

HOUSE BILL No. 1334

DIGEST OF INTRODUCED BILL

Citations Affected: IC 27-8-27.

Synopsis: Health information privacy. Provides standards for insurer collection, use, and disclosure of an insured's health information. Requires an insurer to have and notify insureds of policies and procedures for the management of health information of its insureds. Provides that an insured has a right to examine the insured's health information and request amendments to the health information if the insured believes the information to be erroneous. Requires an insurer to notify an insured, upon request, of disclosure of the insured's health information. Requires an insurer to obtain authorization from an insured to collect, use, or disclose the insured's health information. Provides for unauthorized collection, use, or disclosure of an insured's
(Continued next page)

Effective: July 1, 2000.

Fry

January 12, 1999, read first time and referred to Committee on Insurance, Corporations and Small Business.

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Digest Continued

health information under certain circumstances, including disclosure to research organizations. Specifies unauthorized uses of health information by an insurer. Provides limitations on disclosure by an insurer as requested by the insured. Provides penalties for violation of these provisions.

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Introduced

First Regular Session 111th General Assembly (1999)

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 1998 General Assembly.

HOUSE BILL No. 1334

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

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

1 SECTION 1. IC 27-8-27 IS ADDED TO THE INDIANA CODE AS
2 A NEW CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY
3 1, 2000]:

4 **Chapter 27. Health Information Privacy**
5 **Sec. 1. (a) As used in this chapter, "disclose" means to release,**
6 **transfer, or otherwise divulge protected health information to a**
7 **person other than to the individual who is the subject of the**
8 **protected health information.**
9 (b) As used in this chapter, "encoded" means that personally
10 identifiable information or data is removed or encrypted, and a key
11 to restore protected health information is retained in a secure place
12 within a research organization, with access to the key limited to the
13 minimum number of people necessary to maintain the
14 confidentiality and integrity of the information.
15 (c) As used in this chapter, "facility" means an institution



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1 providing health care services or a health care setting, including
2 hospitals and other licensed inpatient centers, ambulatory surgical
3 or treatment centers, skilled nursing centers, residential treatment
4 centers, diagnostic, laboratory and imaging centers, and
5 rehabilitation and other therapeutic health settings.

6 (d) As used in this chapter, "health care" means:

7 (1) preventive, diagnostic, therapeutic, rehabilitative,
8 maintenance, or palliative care, services, procedures, tests, or
9 counseling that:

10 (A) relates to the physical, mental, or behavioral condition
11 of an individual; or

12 (B) affects the structure or function of the human body or
13 any part of the human body, including the banking of
14 blood, sperm, organs, or other tissue; or

15 (2) prescribing, dispensing, or furnishing drugs or biologicals,
16 medical devices, or health care equipment and supplies to an
17 individual.

18 (e) As used in this chapter, "health care professional" means a
19 physician or other health care practitioner licensed, accredited, or
20 certified to perform specified health services in Indiana.

21 (f) As used in this chapter, "health care provider" or
22 "provider" means a health care professional or facility.

23 (g) As used in this chapter, "health insurance plan" means:

24 (1) a policy of accident and sickness insurance (as defined in
25 IC 27-8-5-11;

26 (2) a preferred provider plan (as defined in IC 27-8-11-1);

27 (3) a health maintenance organization contract (as defined in
28 IC 27-13-1-19);

29 (4) a state employee health benefit plan under IC 5-10-8-7;

30 (5) the state Medicaid plan under IC 12-15;

31 (6) a worker's compensation self-insurer under IC 22-3; or

32 (7) any plan that covers health care services (as defined in
33 IC 27-8-11-1) and is subject to state insurance law.

34 (h) As used in this chapter, "health information" means
35 information or data, whether oral or recorded in any form or
36 medium, and personal facts or information about events or
37 relationships that relate to the:

38 (1) past, present, or future physical, mental, or behavioral
39 health or condition of an individual or a member of an
40 individual's family;

41 (2) provision of health care to an individual; or

42 (3) payment for the provision of health care to an individual.

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1 (i) As used in this chapter, "insurance functions" means claims
 2 administration, claims adjustment and management, fraud
 3 investigation, underwriting, loss control, ratemaking functions,
 4 reinsurance, risk management, case management, disease
 5 management, quality assessment, quality improvement, provider
 6 credentialing verification, utilization review, peer review activities,
 7 grievance procedures, and internal administration of compliance,
 8 managerial, information systems, and policyholder service
 9 functions.

10 (j) As used in this chapter, "insurance support organization"
 11 means a person that regularly engages, in whole or in part, in the
 12 practice of assembling or collecting information from insurers,
 13 agents, or other insurance support organizations for the purpose
 14 of ratemaking or ratemaking related functions, regulatory or
 15 legislative cost analysis, detection or prevention of fraud, material
 16 misrepresentation, or material nondisclosure in connection with
 17 insurance underwriting or insurance claim activity. The term does
 18 not include agents, government institutions, insurance institutions,
 19 medical care institutions, and medical professionals.

20 (k) As used in this chapter, "insured" refers to an individual
 21 who is covered by a health insurance plan.

22 (l) As used in this chapter, "insurer" means a person who
 23 provides and issues health insurance plans in Indiana.

24 (m) As used in this chapter, "person" means an individual, a
 25 corporation, a partnership, an association, a joint venture, a joint
 26 stock company, a trust, an unincorporated organization, any
 27 similar entity, or a combination of the foregoing.

28 (n) As used in this chapter, "protected health information"
 29 means health information:

30 (1) that identifies an individual who is the subject of the
 31 information; or

32 (2) with respect to which there is a reasonable basis to believe
 33 that the information could be used to identify an individual.

34 (o) As used in this chapter, "research" means the process of
 35 systematic investigation or inquiry including the systematic:

36 (1) development and testing of a hypothesis; and

37 (2) description, analysis, and measurement of processes,
 38 behaviors, and physical, social, political, or medical
 39 phenomena.

40 (p) As used in this chapter, "research organization" means a
 41 person or organization, other than the insurer disclosing the
 42 protected health information, engaged in research.



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1 (q) As used in this chapter, "scientific, medical, or public policy
2 research" means research conducted to improve the effectiveness
3 of:

- 4 (1) determining medical causation, diagnosis, and treatment;
5 (2) public health; or
6 (3) the operations of the public or private health care,
7 insurance, or worker's compensation systems.

8 The results of the research are intended for publication and wide
9 dissemination beyond the insurer and research organization to
10 benefit the public good. The term does not include insurance
11 functions.

12 (r) As used in this chapter, "subject" means an individual who
13 is the subject of health information.

14 (s) As used in this chapter, "unauthorized" means a collection,
15 use, or disclosure of protected health information made by an
16 insurer:

- 17 (1) without the authorization of the subject of the protected
18 health information; or
19 (2) that is not in compliance with this chapter.

20 Sec. 2. (a) An insurer shall develop and implement written
21 policies, standards, and procedures for the management of health
22 information, including:

- 23 (1) limitation on access to health information by only those
24 persons who need to use the health information in order to
25 perform their jobs;
26 (2) appropriate training for all employees;
27 (3) disciplinary measures for violations of the health
28 information policies, standards, and procedures;
29 (4) identification of the job titles and job descriptions of
30 persons authorized to disclose protected health information;
31 (5) procedures for authorizing and restricting the collection,
32 use, or disclosure of protected health information;
33 (6) methods for exercising the right to access and amend
34 protected health information as provided in sections 4 and 5
35 of this chapter;
36 (7) methods for handling, disclosure, storage, and disposal of
37 health information;
38 (8) periodic monitoring of employee compliance with the
39 policies, standards, and procedures in a manner sufficient for
40 the insurer to determine compliance with this chapter and to
41 enforce the policies, standards, and procedures; and
42 (9) methods for informing and allowing a subject request



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1 specialized disclosure or nondisclosure of protected health
2 information as required under section 11 of this chapter.

3 (b) In a contractual arrangement between an insurer and a
4 person other than an insured or health care provider where the
5 person collects or uses protected health information on behalf of
6 the insurer or where the insurer discloses protected health
7 information to the person, an insurer shall:

8 (1) require the person to have health information policies,
9 standards, and procedures that comply with this chapter; and

10 (2) inform the person of the obligation to comply with
11 applicable state and federal statutory and regulatory
12 requirements governing the collection, use, or disclosure of
13 protected health information.

14 (c) In a contractual arrangement between an insurer and a
15 health care provider, the insurer shall require that the health care
16 provider have health information privacy policies, standards, and
17 procedures.

18 (d) Contractual arrangements described in this section in effect
19 on July 1, 1999, must comply with this chapter not later than
20 January 1, 2001, or the renewal date of the contract, whichever is
21 earlier.

22 (e) The commissioner may review an insurer's health
23 information policies, standards, and procedures under this section.

24 Sec. 3. (a) An insurer shall provide written notice to each
25 insured of its health information policies, standards, and
26 procedures developed under section 2 of this chapter. The notice
27 must include the:

28 (1) collection, use, and disclosure of protected health
29 information prohibited and permitted by this chapter;

30 (2) procedures for authorizing and limiting disclosures of
31 protected health information and for revoking authorizations;

32 (3) procedures for accessing and amending protected health
33 information; and

34 (4) right of an insured to review a copy of the insurer's health
35 information policies, standards, and procedures.

36 (b) The insurer shall provide the notice under subsection (a) to:

37 (1) a person upon request;

38 (2) an insured at the time a policy is issued; and

39 (3) all other individuals when requesting an authorization to
40 disclose.

41 If subsequent policies are issued to the same insured, no additional
42 notices are required to be provided.



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1 **Sec. 4. (a) Subject to subsection (b)(2), upon written request to**
 2 **the insurer, a subject has the right to examine or receive a copy of**
 3 **the subject's protected health information that is in the possession**
 4 **of the insurer or a person acting on behalf of the insurer.**

5 **(b) Not later than twenty (20) business days after receipt of a**
 6 **written request from a subject for the subject's protected health**
 7 **information, an insurer shall do one of the following:**

8 **(1) Provide a copy of the protected health information**
 9 **requested to the subject or, if providing a copy is not possible,**
 10 **permit the subject to examine the protected health**
 11 **information during normal business hours.**

12 **(2) Notify the subject that the insurer does not have the**
 13 **protected health information and:**

14 **(A) if known, inform the subject of the name and address**
 15 **of the person who has the protected health information; or**

16 **(B) if the insurer will obtain access to the requested**
 17 **protected health information, when the protected health**
 18 **information is expected to be available to the subject.**

19 **(3) Deny the request in whole or in part if the insurer**
 20 **determines that:**

21 **(A) knowledge of the protected health information would**
 22 **reasonably be expected to identify a confidential source**
 23 **that provided the protected health information in**
 24 **conjunction with a lawfully conducted investigation, law**
 25 **enforcement investigation, or court proceeding;**

26 **(B) the protected health information was compiled in**
 27 **preparation for litigation, law enforcement or fraud**
 28 **investigation, quality assurance, or peer review purposes;**

29 **(C) the protected health information is the original work**
 30 **product of the insurer, including interpretation, mental**
 31 **impressions, instructions, and other original products of**
 32 **the insurer or the insurer's employees or agents;**

33 **(D) the subject is a party to a legal proceeding involving**
 34 **the insurer where the health condition of the subject is at**
 35 **issue; or**

36 **(E) disclosure of the protected health information to the**
 37 **subject is prohibited by law.**

38 **Once a legal proceeding is resolved, the subject's right to**
 39 **access protected health information under this section and to**
 40 **amend protected health information under section 5 of this**
 41 **chapter is restored.**

42 **(c) If a request to examine or copy protected health information**

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1 is denied under subsection (b)(3), the insurer shall notify the
2 subject of the reasons for the denial in writing. However, if the
3 protected health information was compiled in preparation for
4 litigation, law enforcement, or fraud investigation, the insurer shall
5 notify the subject that all information required to be released
6 under this chapter has been released, and the insurer is not
7 required to notify the subject of the reasons for the denial.

8 (d) An insurer is not required to create a new record or
9 reformulate an existing record in order to meet a request for
10 protected health information under this section.

11 (e) An insurer may charge a reasonable fee for providing
12 protected health information under this section and shall provide
13 a detailed bill accounting for the charges. However, a charge may
14 not be made for reproduction of protected health information
15 requested to support a claim, support an appeal, or access any
16 federal or state sponsored or operated health benefits program.

17 **Sec. 5. (a)** A subject has the right, upon written request by the
18 subject to the insurer, to amend the subject's protected health
19 information to correct inaccuracies.

20 (b) Within thirty (30) business days after receipt of a written
21 request from a subject to amend protected health information, an
22 insurer shall verify the accuracy of protected health information
23 identified as erroneous by the subject and shall do one (1) of the
24 following:

25 (1) Correct, amend, or delete the portion of the protected
26 health information in dispute and notify the subject of the
27 changes.

28 (2) Notify the subject that the request has been denied, the
29 reason for the denial, and that the subject may:

30 (A) request that the health care provider that created the
31 record in question amend the record, including the name
32 and address of the health care provider; or

33 (B) file a concise statement of what the subject believes to
34 be the correct information and the reasons that the subject
35 disagrees with the denial. The insurer shall retain this
36 statement filed by the subject with the protected health
37 information.

38 (c) If the insurer corrects, amends, or deletes the protected
39 health information as requested under subsection (b)(1), the
40 insurer shall furnish the correction, amendment, or deletion to:

41 (1) all persons who have received from the insurer within the
42 preceding two (2) years the protected health information that

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1 has been corrected, amended, or deleted;

2 (2) an insurance support organization whose primary source
3 of protected health information is insurers, if the insurance
4 support organization has systematically received protected
5 health information from the insurer within the preceding
6 seven (7) years unless the insurance support organization no
7 longer maintains the protected health information that has
8 been corrected, amended, or deleted; and

9 (3) any person that furnished the protected health information
10 that was amended under subsection (b)(1).

11 (d) If the subject files a statement under subsection (b)(2)(B), the
12 insurer shall:

13 (1) clearly identify the matter or matters in dispute and
14 include the statement in a subsequent disclosure of the
15 protected health information; and

16 (2) furnish the statement to the persons described in
17 subsection (c).

18 (e) This section does not require an insurer to alter, delete,
19 erase, or obliterate medical records provided to the insurer by a
20 health care provider.

21 (f) This section does not allow a person access to protected
22 health information described in section 4(b)(3) of this chapter.

23 **Sec. 6. (a) An insurer shall provide to a subject upon request**
24 **information regarding disclosure of the subject's protected health**
25 **information. The information must be sufficient to allow the**
26 **subject to exercise the right to amend the information under**
27 **section 5 of this chapter. The information must include the date,**
28 **purpose, recipient, and relevant authorization or basis for the**
29 **disclosure. The insurer may charge a reasonable fee for providing**
30 **the information regarding disclosure of protected health**
31 **information.**

32 (b) An insurer shall maintain a system that is sufficient for the
33 commissioner to determine that the insurer can produce a
34 complete list of disclosures. The insurer must be able to:

35 (1) for routine disclosures, track when routine disclosures are
36 made, to whom they are made, and for what purpose they are
37 made; and

38 (2) for all other disclosures, identify the authorization or
39 release form or provision of law allowing disclosure of
40 protected health information.

41 (c) An insurer is not required to include in the information
42 developed under subsection (a) disclosures of protected health

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1 information that were compiled in preparation for litigation, law
2 enforcement, or fraud investigation.

3 **Sec. 7. (a) Except as permitted by sections 8 and 9 of this**
4 **chapter or as otherwise permitted or required by law or court**
5 **order, an insurer may not collect, use, or disclose protected health**
6 **information without a valid authorization from the subject.**
7 **Authorization for the disclosure of protected health information**
8 **may be obtained for any purpose if the authorization meets the**
9 **requirements of this section.**

10 **(b) An insurer shall retain an authorization or a copy in the**
11 **record of the subject.**

12 **(c) A valid authorization must be in writing and contain all the**
13 **following:**

14 **(1) The identity of the subject.**

15 **(2) A description of the types of protected health information**
16 **to be collected, used, or disclosed, including a description of**
17 **the tests or examinations to be performed and a statement**
18 **that the tested subject may choose whether to receive the**
19 **results of the tests or examinations.**

20 **(3) A general description of the sources from which protected**
21 **health information will be collected.**

22 **(4) The name and address of the person to whom the**
23 **protected health information is to be disclosed.**

24 **(5) The purpose of the authorization, including the reason for**
25 **the collection, the intended use of the protected health**
26 **information, and the scope of any disclosures that may be**
27 **made in carrying out the purpose for which the authorization**
28 **is requested, provided those disclosures are not prohibited by**
29 **law.**

30 **(6) The signature of the subject or the individual who is**
31 **legally empowered to grant authority and the date signed.**

32 **(7) A statement that the subject may revoke the authorization**
33 **at any time, except as provided in subsection (g).**

34 **(d) An authorization must specify a period that the**
35 **authorization is valid. The period is not to exceed twelve (12)**
36 **months unless the authorization is signed for one (1) of the**
37 **following purposes:**

38 **(1) For the collection of protected health information to**
39 **support insurance functions, in which event the authorization**
40 **remains valid during the entire term of the policy or as long**
41 **as necessary for the insurer to meet its obligations under the**
42 **policy or as otherwise required by law.**

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(2) To support an application for, a reinstatement of, or a change in benefits under a life insurance policy, in which event the authorization shall expire after thirty (30) months or whenever the application is denied, whichever occurs first.

(3) To support or facilitate ongoing management of a chronic condition or illness or rehabilitation from an injury.

(e) An insurer shall obtain a separate authorization to disclose protected health information to a subject's employer or the employer's risk manager unless the protected health information is:

(1) disclosed under the employer's worker's compensation program to the extent necessary for the performance of the employer's and insurer's rights and duties under IC 22-3 and IC 27-7-2;

(2) disclosed under the employer's administration of a health and welfare benefit plan; or

(3) necessary to the administration of claims under a commercial lines policy.

(f) An insurer shall obtain a separate authorization to collect, use, or disclose protected health information if the purpose of the collection, use, or disclosure is for the marketing of services or goods or for other commercial gain. The purpose of the collection, use, or disclosure must be stated in clear and simple terms and appear as a separate paragraph in bold type no smaller than twelve (12) points. The request for authorization must specify that the authorization remains valid for not more than twelve (12) months and may be revoked at any time. The request for authorization must state that the terms and conditions of all insurance policies will not be affected by a refusal to give authorization. The subject shall be given an opportunity to indicate that the subject does not want protected health information used for marketing purposes and shall have given no indication that the subject does not want protected health information used for these purposes.

(g) A subject may revoke an authorization at any time, subject to the rights of any person who acted in reliance on the authorization before notice of revocation. A revocation of an authorization must be in writing, dated, and signed and retained by the insurer in the subject's record. An insurer shall give prompt notice of the revocation to all persons to whom the insurer has disclosed protected health information in reliance on the initial authorization.

(h) An insurer that has collected protected health information

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1 under this chapter may use and disclose the protected health
 2 information to a person acting on behalf of or at the direction of
 3 the insurer for the performance of the insurer's insurance
 4 functions.

5 (i) Protected health information may not be used or disclosed
 6 for a purpose other than in the performance of the insurer's
 7 insurance functions, except as permitted under this chapter.

8 (j) An authorization to collect, use, or disclose protected health
 9 information under this chapter or production of protected health
 10 information under a court order does not constitute a waiver of
 11 any other privacy right of a subject under any other federal, state,
 12 or common law or rules of evidence.

13 (k) A person who receives protected health information from an
 14 insurer may not use the protected health information for a purpose
 15 other than the lawful purpose for which it was disclosed.

16 (l) This chapter does not require an insurer to provide a benefit
 17 or commence or continue payment of a claim in the absence of
 18 protected health information to support or deny the benefit or
 19 claim.

20 (m) An insurer that has collected protected health information
 21 before July 1, 1999, is not required to obtain an authorization for
 22 the information. However, after July 1, 1999, the protected health
 23 information may only be used or disclosed in accordance with this
 24 chapter.

25 **Sec. 8. (a) An insurer may engage in the following activities with**
 26 **regard to protected health information without authorization in**
 27 **the following circumstances or as permitted by law:**

28 (1) Collect protected health information from or disclose
 29 protected health information to an insurer, provided that the
 30 insurer receiving the information:

31 (A) is investigating, evaluating, adjusting, or settling a
 32 claim involving the subject; or

33 (B) has become or is considering becoming liable under a
 34 policy insuring the subject as a result of a merger,
 35 acquisition, or other assumption of liability.

36 (2) Collect, use, or disclose protected health information to the
 37 extent necessary to investigate, evaluate, subrogate, or settle
 38 third party claims provided that the claimant is the subject
 39 and the protected health information is used only for the
 40 authorized purpose or the use is permitted under federal or
 41 state law.

42 (3) Collect, use, or disclose protected health information to or

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1 from an insurance support organization provided that:

2 (A) the insurance support organization has health
3 information policies, standards, and procedures to ensure
4 compliance with this chapter and the protected health
5 information is used only to perform the insurance
6 functions of claims settlement, detection and prevention of
7 fraud, or detection and prevention of material
8 misrepresentation or material nondisclosure;

9 (B) the protected health information is collected and used
10 internally only to perform the insurance functions of
11 ratemaking and ratemaking related functions or
12 regulatory or legislative cost analysis; or

13 (C) additional insurance functions with approval of the
14 commissioner.

15 (4) If the protected health information is necessary to provide
16 ongoing health care treatment, and if the disclosure has not
17 been limited or prohibited by the subject, collect protected
18 health information from or disclose protected health
19 information to a:

20 (A) health care provider employed by the insurer who is
21 furnishing health care to the subject;

22 (B) health care provider with whom the insurer contracts
23 to provide health care services to the subject; or

24 (C) referring health care provider who continues to furnish
25 health care to the subject.

26 (5) Disclose protected health information to a person engaged
27 in the assessment, evaluation, or investigation of the quality of
28 health care furnished by a provider under statutory or
29 regulatory standards or the requirements of a private or
30 public program authorized to provide for the payment of
31 health care.

32 (6) Subject to section 11(b) of this chapter, disclose protected
33 health information to reveal an insured's presence in a facility
34 owned by the insurer and the insured's general health
35 condition, provided that the disclosure is limited to
36 information about the presence or general health condition of
37 the insured who is receiving health care in the facility, unless
38 the insured has restricted the disclosure or the disclosure is
39 prohibited by law.

40 (7) Collect, use, or disclose protected health information when
41 the protected health information is necessary to the
42 performance of the insurer's obligations under IC 22-3 or

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1 **IC 27-7-2.**

2 **(8) Collect protected health information from or disclose**
 3 **protected health information to a reinsurer, stop loss, or**
 4 **excess loss insurer for the purpose of underwriting, claims**
 5 **adjudication, and conducting claim file audits.**

6 **(9) Collect protected health information from the subject.**

7 **(10) Collect, use, or disclose protected health information**
 8 **when the protected health information is obtained from public**
 9 **sources such as newspapers, public agency reports, law**
 10 **enforcement reports, or public safety reports.**

11 **(b) Unless restricted by this section, an insurer that has collected**
 12 **protected health information without an authorization under**
 13 **section 8(a) of this chapter may use and disclose the information to**
 14 **a person acting on behalf of or at the direction of the insurer to**
 15 **perform insurance functions.**

16 **(c) An insurer shall disclose protected health information under**
 17 **the following circumstances:**

18 **(1) To federal, state, or local governmental authorities to the**
 19 **extent required by law or for fraud reporting purposes.**

20 **(2) The protected health information is needed to:**

21 **(A) identify a deceased individual;**

22 **(B) determine the cause and manner of death by a chief**
 23 **medical examiner or the medical examiner's designee; or**

24 **(C) provide necessary protected health information about**
 25 **a deceased individual who is a donor of an anatomical gift.**

26 **(3) To a state department of insurance that is performing an**
 27 **examination, investigation, or audit of the insurer.**

28 **(4) Under a court order issued after the court's determination**
 29 **that the public interest in disclosure outweighs the subject's**
 30 **privacy interest and that the protected health information is**
 31 **not reasonably available by other means.**

32 **(d) A disclosure of protected health information made under**
 33 **subsection (c) may not operate as a waiver of privacy rights**
 34 **provided by other federal, state, or common law, or rules of**
 35 **evidence.**

36 **Sec. 9. (a) An insurer may disclose protected health information**
 37 **without authorization to research organizations conducting**
 38 **scientific, medical, or public policy research as provided in this**
 39 **chapter if:**

40 **(1) the research organization agrees not to disclose the**
 41 **protected health information to a third person, except the**
 42 **research organization's agent, collaborator, or contractor as**

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- needed in compliance with this chapter;
- (2) the insurer discloses only the minimum data necessary to conduct the intended research;
- (3) identification is necessary to conduct the research; and
- (4) the insurer keeps a record of research organizations to which it discloses protected health information for five (5) years after disclosure.

(b) If scientific, medical, or public policy research does not require contact with the subject, the following protections must exist before disclosure:

- (1) The research organization shall implement a written policy to ensure the security and privacy of protected health information, including:
 - (A) training and disciplinary procedures to ensure that persons involved in research comply with the provisions of this chapter;
 - (B) safeguards to ensure that information in a report of the research project does not contain protected health information and a system to ensure that only authorized persons may establish a link between an individual and the health information; and
 - (C) a method to remove all information that directly or indirectly identifies the subject when identification is no longer needed for research.

The policy may also provide that the research organization may retain protected health information for an indefinite period if archived in an encoded form and not used for other research unless the requirements of this section are met.

- (2) The research organization shall prepare a research plan that:
 - (A) explains the purposes of the research;
 - (B) contains a general description of research methods to be used and the potential benefits of the research;
 - (C) is available to the public and may be obtained by written request to the research organization or insurer. However, if the research plan contains information that is proprietary or protected from disclosure by contract or statute, the information may be deleted from the copy made available to the public; and
 - (D) is kept on file by the research organization for at least five (5) years.
- (3) The insurer and the research organization shall execute a

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written agreement that:

- (A) states the purposes of the research;
- (B) explains how the purposes qualify as scientific, medical, or public policy research;
- (C) documents that the organization is qualified to perform the research;
- (D) states the expected time during which the data will be used for the stated purposes;
- (E) states the planned method of disposition of the protected health information at the end of the term of use;
- (F) states that the written agreement must be available to the public and can be obtained by written request to the research organization; and
- (G) is kept on file by the insurer for at least five (5) years.

(4) The insurer shall provide a copy of the written agreement executed under subdivision (3) upon request to any person. If the executed agreement contains information that is proprietary or protected from disclosure by contract or statute, the information may be deleted from the copy that is made available.

(c) If the scientific, medical, or public policy research requires contact with the subject, the following protections must exist before disclosure:

- (1) The research organization and insurer shall meet the requirements of subsection (b).
- (2) The research organization shall obtain a legally effective informed consent from the subject or the subject's legally authorized representative. The informed consent may be obtained only under circumstances that provide the prospective subject or representative with sufficient opportunity to consider whether to participate in the research and that minimize the possibility of coercion or undue influence.
- (3) In seeking informed consent, the following information shall be provided in understandable language to the subject or representative:
 - (A) A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of procedures that are experimental.
 - (B) A description of reasonably foreseeable risks or

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- discomforts to the subject.
 - (C) A description of benefits to the subject or to others that may reasonably be expected from the research.
 - (D) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
 - (E) A statement describing the extent to which confidentiality of records identifying the subject will be maintained.
 - (F) For research involving more than minimal risk, an explanation as to whether any compensation and medical treatments are available if injury occurs and, if so, what they consist of.
 - (G) An explanation of whom to contact for answers to pertinent questions about the research and the research subject's rights.
 - (H) The name of a person to contact in the event of a research related injury to the subject.
 - (I) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is entitled.
- No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative waives or appears to waive any of the subject's legal rights or releases or appears to release the investigator, sponsor, research organization, or agents from liability or negligence.
- (4) When appropriate, one (1) or more of the following shall also be provided to each subject:
- (A) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus if the subject is or may become pregnant) that are currently unforeseeable.
 - (B) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
 - (C) Any additional costs to the subject that may result from participation in the research.
 - (D) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination

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1 of participation by the subject.

2 (E) A statement that significant new findings developed
3 during the course of the research that may relate to the
4 subject's willingness to continue participation will be
5 provided to the subject.

6 (F) The approximate number of subjects involved in the
7 research.

8 (5) If a research organization submits research for approval
9 by an institutional review board under the Federal Policy for
10 the Protection of Human Subjects, as originally published in
11 56 Federal Register 28000 (1991) and as adopted and
12 implemented by a federal department or agency, compliance
13 with that process will be considered compliance with the
14 provisions of subsections (b)(2) and (c)(2).

15 (d) If an insurer discloses to an organization conducting
16 scientific, medical, or public policy research health information
17 that is not protected health information because all identifying
18 information is encrypted, the insurer and research organization
19 shall execute a written agreement that provides:

20 (1) that the research organization will not rerelease the data
21 accompanied by the encrypted identifying information to a
22 third person except the research organization's agents,
23 collaborators, or contractors as needed to conduct or assist
24 with the research in compliance with this section;

25 (2) that the research organization may make no efforts to link
26 any health information it received with encrypted identifying
27 information to any other data that may identify the subject;
28 and

29 (3) that the research organization may make no efforts to link
30 any encrypted protected health information with any other
31 identifiable data.

32 (e) Before any encrypted information is decrypted or linked to
33 identifying data, the research organization shall comply with this
34 section and health information with decrypted identifying
35 information shall be considered protected health information.

36 (f) This chapter does not prevent the creation, use, or release of
37 anonymized data for which there is no reasonable basis to believe
38 that the information could be used to identify an individual.

39 (g) This section may not be construed to supersede a federal law
40 or regulation governing scientific, medical, and public policy
41 research.

42 Sec. 10. An unauthorized collection, use, or disclosure of

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1 protected health information by an insurer, including:

- 2 (1) unauthorized publication of protected health information;
 3 (2) unauthorized collection, use, or disclosure of protected
 4 health information for personal or professional gain,
 5 including unauthorized research that does not meet the
 6 requirements of this chapter;
 7 (3) unauthorized sale of protected health information;
 8 (4) unauthorized manipulation of coded or encrypted health
 9 information that reveals protected health information; and
 10 (5) use of deception, fraud, or threat to procure authorization
 11 to collect, use, or disclose protected health information;

12 is prohibited and subject to the penalties under section 12 of this
 13 chapter.

14 Sec. 11. (a) This section does not apply to subjects who are less
 15 than eighteen (18) years of age.

16 (b) An insurer shall limit disclosure of information about the
 17 subject if the subject clearly states in writing that disclosure to
 18 specified individuals of all or part of the information could
 19 jeopardize the safety of the subject. Disclosure of information
 20 under this subsection must be limited consistent with the subject's
 21 request.

22 (c) Except as required by law, upon written request by the
 23 subject an insurer shall not disclose protected health information
 24 concerning health services related to reproductive health, sexually
 25 transmitted diseases, substance abuse, and behavioral health,
 26 including mailing appointment notices, calling the home to confirm
 27 appointments, or mailing a bill or explanation of benefits to a
 28 policyholder or certificate holder. The written request must include
 29 information as to how any amounts payable by the subject will be
 30 handled. In addition, an insurer shall not require the subject to
 31 obtain the policyholder's or certificate holder's authorization to
 32 receive health care services or to submit a claim.

33 (d) An insurer that cannot comply with the requirements of this
 34 section relating to the suppression of benefit, payment, and similar
 35 information by July 1, 1999, because of demonstrated financial or
 36 technological burdens may make a written request to the
 37 commissioner for an extension of the time permitted for
 38 compliance. The request shall propose a plan and a timetable for
 39 compliance not later than January 1, 2001. Insurers that are
 40 granted an extension by the commissioner shall report this
 41 extension and the lack of current compliance with the provisions
 42 of this section in the notice of health information policies,



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standards, and procedures required under section 3 of this chapter.

Sec. 12. (a) If the commissioner has reason to believe that a person has committed gross negligence in violation of a material provision of this chapter and that an action under this section is in the public interest, the commissioner may bring an action in the Marion County circuit court to enjoin violations of this chapter.

(b) In addition to the relief available under subsection (a), the commissioner may request and the court may order any other temporary or permanent relief as may be in the public interest, including any of the following or any combination of the following:

(1) A civil penalty of not more than ten thousand dollars (\$10,000) for each violation, not to exceed fifty thousand dollars (\$50,000) in the aggregate for multiple violations.

(2) A civil penalty of not more than two hundred fifty thousand dollars (\$250,000) if the court finds that violations of this chapter have occurred with sufficient frequency to constitute a general business practice.

(3) Reasonable attorney's fees, investigation costs, and court costs.

(c) A person that knowingly or intentionally collects, uses, or discloses protected health information in violation of this chapter commits a class A misdemeanor.

(d) If the offense under subsection (c) is committed under false pretenses, the person commits a class D felony.

(e) If the offense under subsection (c) is committed with the intent to sell, transfer, or use protected health information for malicious harm, the person commits a class C felony.

(f) In a claim made under this section relating to an unauthorized disclosure in which an insurer is being sued under a theory of vicarious liability for the actions or omissions of the insurer's employees, it is an affirmative defense that the insurer substantially complied with section 2 of this chapter.

(g) An individual may not maintain an action against an insurer that disclosed protected health information in good faith reliance on the subject's authorization if the authorization meets the requirements of section 7 of this chapter and the disclosure was made in compliance with this chapter.

(h) A person may not maintain an action against an insurer for refusing to provide information or limiting disclosure of protected health information when the refusal or limitation is based upon a subject's request under section 11 of this chapter.

Sec. 13. The commissioner may adopt rules under IC 4-22-2 to



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1 **implement this chapter.**

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