ~~practices used by providers involved in patient care to manage the~~
19 ~~enrollee's care, in which the different tasks, interventions, or~~
20 ~~treatment regimens used by the provider involved in the enrollee's~~
21 ~~care are defined, optimized, and sequenced.~~

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

24 ~~10123.25. (a) On and after January 1, 2017, a health insurer~~
25 ~~that provides coverage for hospital, medical, or surgical expenses~~
26 ~~shall not implement clinical care pathways for use by providers in~~
27 ~~order to manage an insured's care.~~

28 ~~(b) For purposes of this section, "clinical care pathways" means~~
29 ~~a multidisciplinary management tool based on evidence-based~~
30 ~~practices used by providers involved in patient care to manage the~~
31 ~~insured's care, in which the different tasks, interventions, or~~
32 ~~treatment regimens used by the provider involved in the insured's~~
33 ~~care are defined, optimized, and sequenced.~~

34 ~~SEC. 3. No reimbursement is required by this act pursuant to~~
35 ~~Section 6 of Article XIII B of the California Constitution because~~
36 ~~the only costs that may be incurred by a local agency or school~~
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39 ~~for a crime or infraction, within the meaning of Section 17556 of~~
40 ~~the Government Code, or changes the definition of a crime within~~

1 ~~the meaning of Section 6 of Article XIII B of the California~~
2 ~~Constitution.~~

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