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 stat-
- (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 (including 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) of this section.

(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 ap-