ganizations and individuals that gain access to protected health information, including Federal officials who gain access to health records during health oversight activities.

Under the new HIPAA regulations, health oversight investigators will appropriately have ready access to medical records for oversight purposes. Health oversight investigators generally do not seek access to the medical records of a particular patient, but instead review large numbers of records to determine whether a health care provider or organization is violating the law, such as through fraud against the Medicare system. Access to many health records is often necessary in order to gain enough evidence to detect and bring enforcement actions against fraud in the health care system. Stricter rules apply under the HIPAA regulations, however, when law enforcement officials seek protected health information in order to investigate criminal activity outside of the health oversight realm.

In the course of their efforts to protect the health care system, health oversight investigators may also uncover evidence of wrongdoing unrelated to the health care system, such as evidence of criminal conduct by an individual who has sought health care. For records containing that evidence, the issue thus arises whether the information should be available for law enforcement purposes under the less restrictive oversight rules or the more restrictive rules that apply to non-oversight criminal investigations.

A similar issue has arisen in other circumstances. Under 18 U.S.C. 3486, an individual's health records obtained for health oversight purposes pursuant to an administrative subpoena may not be used against that individual patient in an unrelated investigation by law enforcement unless a judicial officer finds good cause. Under that statute, a judicial officer determines whether there is good cause by weighing the public interest and the need for disclosure against the potential for injury to the patient, to the physician-patient relationship, and to the treatment services. It is appropriate to extend limitations on the use of health information to all situations in which the government obtains medical records for a health oversight purpose. In recognition of the increasing importance of protecting health information as shown in the medical privacy rule, a higher standard than exists in 18 U.S.C. 3486 is necessary. It is, therefore, the policy of the Government of the United States that law enforcement may not use protected health information concerning an individual, discovered during the course of health oversight activities for unrelated civil, administrative, or criminal investigations, against that individual except when the balance of relevant factors weighs clearly in favor of its use. That is, protected health information may not be so used unless the public interest and the need for disclosure clearly outweigh the potential for injury to the patient, to the physician-patient relationship, and to the treatment services.

SEC. 2. *Definitions.*

(a) ''Health oversight activities'' shall include the oversight activities enumerated in the regulations concerning the confidentiality of individually identifiable health information promulgated by the Secretary of Health and Human Services pursuant to the ''Health Insurance Portability and Accountability Act of 1996,'' as amended [Pub. L. 104–191, see Tables for classification].

(b) ''Protected health information'' shall have the meaning ascribed to it in the regulations concerning the confidentiality of individually identifiable health information promulgated by the Secretary of Health and Human Services pursuant to the ''Health Insurance Portability and Accountability Act of 1996,'' as amended.

(c) ''Injury to the patient'' includes injury to the privacy interests of the patient.

SEC. 3. *Implementation.*

(a) Protected health information concerning an individual patient discovered during the course of health oversight activities shall not be used against that individual patient in an unrelated civil, administrative, or criminal investigation of a non-health oversight matter unless the Deputy Attorney General of the U.S Department of Justice, or insofar as the protected health information involves members of the Armed Forces, the General Counsel of the U.S. Department of Defense, has authorized such use.

(b) In assessing whether protected health information should be used under subparagraph (a) of this section, the Deputy Attorney General shall permit such use upon concluding that the balance of relevant factors weighs clearly in favor of its use. That is, the Deputy Attorney General shall permit disclosure if the public interest and the need for disclosure clearly outweigh the potential for injury to the patient, to the physician-patient relationship, and to the treatment services.

(c) Upon the decision to use protected health information under subparagraph (a) of this section, the Deputy Attorney General, in determining the extent to which this information should be used, shall impose appropriate safeguards against unauthorized use.

(d) On an annual basis, the Department of Justice, in consultation with the Department of Health and Human Services, shall provide to the President of the United States a report that includes the following information:

(i) the number of requests made to the Deputy Attorney General for authorization to use protected health information discovered during health oversight activities in a non-health oversight, unrelated investigation;

(ii) the number of requests that were granted as applied for, granted as modified, or denied;

(iii) the agencies that made the applications, and the number of requests made by each agency; and

(iv) the uses for which the protected health information was authorized.

(e) The General Counsel of the U.S. Department of Defense will comply with the requirements of subparagraphs (b), (c), and (d), above. The General Counsel also will prepare a report, consistent with the requirements of subparagraphs (d)(i) through (d)(iv), above, and will forward it to the Department of Justice where it will be incorporated into the Department's annual report to the President.

SEC. 4. *Exceptions.*

(a) Nothing in this Executive Order shall place a restriction on the derivative use of protected health information that was obtained by a law enforcement agency in a non-health oversight investigation.

(b) Nothing in this Executive Order shall be interpreted to place a restriction on a duty imposed by statute.

(c) Nothing in this Executive Order shall place any additional limitation on the derivative use of health information obtained by the Attorney General pursuant to the provisions of 18 U.S.C. 3486.

(d) This order does not create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, the officers and employees, or any other person.

WILLIAM J. CLINTON.

§ 1320d–3. Timetables for adoption of standards

(a) Initial standards

The Secretary shall carry out section 1320d–2 of this title not later than 18 months after August 21, 1996, except that standards relating to claims attachments shall be adopted not later than 30 months after August 21, 1996.

(b) Additions and modifications to standards

(1) In general

Except as provided in paragraph (2), the Secretary shall review the standards adopted under section 1320d–2 of this title, and shall adopt modifications to the standards (includ-

ing additions to the standards), as determined appropriate, but not more frequently than once every 12 months. Any addition or modification to a standard shall be completed in a manner which minimizes the disruption and cost of compliance.

(2) Special rules

(A) First 12-month period

Except with respect to additions and modifications to code sets under subparagraph (B), the Secretary may not adopt any modification to a standard adopted under this part during the 12-month period beginning on the date the standard is initially adopted, unless the Secretary determines that the modification is necessary in order to permit compliance with the standard.

(B) Additions and modifications to code sets

(i) In general

The Secretary shall ensure that procedures exist for the routine maintenance, testing, enhancement, and expansion of code sets.

(ii) Additional rules

If a code set is modified under this subsection, the modified code set shall include instructions on how data elements of health information that were encoded prior to the modification may be converted or translated so as to preserve the informational value of the data elements that existed before the modification. Any modification to a code set under this subsection shall be implemented in a manner that minimizes the disruption and cost of complying with such modification.

(Aug. 14, 1935, ch. 531, title XI, § 1174, as added Pub. L. 104–191, title II, § 262(a), Aug. 21, 1996, 110 Stat. 2026.)

§ 1320d–4. Requirements

(a) Conduct of transactions by plans

(1) In general

If a person desires to conduct a transaction referred to in section 1320d–2(a)(1) of this title with a health plan as a standard transaction—

(A) the health plan may not refuse to conduct such transaction as a standard transaction;

(B) the insurance plan may not delay such transaction, or otherwise adversely affect, or attempt to adversely affect, the person or the transaction on the ground that the transaction is a standard transaction; and

(C) the information transmitted and received in connection with the transaction shall be in the form of standard data elements of health information.

(2) Satisfaction of requirements

A health plan may satisfy the requirements under paragraph (1) by—

(A) directly transmitting and receiving standard data elements of health information; or

(B) submitting nonstandard data elements to a health care clearinghouse for processing into standard data elements and transmission by the health care clearinghouse, and receiving standard data elements through the health care clearinghouse.

(3) Timetable for compliance

Paragraph (1) shall not be construed to require a health plan to comply with any standard, implementation specification, or modification to a standard or specification adopted or established by the Secretary under sections 1320d–1 through 1320d–3 of this title at any time prior to the date on which the plan is required to comply with the standard or specification under subsection (b).

(b) Compliance with standards

(1) Initial compliance

(A) In general

Not later than 24 months after the date on which an initial standard or implementation specification is adopted or established under sections 1320d–1 and 1320d–2 of this title, each person to whom the standard or implementation specification applies shall comply with the standard or specification.

(B) Special rule for small health plans

In the case of a small health plan, paragraph (1) shall be applied by substituting ''36 months'' for ''24 months''. For purposes of this subsection, the Secretary shall determine the plans that qualify as small health plans.

(2) Compliance with modified standards

If the Secretary adopts a modification to a standard or implementation specification under this part, each person to whom the standard or implementation specification applies shall comply with the modified standard or implementation specification at such time as the Secretary determines appropriate, taking into account the time needed to comply due to the nature and extent of the modification. The time determined appropriate under the preceding sentence may not be earlier than the last day of the 180-day period beginning on the date such modification is adopted. The Secretary may extend the time for compliance for small health plans, if the Secretary determines that such extension is appropriate.

(3) Construction

Nothing in this subsection shall be construed to prohibit any person from complying with a standard or specification by—

(A) submitting nonstandard data elements to a health care clearinghouse for processing into standard data elements and transmission by the health care clearinghouse; or

(B) receiving standard data elements through a health care clearinghouse.

(Aug. 14, 1935, ch. 531, title XI, § 1175, as added Pub. L. 104–191, title II, § 262(a), Aug. 21, 1996, 110 Stat. 2027.)

EXTENSION OF DEADLINE FOR COVERED ENTITIES SUBMITTING COMPLIANCE PLANS

Pub. L. 107–105, § 2, Dec. 27, 2001, 115 Stat. 1003, provided that:

''(a) IN GENERAL.—